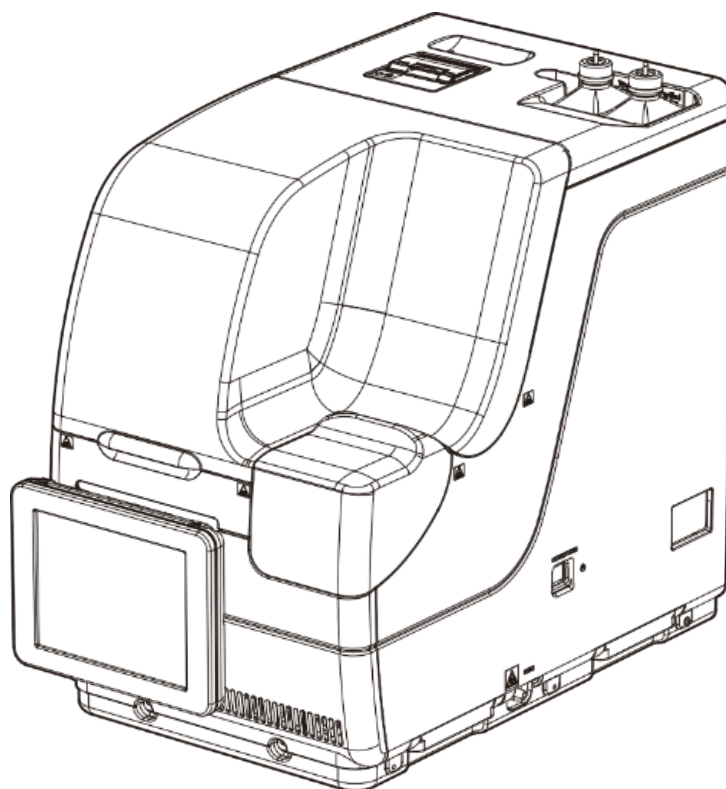# OC-SENSOR
Ceres
Operation Manual

NN1-1741

REF   MV5K00

Be sure to read this Operation Manual and all the Safety Precautions carefully for safe usage of this product.
Store this Operation Manual in a place so that it can be referred to when necessary.

Manufacturer : EIKEN CHEMICAL CO., LTD.

4-19-9 TAITO, TAITO-KU, TOKYO 110-8408 JAPAN

Authorized Representative : Advena Ltd.

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CE

Important

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• The content of 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 2017/746

• 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) medical equipment.

Introduction

Prior to reading this Operation Manual

OC-SENSOR Ceres is a mobile discrete method fully automated fecal occult blood analyzer (hereinafter referred to as the "system").

The system and its Operation Manual are 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 under 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.

All serious accidents occurred in connection with the system need to be reported to regulating authorities of the countries in which the manufacturer, users, and/or patients live.

Operation Manual organization

This Operation Manual consists of the following chapters:

Introduction		:	Describes the organization and notation of this Operation Manual, as well as Safety Precautions for using the system.
Chapter 1	Overview	:	Gives an overview of the system, including measurement principles and analysis flow, as well as the names and functions of each part.
Chapter 2	Basic Operation	:	Gives an overview of initial settings prior to use and basic operation of the system.
Chapter 3	Applied Operations	:	Describes advanced operation of the system, such as searching, recalculation, output, deletion, and accuracy control of the test data.
Chapter 4	Prep Functions	:	Describes preparatory functions such as priming.
Chapter 5	Maintenance	:	Describes inspections and maintenance procedures 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	:	Gives details on initial settings for operating the system.
Chapter 7	Error Handling	:	Explains how to read the error screen.
Appendix		:	Explains data processing, analysis operations, printing examples, and errors.
Index/Glossary			

Operation Manual Notation

This Operation Manual explains 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"

| ⚠ Warning | Indicates the possibility that improper use of the system will cause death or severe personal injury. |

| ⚠ Caution | Indicates the possibility that improper use of the system will cause personal injury or damage to property. |

| ⚠ Request | Indicates something the user should do to prevent damage or degradation to the product and to use the system efficiently. |

Severe injuries: Injuries that result in permanent damage or which require long-term hospitalization or outpatient treatment. Examples include loss of eyesight, injury, burns, electric shock, fractures, poisoning, and infection.

Slight injuries: Injuries that do not require long-term hospitalization or outpatient treatment.

■ Symbols

Caution symbols: Indicate that users should use caution.

Attention   Biohazard   Electrical shock   Pinching hazard
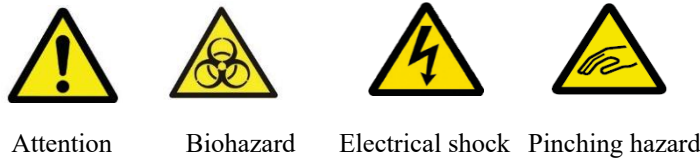
Prohibition symbols: Indicate prohibited actions.

Prohibited   Disassembly prohibited

Instructional symbol: Indicate instructions users must follow.

Required

■ Other notations

(Note)   :   Describe related supplementary notes.

{   } :   Indicate something that can be operated, such as a tab or a button on the screen.

[   ] :   Indicate the name of a screen, or settings that require selection or input.

☞ :   Indicate reference locations.

Safety Precautions

Be sure to read this section before using the system.

Installation precautions

Power supplies and cords

⚠ Warning	
🚫 Prohibited	• Do not connect the power cord to an extension cord or an adaptor plug. • Do not connect or disconnect 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.

⚠ Warning	
❗ Required	• Make sure that the system is grounded. Failure to observe this precaution may lead to electric shock.
❗ Required	• Connect to the appropriate power supply. Power supply voltage: 230 V AC Frequency: 50/60 Hz Power consumption: 630 VA or lower 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 precaution may lead to electric shock or fire.

Installation conditions

⚠ Caution	
! Required	• Use indoors. • Install and store at locations not exposed 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 location other than a chemical storage area or in a location free from gas emissions. • The installation location must be horizontal.

⚠ Caution	
! Required	• Do not move the system. 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. (The maximum height when the safety guard is opened is approx. 90 cm. Therefore, the height from the floor to the ceiling must be 100 cm or higher.) (See the following drawing for the installation spacing.) 10 cm or more 63 cm 20 cm or more 36 cm 20 cm or more • Do not place the system near the exhaust ports of heating and cooling equipment. Failure to observe this precaution may lead to erroneous analysis result.
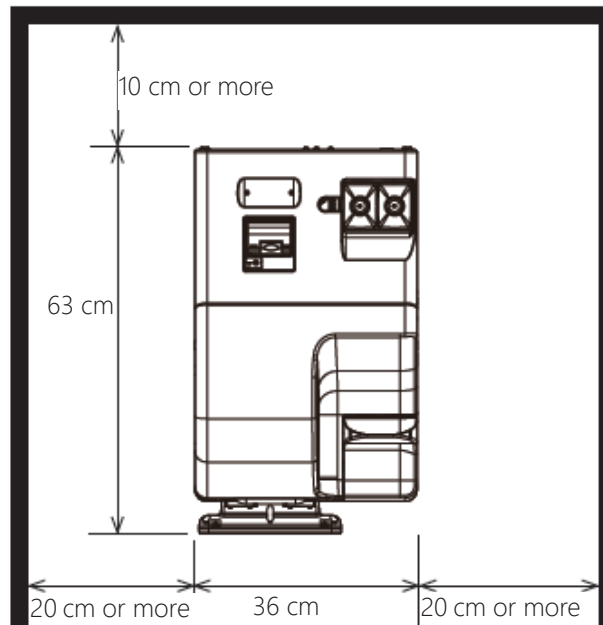
Environmental conditions

⚠ Caution

🛈 **Required**	• Adhere to the following environmental conditions:

Usage conditions	Temperature: 15 - 30℃
	(Within ± 2 ℃ change during testing)
	Altitude: 20 - 80% (no condensation)
	Height of 2,000 m or less
	Pollution degree 2
	Over-voltage category II*
Storage conditions	Temperature: -10 - 50 ℃
	Humidity: 10 - 90 % (no condensation)
Transport conditions	Temperature: -10 - 50 ℃
	Humidity: 10 - 90 % (no condensation)

(Note) Items marked with "*" are standard conditions based on EN 61010-1

Security

⚠ Caution

🛈 **Required**	Observe the following to prevent leakage or falsification of data. • To avoid unauthorized access, restrict the operation of the system to authorized personnel only. • Make sure that only verified computers are connected to the system network. • Conduct cybersecurity assessments regularly to ensure an appropriate level of data security. • Do not use personally identifiable information for sample IDs and patient IDs. Instead, use anonymized IDs for management. • For network security, address the security of IT infrastructure in your facility to ensure that IT security is not compromised by malicious software or hacker attacks. 　- Protect all devices and services used in your facility from malicious software and unauthorized access. 　- Connect the system only to the internal network of your facility that is not connected to the external network.

Failure to observe this precaution may lead to infection by computer viruses.

Failure to observe this precaution may lead to leakage or falsification of information.

Usage precautions

Work and operation precautions

⚠ Warning	
Biohazard	• Wear protective gear when handling the samples, reagents, washing solution, and test cells. • After using the system, wash hands thoroughly. Failure to observe this precaution may lead to infection from samples.
Biohazard	• Dispose of drainage after using the system. • Make sure that drainage does not leak into the area surrounding the device when 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.
Biohazard	• Be careful of sample splattering when removing sampling bottles from a rack. • Be careful of sample splattering when disposing of measurement cells. Failure to observe this precaution may lead to infection from sample.
Disassembly prohibited **Electrical shock**	• Do not disassemble the system. • Do not remove any of the system's exterior parts. Failure to observe this precaution may lead to electric shock.
Prohibited	• Do not spill any samples or reagents inside the system. • Do not touch the system with wet hands. Failure to observe this precaution may lead to electric shock.
Prohibited	• Do not mix the washing solution with acid washing solution. Failure to observe this precaution may damage the operator's health.

Usage precautions

⚠ Caution
❗ **Required**	• Correctly connect the purified water/washing solution bottle, drain tank, and each hose. • Periodically monitor the accuracy control function. Failure to observe this precaution may lead to false diagnoses.

⚠ Caution
❗ **Required**	• Do not connect to any device other than a USB stick. For details of recommended items, contact the manufacturer. • Manage external media appropriately. Check for computer viruses periodically. Failure to observe this precaution may lead to infection from a computer virus.

⚠ Caution
❗ **Required**	• Use only reagents that have not expired. Failure to observe this precaution may lead to false diagnoses.

⚠ Caution
❗ **Required**	• If the reagent refrigerator becomes abnormally hot, dispose of the stored reagents. Failure to observe this precaution may lead to false diagnoses.

⚠ Caution
❗ **Required**	• Do not turn off the power while testing. • Do not turn off the primary power switch until the system shut downs completely. Failure to observe this precaution may lead to a damaged hard disk or loss of data.

⚠ Caution
❗ **Required**	• Use the designated sample cup. • Do not reuse measurement cells. Failure to observe this precaution may lead to false diagnoses.

⚠ Caution
❗ **Required**	• Do not touch the touch panel with wet hands. Failure to observe this precaution may lead to system breakdown.

Maintenance and inspections

⚠ Warning
Biohazard	• Wear protective gear when performing maintenance and inspections. • The tip of the nozzle is sharp. Use caution when handling it. • The tip of the puncture needle is sharp. Use caution when handling. Failure to observe these precautions may lead to infection from the samples.

⚠ Request
• Inspect the system before starting operations each time. 　• Check that there is no water leakage. 　• No devices other than the designated ones should be connected. 　• The environmental conditions are satisfied.

⚠ Request
• If the system has not been used for some time, check that the system operates 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.

Disposing of drainage and waste

⚠ Warning
Biohazard	• Dispose of drainage and waste (reagent containers, reaction containers, sampling bottles, sample cups, and measurement cells) appropriately by following the facility 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, sample cups, and measurement cells.) • Refer to the usage instructions attached to the reagent for information on how to dispose the reagent containers and drainage. • Contact the manufacturer or your legal representative when disposing the system. • Wear protective tools when disposing. Failure to observe this precaution may lead to environmental pollution.

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.
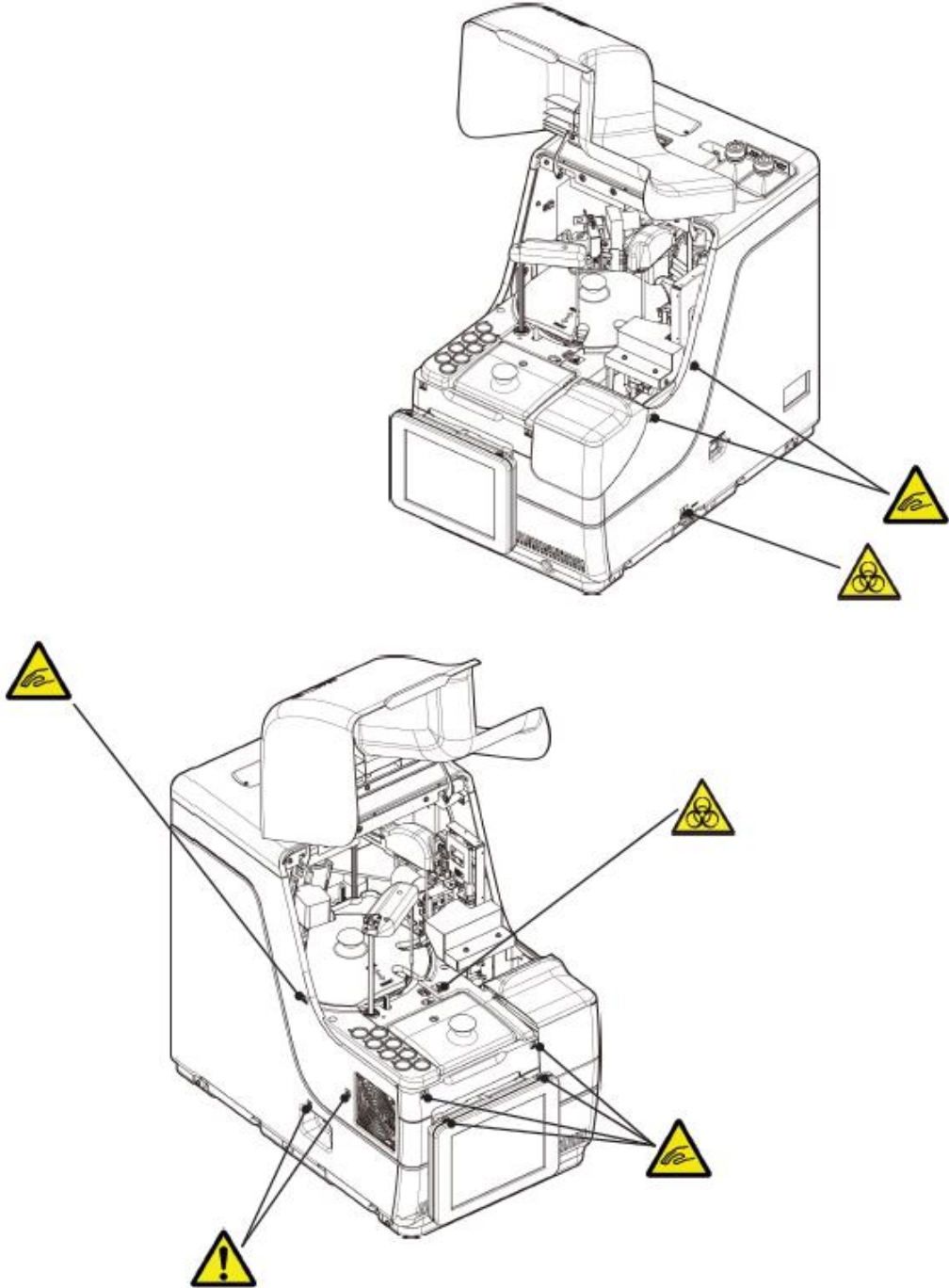
Drainage tank

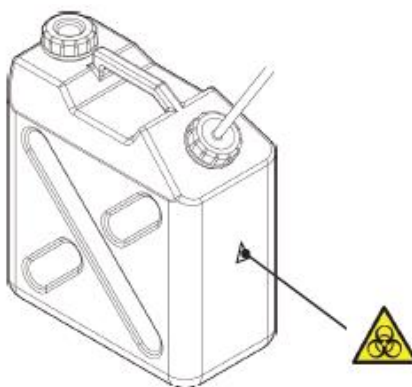| Caution Label	Meaning
	Keep out of operational range during system operation. Failure to observe this precaution may lead to injury.
	Do not handle drainage with bare hands. Failure to observe this precaution may lead to infection and pollution.
	(Fan) Do not touch the fan while it is operating. Failure to observe this precaution may lead to injury.
	(Connecting port) Connect only permitted device. When any device other than those permitted is connected, the system may experience erroneous operation.

Primary power switch and system switch

◯　　Primary power switch OFF

❘　　Primary power switch ON

⏻　　System switch

Identification plate

Identification Label (DRAFT)

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Chapter7 Error Handling

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Chapter 1   Overview

Ceres OC-SENSOR

Chapter 1 Overview

This section describes the general outline and the configuration of the system, "Mobile discrete method Fully automated fecal occult blood analyzer (fecal occult blood test) OC-SENSOR Ceres"

1.1   Features of OC-SENSOR Ceres

● The OC-SENSOR Ceres (hereinafter called "the system") features automatic sample dilution, a wide test range, countermeasures against carryover, prozone judgment, and more.

● The system is always cooling the reagents. Therefore, samples can be tested anytime.

1.2   Application

The system measures the objective material in the sample or hemoglobin in feces by detecting changes in transmitted light by latex agglutination reaction.

1.3   Measurement Principles

Latex agglutination 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. Light is passed through the reaction liquid to measure changes in the intensity of the transmitted light beam. This method, used by this system, is called "latex turbidimetry."

1.4   System Configuration

Before using the system, check the configuration.

Name		Q'ty	Remarks
Main body	Mobile discrete method Fully automated fecal occult blood analyzer (OC-SENSOR Ceres)	1 set	
Accessories	① Software package		
	・Software program	1 set	Installed on the hard disk
	② Racks		
	・Sample rack	1 box	2 pc/box
	・STD and QC rack	1 box	1 pc/box
	③ Tanks and bottles		
	・Purified water bottle (Purified Water)	1	500 mL bottle
	・Washing solution bottle (Wash Solution)	1	500 mL bottle
	・Drain tank	1	5L tank
	・Beaker	1	
	・Replacement bottle for purified water	1	500 mL bottle
	④ Others		
	・Power supply cable	1	
	・Barcode labels for racks	3 pc	"01-10," "11-20," "91-100"
	・Bottle and tank labels	1 set	Already attached to the bottles and tanks
	・Sample cup	1 bag	
	・Thermal roll paper	1 roll	W : 58mm / D : 40mm
	・Binding band	5 pc	
Documents	・Operation Manual	1	

■ Accessories (sold separately)

Name	Product code	Quantity	Remarks
DISPO-11	MV5K12	1 box	55 x 20 pc

■ Option

Name	Quantity	Remarks
Handy barcode reader	1 pc/box	Used to read the calibrator and QC barcodes.
2D code reader replacement kit	1 pc/box	
340 nm detection kit	1 pc/box	Used when developing a new item
600 nm detection kit	1 pc/box	Used when developing a new item
800 nm detection kit	1 pc/box	Used when developing a new item

1.5   Test Flow

The test flow of this system is as follows

1	R1 reagent dispense	The reagent nozzle dispenses R1 reagent to the test cells.
	↓	
	Sample dispense	The sample nozzle dispenses the sample to the test cells.
	↓	
	Mix ①	The mixer mixes the liquid in the test cells.
	↓	
	R2 reagent dispense	The reagent nozzle dispenses R2 reagent to the test cells.
	↓	
	Mix ②	The mixer mixes the liquid in the test cells.
	↓	
2	Test	The transmitted light is measured in each cycle after the second cycle.
	↓	
3	Test	
:	↓	
:	Test	
:	:	

Number of cycles (T)

(Note)   The required time for one cycle is 40 seconds.

1.6 System Specification

■ Basic specifications

Name	Specification
Measurement principles	Latex turbidimetry method
Method	Discrete method, random access method (max. 3 items)
Test mode	1-step rate
Samples	Feces
Processing capacity	Up to 90 tests/hour (40 seconds per cycle)
Sample setting	20 samples:10 samples x 2 racks
Sample container	OC-Auto Sampling Bottle 3 (Eiken Chemical proprietary bottle) Sample cup (A10)
Calibration curves	Automatic generation of calibration curves
Retest	Automatic re-test function
	Dilution re-test function (x10, x20, x100, x200, x400)
Reaction cuvette	Five disposable cuvettes (5 x 11 reaction cells)
Sample dispensing	Sampling nozzle with liquid level detection sensor and nozzle cleaning function
Sample dispensing range	0, 3-21µL (0.1µL unit) * For protocol settings, please set dispensing volume specified by the manufacturer.
Reagent dispensing	Sampling nozzle with liquid level detection sensor and nozzle cleaning function
Reagent dispensing range	0, 30-210µL (1µL unit) * For protocol settings, please set dispensing volume specified by the manufacturer.
Mixing	Mixer rotating system (with cleaning function)
Barcodes	Rack barcodes/Sample barcodes and Reagent barcodes
Prozone check	PRC method, RBC method, OR method
Check reagent blank	Detection using A1 value check
Reagent loading capacity	3reagent sets (R1, R2) and 2 sample diluent buffers Hemoglobin, Calprotectin
Cooling system	Peltier cooling system surrounding reagent storage area (working for 24 hours)
Thermal insulation system	Reaction table, Silicone rubber heating System
Light source	LED (wavelengths: 660 nm, 340 nm,* 600 nm,* 800 nm*) *: Optional wavelengths.
Detector	Photodiode
Operation control/data processing	Multiple CPU configuration with internal network
External connections	RS-232C, Ethernet
Sample dispensing accuracy	CV0.5% or less at 10 µL
Reagent dispensing accuracy	CV0.5% or less at 30 µL

Name	Specification
Inputs	Color LCD (8.4 inch) touch panel, barcode reader
Outputs	Thermal printer (58 mm wide thermal paper) Integrated hard disk External media USB connection
Dimensions	Approx. 360 mm x 625 mm x 545 mm (W x D x H)
Weight	Approx. 43 kg
Power	~100-240 V 50/60 Hz 630VA

(Note) The dimensional tolerance is +/- 10%, and weight tolerance is +/- 10%.

■   Sample barcode specification

Type	Number of digits	Check digit	Remarks
NW-7	5- 17 (including start and stop characters)	Modulus 10/3 weight Modulus 16 Modulus 11 Modulus 10/2 weight 7 check DR Weighing modulus 11 Loons	
ITF	6- 15	Modulus 10/3 weight	
IND 2 of 5	6- 15	None	
COOP 2 of 5	6- 15	None	
CODE39	5- 15 (Including start and stop characters)	Modulus 43	
JAN	5- 15	Modulus 10/3 weight	
CODE128	5- 15	None	
QR	6- 50	None	2D code reader (optional)
Data Matrix	6- 50	None	
PDF417	6- 50	None	
GS1 DataBar Omni-directional	6- 50	None	

■   Usable life

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

* Assuming periodic inspection/maintenance, parts replacement, and repairs/overhaul (as required after inspection) are conducted as described in this Operation Manual.

1.7 Reagents Used by the System

Refer to the attached documents for reagents used in this system.

■ Reagents for hemoglobin testing

Product name	Product code	Package
OC-SENSOR FIT (for OC-SENSOR Ceres)	V-PH01	2 × 6 mL 2 × 20 mL
OC-FIT Calibrator (for OC-SENSOR Ceres)	V-PH02	6 × 1 mL (concentration in 6 levels)
OC-FIT Control LV1	V-PH53	2 × 5 mL
OC-FIT Control LV2	V-PH54	2 × 5 mL
OC-FIT Control LV3	V-PH59	2 × 5 mL

■ Common

Product name	Product code	Package
OC-SENSOR Sample Diluent	V-PH08	2 × 20 mL

■ Reagents for calprotectin testing

Product name	Product code	Package
OC-FCa Reagent (for OC-SENSOR Ceres)	V-PH09	2 × 8 mL 2 × 15mL
OC-FCa Calibrator	V-PH12	6 × 1 mL (concentration in 6 levels)
OC-FCa Control LV1	V-PH13	2 × 5 mL
OC-FCa Control LV2	V-PH14	2 × 5 mL
OC-FCa Control LV3	V-PH15	2 × 5 mL

1.8   System Dimensions

36 cm

63 cm

Top view

36 cm

55 cm
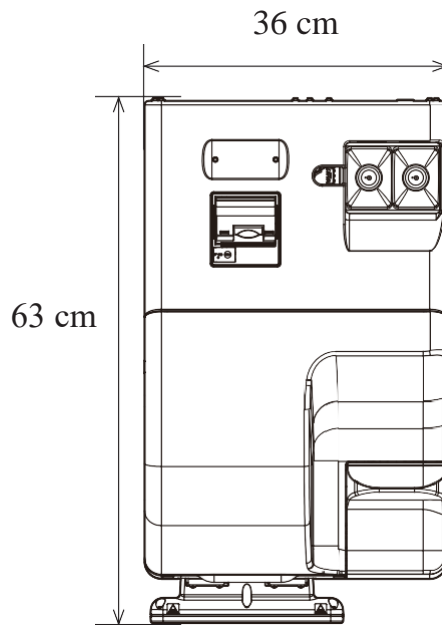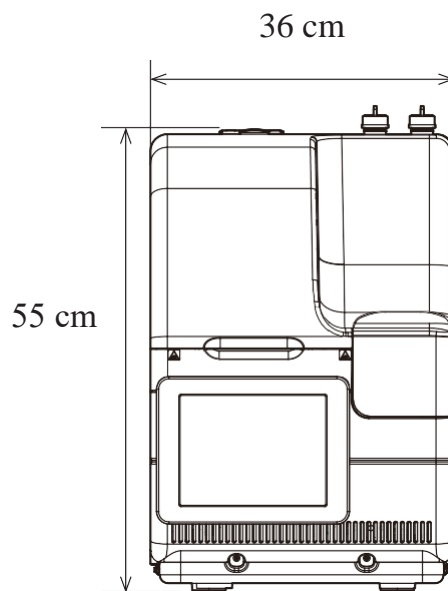
Front view

1 Overview	1.9 Names and Functions of Parts

1.9.1 Exterior Parts

(5) Thermal printer

(9) Bottle compartment
(Wash, Purified water)

(3) Safety guard

(6) Control panel

(2) System switch

(4) Rack lane cover

(1) Primary power switch

(8) Power cord

(7) External media port
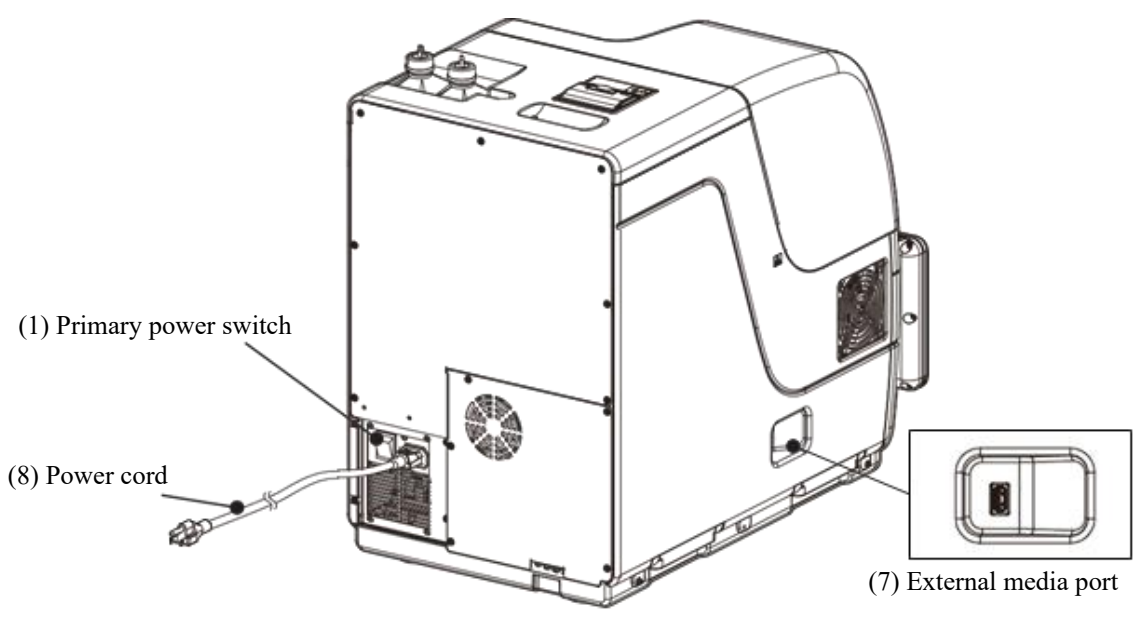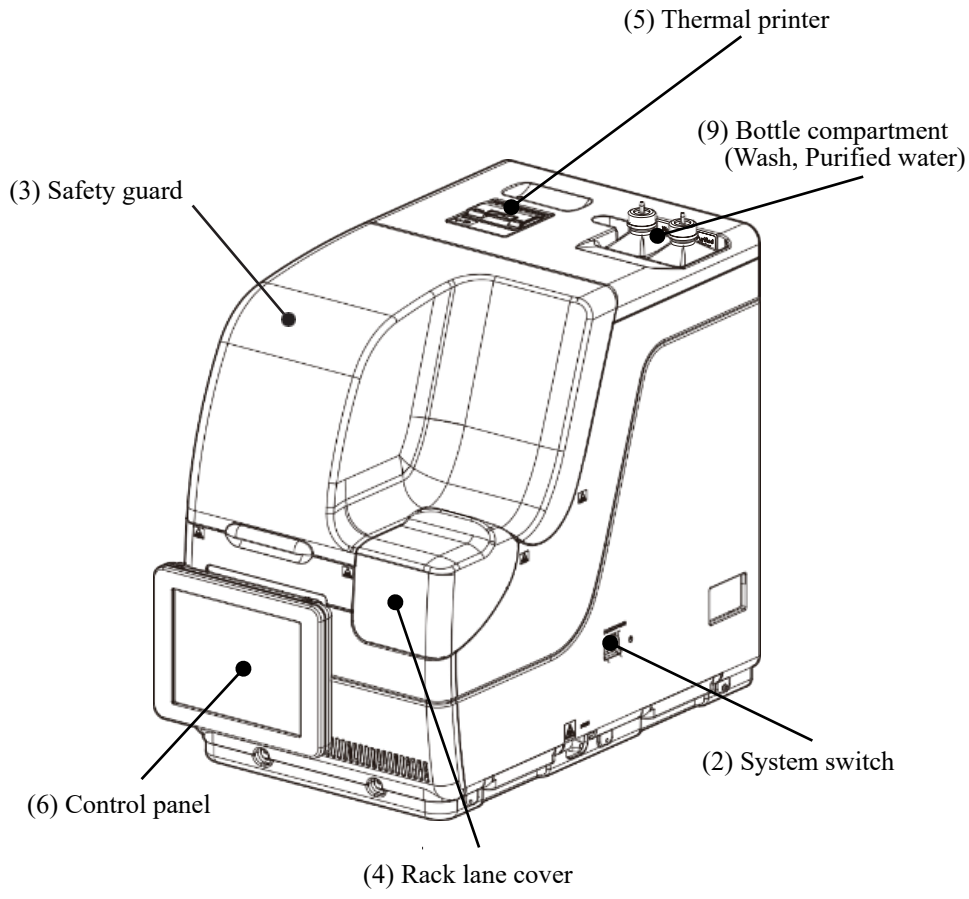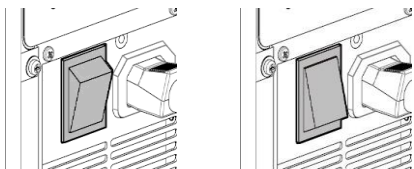
⑩ Washing solution bottle
(Wash Solution)
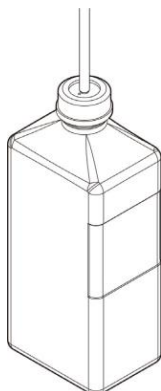
⑪ Purified water bottle
(Purified Water)
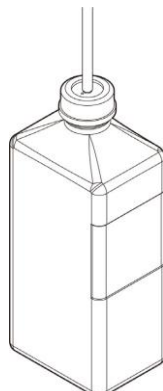
⑫ Drain tank (Drain)

Name	Function
① Primary power switch	When turning on the primary power switch, the system is powered on. Usually, keep the system power on. Switch OFF Switch ON (Note) After turning on the primary power switch, cold storage of the reagent starts when the application starts up. When turning off the primary power switch, cold storage of the reagent cooler is turned off.
② System switch	When turning on the system, the application starts, and the reaction table temperature is controlled.
③ Safety guard	The cover to prevent accidents during the system operation. It is automatically locked during the system operation.
④ Rack lane cover	The rack lane cover. It is automatically locked while using the rack.
⑤ Thermal printer	Prints setup conditions, test results, error messages, or other data.
⑥ Control panel (Including the touch panel)	Shows operation screens and analytical results. Operate by directly touching the screen.
⑦ External media connector	The external media to save the test data is connected.
⑧ Power supply cord	The power cord for this system.
⑨ Washing solution and purified water setting section	Section to set the washing solution bottle and the purified water bottle.
⑩ Washing solution bottle (Wash Solution)	Fill with wash solution.
⑪ Purified water bottle (Purified Water)	Fill with purified water.
⑫ Waste liquid tank(Drain)	The wasted liquid is stored from the sample nozzle, reagent nozzle, and mixer.

1
Overview

1.9.2   Internal Parts

(8) Reagent dispensing pump

(9) Sample dispensing pump

(10) Sample nozzle

(11) Squeezing system

(7) Mixer

(4) Overflow cell for sample

(3) Puncturing system

(12) Barcode reader (inside the cover)

(1) Rack lane

(13) Cell batch replacement tool

(4) Overflow cell for mixer

(6) Reaction table

(5) Reagent nozzle

(14) Reagent cap tray

(4) Overflow cell for reagent

(2) Reagent refrigerator

12

Name	Function
① Rack lane	Rack setting location. Up to two racks can be set.
② Reagent refrigerator	Reagent (20 mL special container) location. The temperature is always kept at 9 to 15 ℃.
③ Puncturing system	Punctures the double aluminum seals on the sample bottle.
④ Overflow cell (OF)	For sample nozzle Washes the sample nozzle inner and outer walls with purified water and washing solution. Waste liquid is sent to the drain tank. For reagent nozzle Washes the reagent nozzle inner and outer walls with purified water. Waste liquid is sent to the drain tank. For mixer Washes the mixer needle with purified water and washing solution. Waste liquid is sent to the drain tank.
⑤ Reagent nozzle	Dispenses the reagent.
⑥ Reaction table	Location of the antigen-antibody reaction and photometry.
⑦ Mixer	Mixes the sample and the reagent.
⑧ Reagent dispensing pump	Absorbs and flushes samples.
⑨ Sample dispensing pump	Absorbs and flushes samples.
⑩ Sample nozzle	Dispenses samples.
⑪ Squeezing system	Raises the sample level in the sampling bottle.
⑫ Barcode reader	Reads barcodes on reagent bottles and racks.
⑬ Cell batch replacement tool	Used to replace test cells in a batch.
⑭ Reagent cover storage place	Used to store the reagent cover.

1.9.3 Accessories and Others

① Sample rack (light blue)
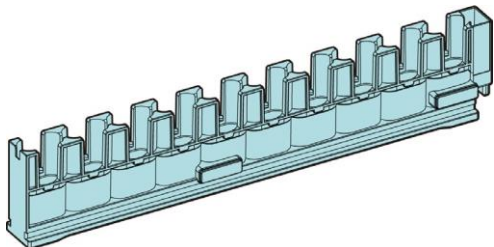
② STD and QC rack (blue)
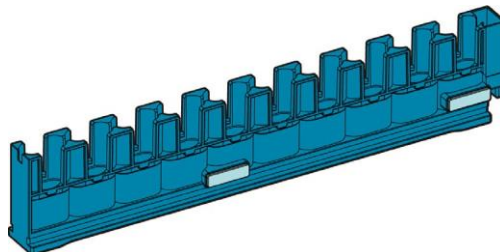
Name	Function
① Sample rack	Holds sample bottles and sample cups.
② STD and QC rack	

Chapter 2 Basic Operation

OC-SENSOR
Ceres

Chapter 2 Basic Operation

2.1 Basic Screen Operation

This section describes the functions provided on the [MENU] screen, as well as the buttons on the screen and their basic operations.

2.1.1 [MENU] screen and functions

On the [MENU] screen, functions (a) through (h) can be performed.
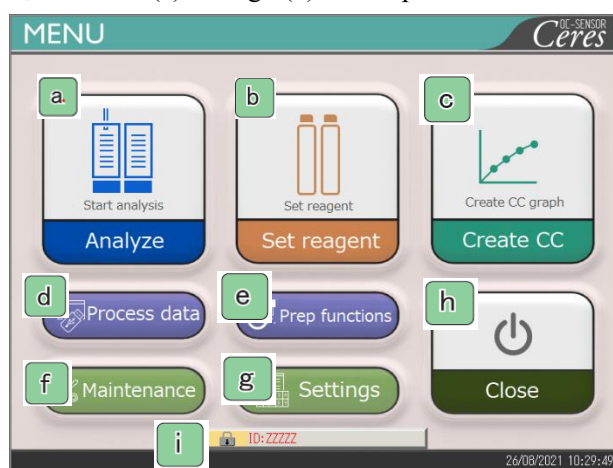
[MENU] screen

a.	Analyze	Starts analyzing. Sets conditions to start analyzing.
b	Set reagent	Sets the reagent. The barcode is automatically read. Touching {Set complete} ends the setting of the reagent.
c	Create CC	Creates CC. Checking and editing CC are also available here.
d	Process data	Performs "Process data" or "Process quality control." To open the [Process data] screen, a password is required (if a password was set).
e	Prep functions	Performs prep functions (Initialize, Prime, Cleaning).
f	Maintenance	Performs inspections, replacement parts check, and maintenance.
g	Settings	Performs "System setting" and "Protocol setting" for the system.
h	Close	Turns off the system. After touching this button, the system switch automatically turns off.
i	ID	Used to log in. After log-in, the ID of the operator who logged in is displayed.

2.1.2 Screen Configuration and Button Operations

This section describes the [Buttons] and [Tabs] on the screen and how to enter settings.

■ Screen configuration

[Assay] screen
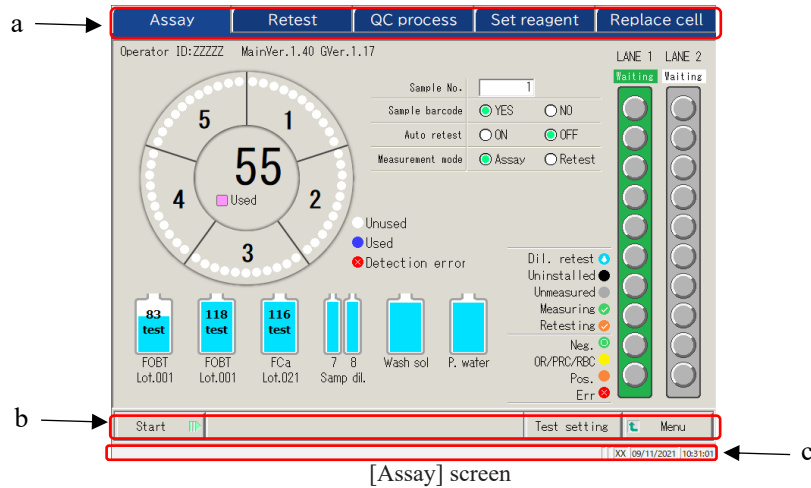
a	Tabs	Tabs are used to select functions. Tabs are provided at the top of the screen.
b	Buttons	Buttons are used to perform processes. At the bottom of the screen, buttons corresponding to the selected screen are displayed. ([Run/Cancel], [Register/Cancel], [Close], etc.)
		☞ Page 18 "■ {Continue} buttons"
c	Status bar	Displays the message and the date and time.

(Note) The screen is only an example.

2.1 Basic Screen Operation

■ {Continue} buttons

A {Continue} button for close/start is provided on the Time course data range change screen, and {Continue} for close/register is provided on the Test setting screen. In this section, the [Time course data range change] screen and [Test setting] screen are used as examples.

[Time course data range change] screen

When {Continue} is touched, a dialog box opens

↓
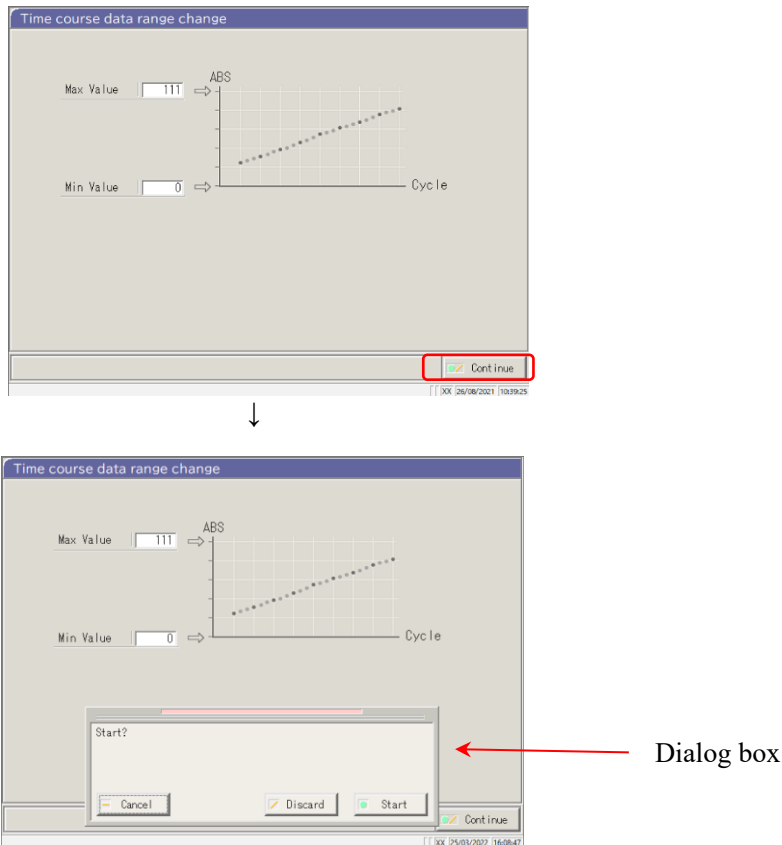
Dialog box

{Cancel}: Closes the dialog box.

{Discard}: Aborts the process and returns to the previous screen (in this case, the [Time course data range change] screen).

{Start}: Executes the process (in this case, the time course range is changed).

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[Test setting] screen

Touching the {Register/cancel} button opens a dialog box

↓
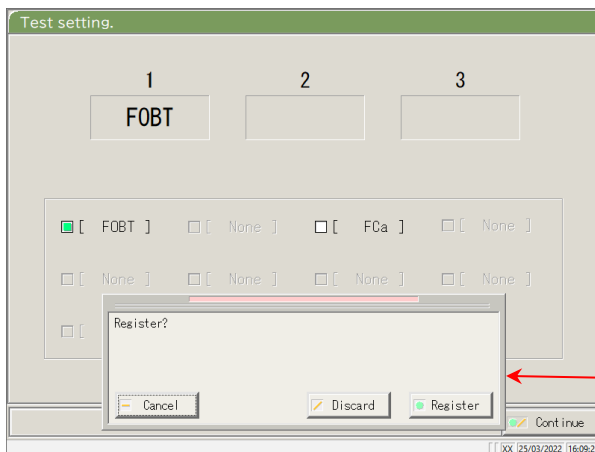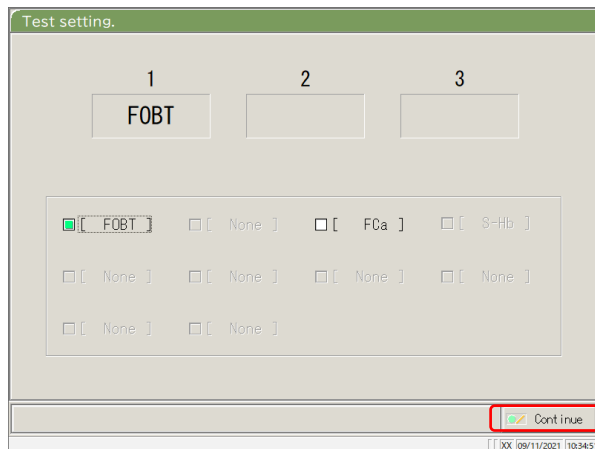
Dialog box

{Cancel} : Closes the dialog box.

{Discard} : Aborts the registration of settings and returns to the previous screen. (In this case, the [Assay] screen or [Output settings] screen.)

{Register}: Registers the settings (in this case, the analysis items are registered.)

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2.1 Basic Screen Operation

■ Entering a setting

This section describes how to enter, insert, and delete numbers.
([MENU] – [Settings] – [Protocol Settings] – [CC Protocol])
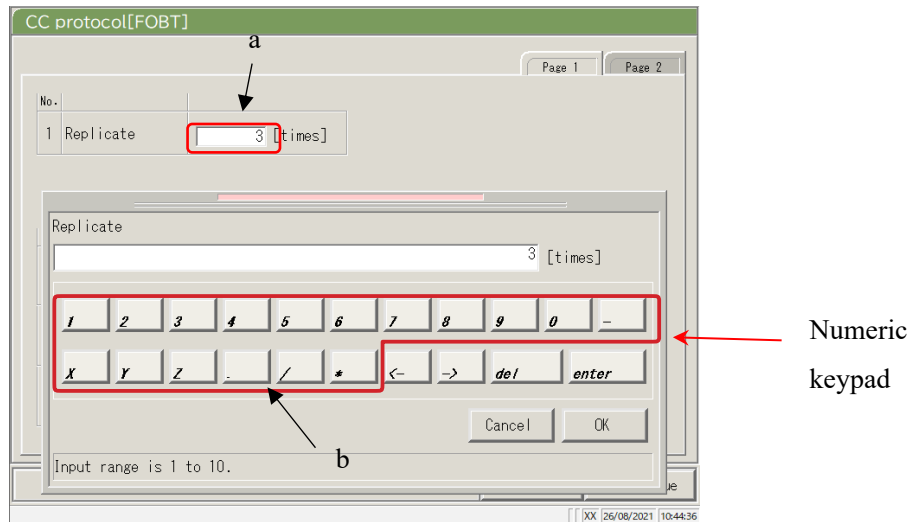
[CC Protocol] screen

Entering a numerical value

① Touch the entry field (a). The numeric keypad opens.
② Touch the numeral buttons (b) to enter a numerical value.
③ Touch {OK} or {enter}. The numeric keypad closes, and the number is entered in the entry field.
④ To cancel the entry, touch {Cancel}. The numeric keypad closes.

Inserting one character

① Touch the entry field (a). The numeric keypad opens.
② Use {←} and {→} to move the cursor to the desired position to enter a character.

Deleting one character

① Touch the entry field (a). The numeric keypad opens.
② Use {←} and {→} to move the cursor to the desired position to enter a character.
③ Touch the {del} key.

> (Note) When an asterisk (*) is entered, the value of the corresponding item can be omitted.
> Entering "*" is not available for some settings. Check the available range by checking the status bar at the bottom of the numeric keypad.
>
> (Note) Entering characters from the keyboard is the same as entering numbers from the numeric keypad (next page).
> Switching between capital letters and small letters is available by touching [A/a], and entering symbols is available by touching [Sign].

■ Radio buttons and check boxes

Radio buttons and check boxes are used to select one or several conditions when setting the condition items.
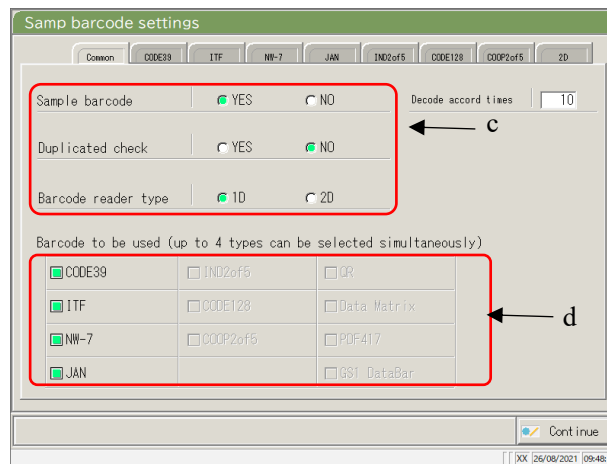
[Samp barcode settings] screen

c	Radio button	●	Used to select only one item.
d	Check box	■	Used to select one or more items.

Keyboard

Switches between capital letters and small letters

Shifts to entering symbols
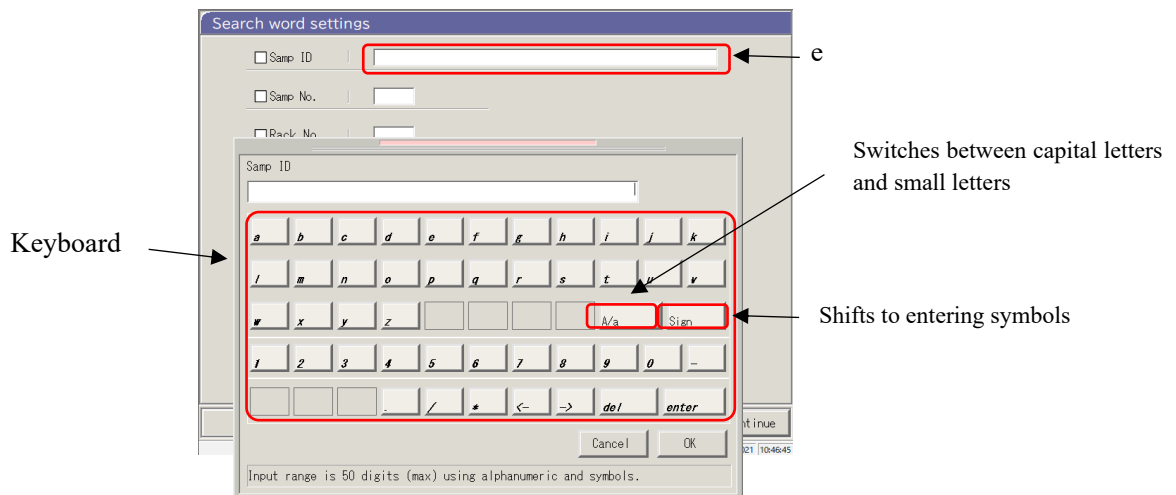
[Search word settings] screen

Entering characters

① Touch the entry field (e). The keyboard opens.
② Touch the keyboard keys to enter text value.
③ Touch {OK} or {enter}. The keyboard closes, and the entered value appears in the entry field.
④ To cancel the entry, touch {Cancel}. The keyboard closes.

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■   Selecting from a pull-down window

A pull-down window is used to select one item from the provided list.
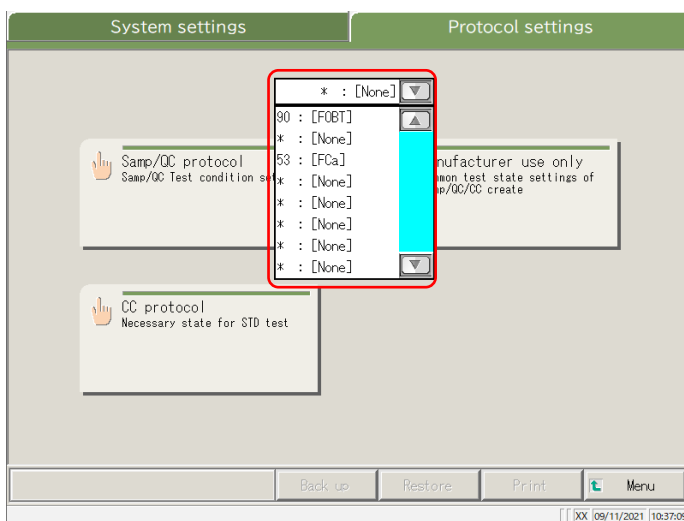
[Protocol settings] screen

Inputting characters

① Touch [▼] . The pull-down window opens as shown above.
② If the desired item is not displayed in the selection list, find the item by scrolling with [▼] and [▲] .
③ Touch the desired item in the selection list.
④ To cancel the entry, touch outside the pull-down window. The selection list closes.

<div style="border:1px solid;">

2.1.3 [Analyzing] Screen and Functions

</div>

When touching {Start} on the [Analyze start] screen, [Retest] screen, [QC process] screen, or [Create CC] screen, the [Analyzing] screen opens.

The following functions can be performed from the [Analyzing] screen.
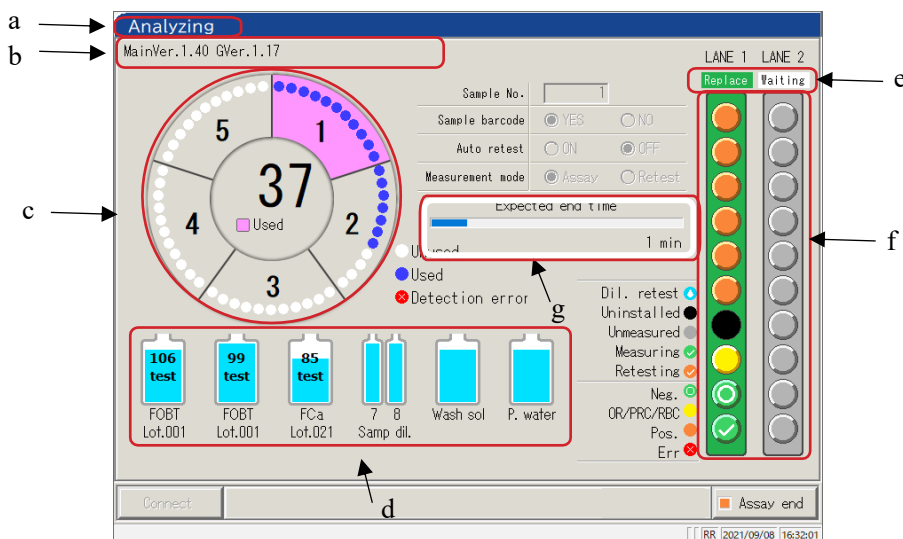
Analyzing] screen

a	Title	Displays the test mode.
		Initial test, retest analysis : Testing
		Retest, automatic retest : Retesting
		QC test : QC testing
		CC create : CC creation
b	Operator ID software version	The ID of the operator who is currently logged in is displayed. The system software version is also displayed.
c	Cell information	The cell use status is displayed.
d	Reagent information	The reagent used in the measurement is displayed.
e	Rack info	The sample setting lane status is displayed. When the rack is drawn in, the display changes from "Replaceable" to "Using." For the using lane, replacement of the rack and setting a new rack are not available.
f	Sample information	The process status and measurement result for each sample are displayed. (Note) If the rack is replaced during the analysis, QC process, or CC creation, the result will not be reflected.
g	End schedule time (min)	After dispensing the last sample, the remaining time until the system stops will be displayed. (Note) While sample dispensing continues, the time display does not change.

2.1 Basic Screen Operation
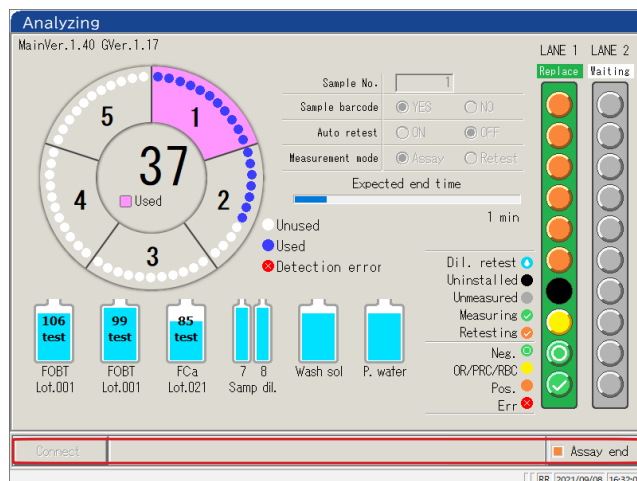
[Analyzing] screen

h	Buttons	
{Connect}	When the connection with the external computer fails and communication is shut down, {Connect}is displayed. Restart the connection by taking the following procedure.	

    ① Remove the cause of the connection failure.

    ② Touch {Connect}.

       * The connection restarts, and any data which was not output is output.

    (Note) When the analysis is ended using {Assay end}, transmission ends even if there is data which was not output. In that case, specify the range of the measurement data on the [Test data] screen.

{Assay end}	Ends the testing.

<div style="border:1px solid;">

2.1.4 [Set reagent] Screen and Functions

</div>

After logging in, the [Set reagent] screen opens.

R1 reagent, R2 reagent, and sample diluent are set in the reagent refrigerator.

(Note) The reagent can be set on the {Set reagent} tab on the [Create CC] screen.

(Note) Be sure to remove the reagent cap before executing the test.
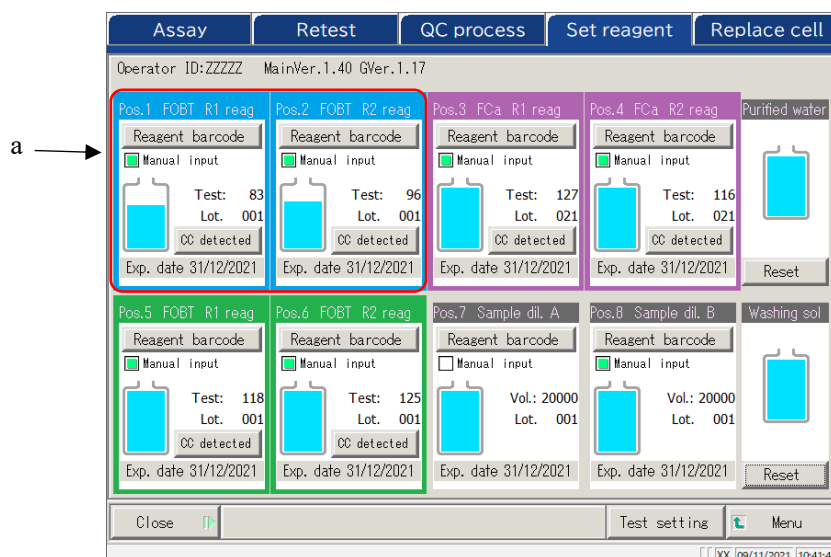
[Set reagent] screen

a	Reagent information	
Paring condition	Paired R1 reagent and R2 reagent are displayed in different colors. There are three colors: blue■, purple■, and green■.
Reagent barcode	The reagent barcode can be edited manually. When edited, the check box for "Manual input" will be selected (■). When the check mark is removed, the barcode returns to the previous barcode. ☞ Page 39 "<Entering a reagent barcode using the numeric keypad>" (Note) Manual input and editing are available only when the user is logged in using an administrator ID, or when the operator control is "No."
{CC detected} {No CC}	When there is a CC for the reagent lot, "CC detected" is displayed. When there is no CC, "No CC" is displayed. Touching this button displays the CC. (Note) When there is no CC, the test cannot be started. In that case, create a CC.
Exp. date	An expiration date is displayed. When there is a sample condition error, it is displayed here (expired, volume shortage, etc.).
Test/Vol.	The sample volume is displayed with a graphic and a numerical value. (The displayed number of tests correspond to the use count.)
Lot.	Displays the sample lot.

2.1 Basic Screen Operation
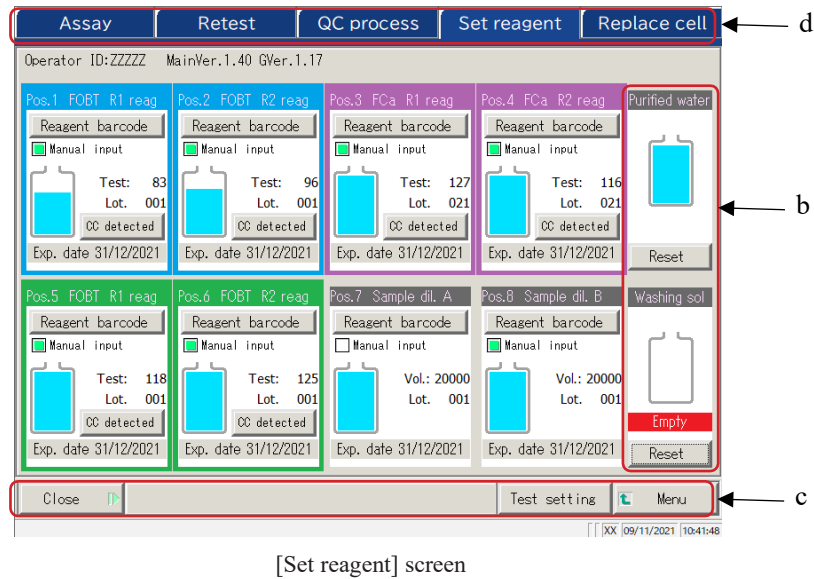
[Set reagent] screen

b	Washing solution/Purified water information	
	Remaining volume	Remaining volume Remaining volumes of the washing solution and purified water bottles are displayed graphically. When the sensor detects zero volume, "Empty" is displayed.
	{Reset}	This is used after replacing the washing solution or purified water bottles. Touch {Reset} and {Close} to reset the volume display for the bottles.
c	Buttons	
	{Close}	Touch this after completing the reagent setting. The system reads the barcode and updates the statuses of the reagent refrigerator/washing solution and purified water bottles.
	{Test setting}	Sets test items. ☞ Page 198 "6.1.7 Data output – [Test Setting]"
	{Menu}	Returns to the [MENU] screen.
d	Tabs	Moves to other screens.

Note If {Close} is not touched after setting a reagent or editing a barcode, the screen cannot be changed using the tabs or buttons.

2.2　Starting the System

Start the system by turning on the switch.

1　Check that the primary power switch is on.

　　If the system is not on, turn on the primary power switch.

2　Turn on the System switch.

　　* The startup screen opens.

[Startup] screen

3　If "Exchange buffer and wash sol to P. water" were set to "Yes" in the previous shutdown of the system, the message screen opens. Set the washing solution bottle.

　　① Remove the washing solution bottle filled with purified water.
　　② Pour the washing solution into the washing solution bottle.
　　③ Touch the {Close} button.

　　* The [LOGIN] screen opens.

[Message] screen

[LOGIN] screen

(Note)　When "Operator mode" is set to "No," the [Set reagent] screen opens.

2.3 Logging In

To use all functions of the system, logging in is required.
After the ID information is entered on the [LOGIN] screen, the operator can log in to the system. The ID of the operator who logged in is displayed.

[LOGIN] screen

1 Enter an operator ID.

①Touch the operator ID field.

Number of registration available: Number of operator IDs which can be additionally registered.

{User list}: The list of registered operator IDs is displayed.
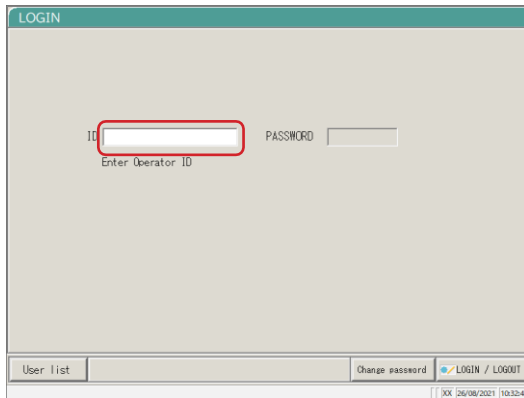
(Note) Entering an operator ID is also available by selecting from the {User list}.
☞ Page 30 "■ User list"
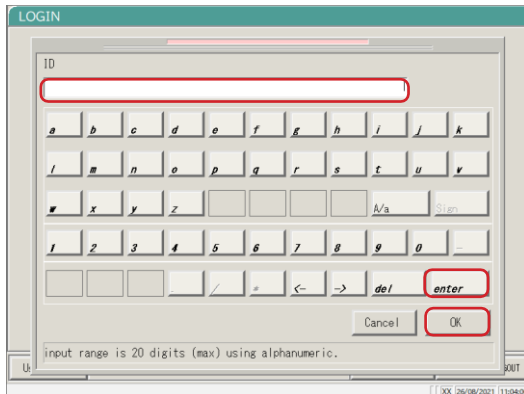
② Enter an operator ID and touch {OK} or {enter}.
 * The keyboard dialog closes.
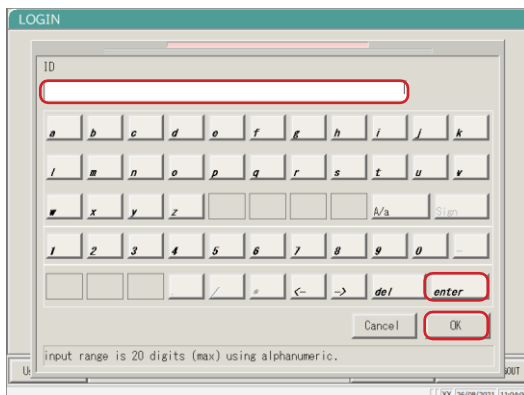
2 Enter a password.
 ① Touch the password entry field.

 ② Enter a password and touch {OK} or {enter}.

 * The keyboard dialog closes.
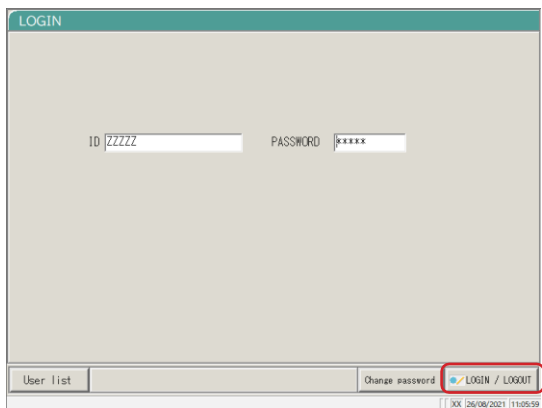
3   *Touch {LOGIN/LOGOUT}.*
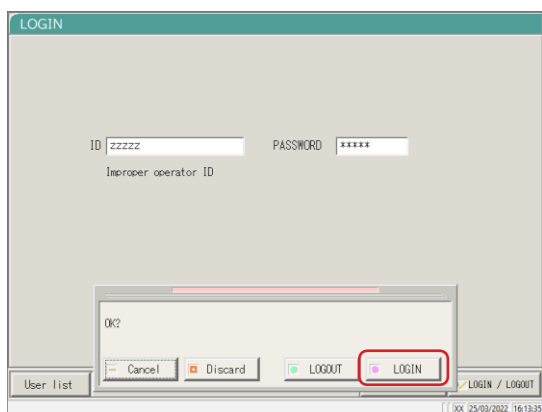
4   *Touch {LOGIN}.*

* The user is logged in to the system. The [Set reagent] screen opens.

{Cancel}: Closes the dialog box.
{Discard}: Returns to the [MENU] screen while keeping the current logged in/out condition.
{LOGOUT}: Logs out. The screen returns to the [MENU] screen.
{LOGIN}: Logs in.

2.3　　Logging In

■　　User list

On the [LOGIN] screen or "User account setting" of the System setting, selecting an operator ID from the User list is available instead of entering an operator ID.
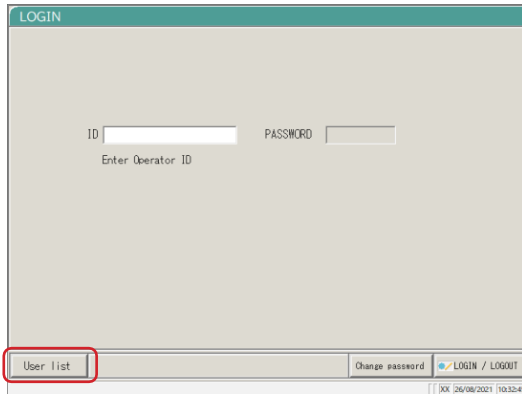
[LOGIN] screen
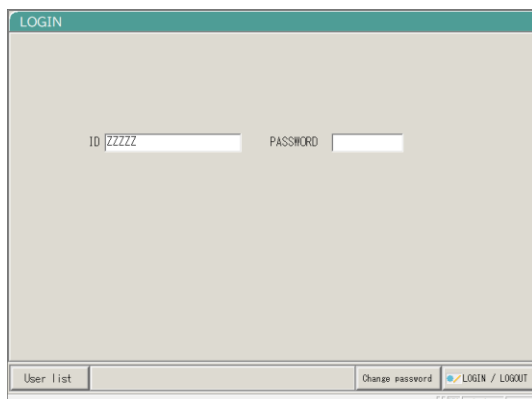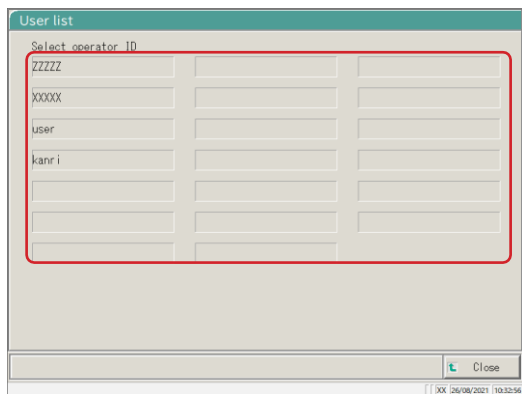
1　Touch {User list}.
* The [User list] screen opens.

2　From the displayed list, touch an operator ID to login.

{Close}: The screen returns to the previous screen.

3　The operator ID is displayed.

☞　For the procedure to enter the password, see page 28 "2.3 Logging In."

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2.4 Initial Settings

Before using the system for the first time, initial settings are required.

The initial settings are roughly divided into "System settings" and "Protocol settings."

For both settings, touching {Settings} on the [MENU] screen displays the corresponding screen to make each setting. This section describes the outline of the system settings and the protocol settings.

For detailed operating procedures, see "Chapter 6 Settings" on page 182.

(Note) When the user is logged with an administrator ID, or when "No" is selected for "Operator mode," settings cannot be changed.

2.4.1 System Settings
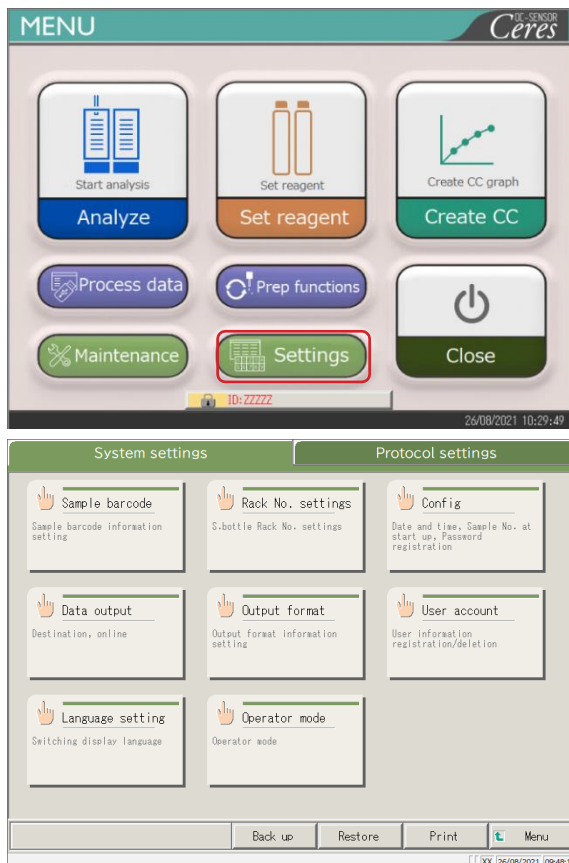
1 Touch {Settings}.

2 Touch the button for the item to be set.

* The corresponding setting screen opens. (See the next page.)
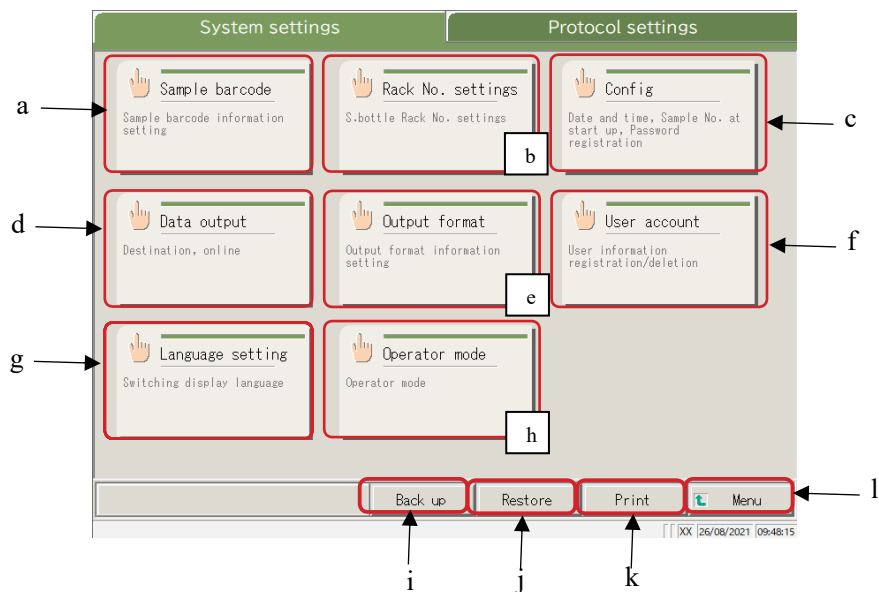
[System settings] screen

a	Sample barcode	Set conditions for reading sample barcodes.
b	Rack No. settings	Register racks for new and former sampling bottles.
c	Config	Set the date and time.
		Register a password.
		Select the purified water supply method and waste water drain method.
d	Data output	Select a data output destination.
		Select formats for the printer output, external media output, and online output.
		Set the online communication control.
		Set the analysis items.
e	Output format	Select the output format.
		Select items for the printer output and online output.
		Set the output items and output order for external media.
f	User account	Register, change, and delete the IDs of the operators who can log in to the system.
g	Language setting	Switch the system display language.
h	Operator mode	Switch the system operator mode.
i	Back up	Save the system settings and protocol settings to external media.
j	Restore	Restore the system settings and protocol settings saved on external media.
k	Print	Print the system settings.
l	Menu	Return to the [MENU] screen.

2.4.2　Protocol Settings
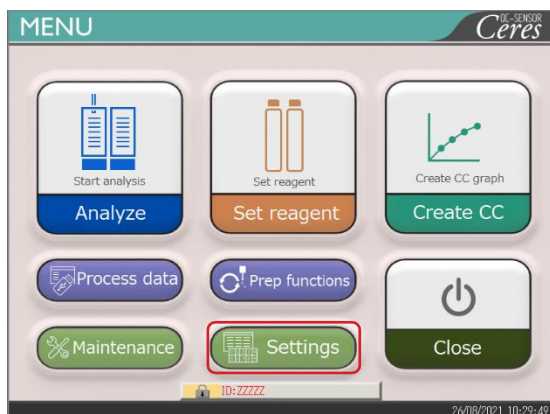
1　Touch {Settings}.
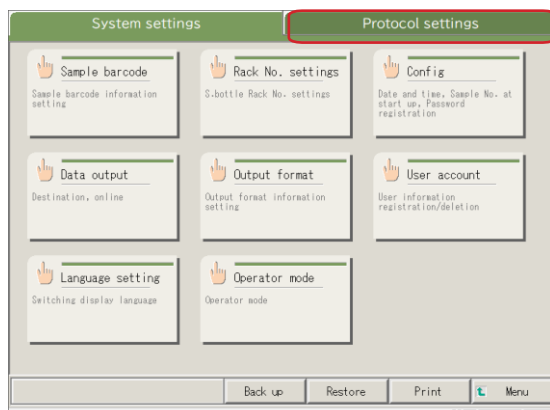
2　Touch the {Protocol settings} tab.
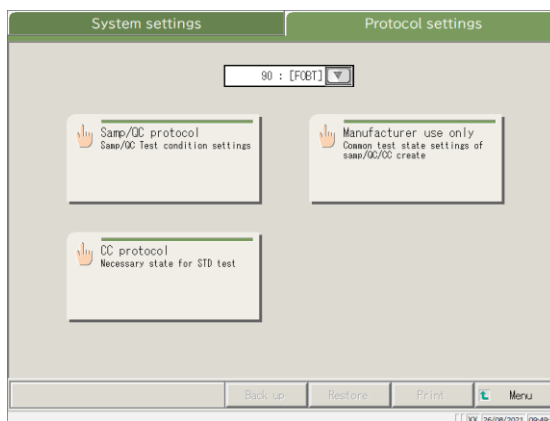
3　Touch the button of a setting item.

＊ Corresponding setting screen opens. (See the next page.)

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Operation
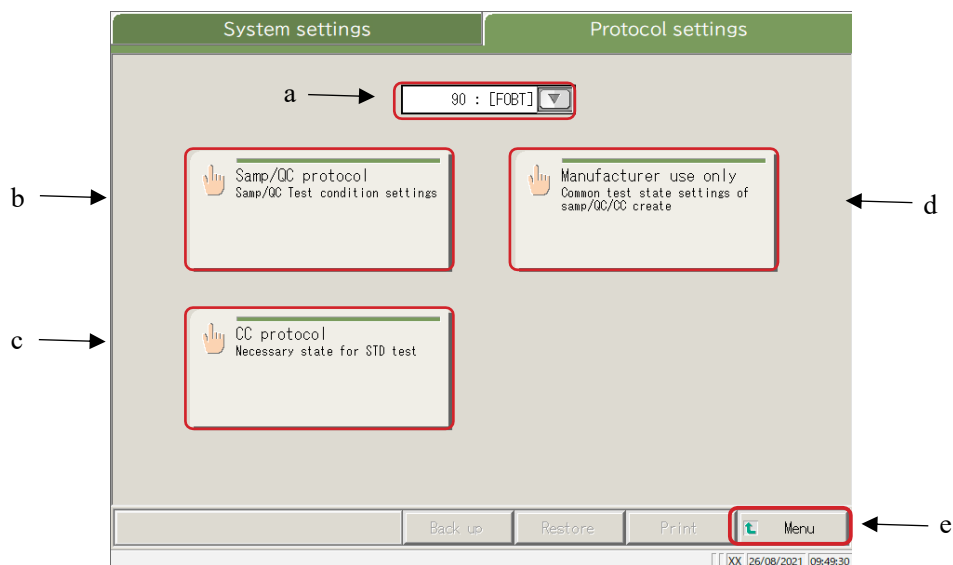
Protocol Settings screen

a	Test item	Select the test item to be set.
b	Samp/QC protocol	Set the test conditions used when measuring samples/QC samples.
c	CC protocol	Set the conditions used when creating a CC.
d	Manufacturer use only	Set the common conditions necessary for measuring samples, QC samples, and STD samples (for maintenance).
e	Menu	Return to the [MENU] screen.

2

Basic
Operation

2.5　Daily Operations

This section describes the flow of daily operation and the operation procedures.

2.5.1　Flow of Daily Operations

(Note)　Complete the initial setting of the system before starting operations.

Startup Inspection	Perform the startup inspection	☞ Page ix

System startup	Check that the primary power switch is on	

(Normally, the primary power switch is ON.)

	Start the system	☞ Page 27
	Log in	☞ Page 28

Preparation before the test	Set the reagents	☞ Page 37
	Set the purified water and washing solution	☞ Page 41
	Check initial settings	☞ Page 31

(Check when the setting is changed.)

	Set the printer sheets	☞ Page 44
	Set the drain tank	☞ Page 46
	Create the CC	☞ Page 47
	Set the samples	☞ Page 58

To the next page.

2
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Operation

Test start	Open the [Assay] screen	☞ Page 60
	Set the test conditions	☞ Page 60
	Start analyzing (Initial/Retest/QC)	☞ Page 60

| Testing | <When necessary> | Add samples | ☞ Page70 |
| | | Rack information | ☞ Page 73 |

| Test finish | Ending the analysis | ☞ Page75 |

	End
	Abort
	Automatic stop

| Inspection and cleaning | Replace the cells | ☞ Page78 |
| | Clean various sections | ☞ Pages 84 and 170 |

	Daily
	Weekly
	Monthly

System shutdown	Shut down the system	☞ Page 89
	* The System switch automatically turns off.
	Process the drain tank	☞ Page 91

2.5.2 Setting the Reagent

Preparation before the test

R1 reagent, R2 reagent, and diluent are set in the reagent refrigerator.

A maximum of three sets of reagents can be set for one item.

> ⚠ **Warning**
>
> | Biohazard | · | Wear protective gears (gloves, goggles, etc.) when handling the reagents. |
> |---|---|---|
> | | | Failure to observe this precaution may lead to infection from the reagents. |

(Note) The reagents can also be set in the {Set reagent} tab on the [Analyze] screen or [Create CC] screen.
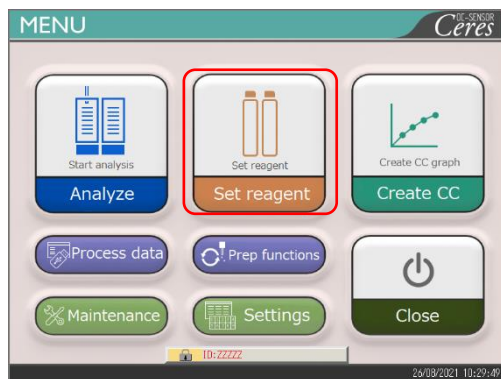
1 Touch {Set reagent}.

2 Set the reagent bottles into the reagent refrigerator.

① Open the safety guard.
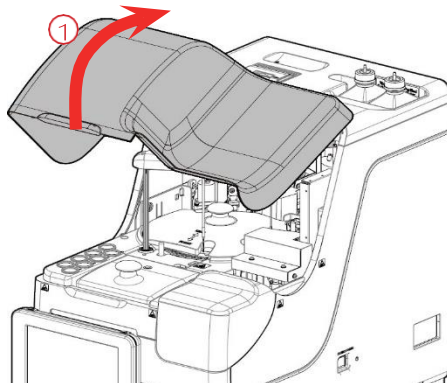
② Open the reagent refrigerator cover.

2
Basic Operation
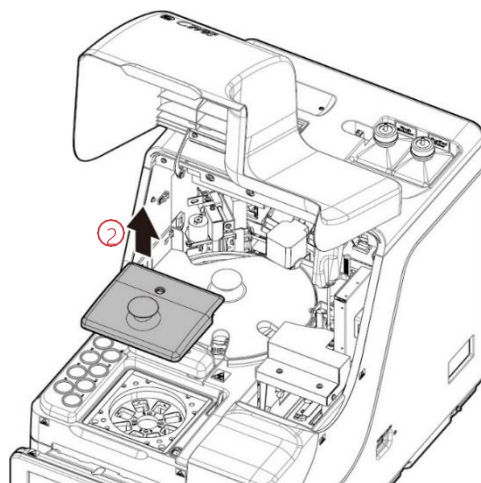
Preparation before the test
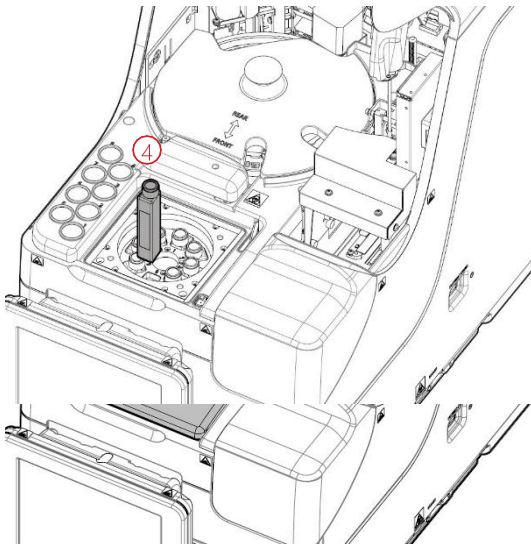
③ Remove the cover of the reagent bottle to be set.

④ Remove the reagent bottles currently set. Set the new reagent bottles in the proper positions.

Set R1 or R2 reagents in Pos. 1 to 6.
Set the diluent in Pos. 7 and 8.
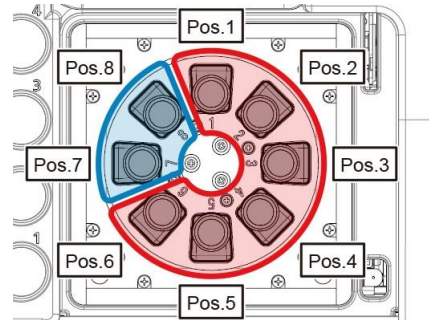
Top view
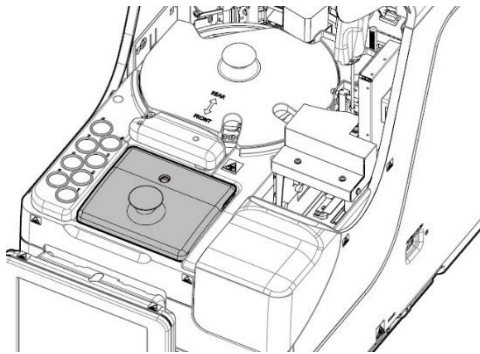
⑤ Set all reagents and close the reagent refrigerator cover.
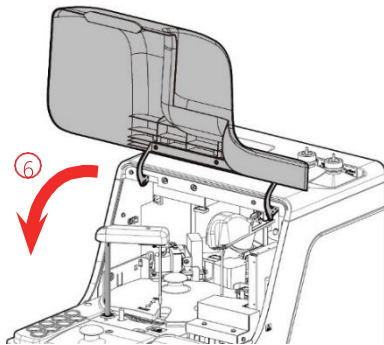
⑥ Close the safety guard.

(Condition that the safety guard is closed.)

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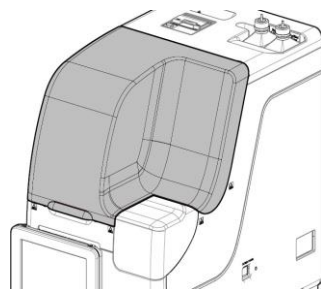
⚠	Caution
🛈 Required	· After setting the reagent bottles, close the reagent refrigerator cover and the safety guard. Failure to observe this precaution could result in a reagent nozzle contacting the cover.
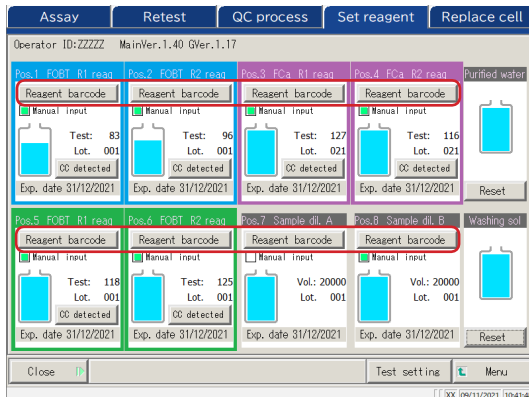
<Entering a reagent barcode using the numeric keypad>
① Touch {Reagent barcode}.
  * The numeric keypad opens.
② Check the 24-digit barcode on the reagent bottle. Enter the first 23 digits (exclude the last digit, the check digit) using the numeric keypad.
③ Touch {OK} or {enter}.
  * The numeric keypad closes.
  * A check mark is placed in the [Manual input] check box.

(Note) {Reagent barcode} becomes active only when the user is logged in with an administrator ID or when the Operator mode is set to "No."
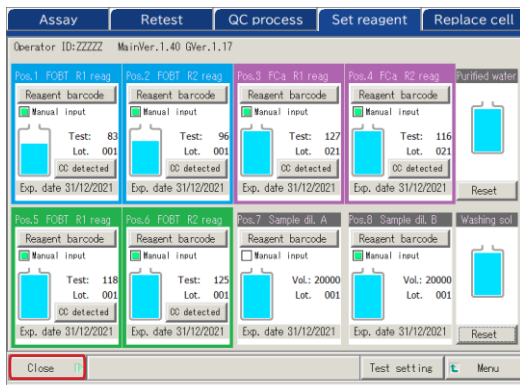
3 Touch {Close}.

  * The reagent barcode is automatically read.
  * The reagent information is updated.

4 Check the reagent information (barcode, pairing condition, etc.)

{CC detected} : Displays CC.

{Test setting} : Sets a test item.

☞ Page 198

{Menu}   : Returns to the [MENU]

(Note) If there is no CC for the set R1 and R2 reagents, "No CC" is displayed. In that case, create a CC.

(Note) Pairing indicates the condition in which R1 and R2 reagents in the same lot in the same test item are set as a pair.

(Note) After the reagent barcodes are read, the system automatically conducts pairing.

(Note) Do not open the reagent refrigerator cover while reading the reagent barcode. If the cover is opened, reading the barcode fails, and an error (ERR#2-103) is output.

(Note) Expired reagents are not tested.

> ⚠   Request
>
> Reagent barcode configuration
>
> ・ The barcodes on the reagent bottles are 23-digit ITFs (excluding the check digit).
> ・ When entering a barcode, follow the configuration below.
>
> KKKAABBCRYYMMDDXXXNNNNNM (barcode)
>
> KKK: 3-digit manufacturer code (026)
>
> AA: 2-digit item code (01 to 99)
>
>   90:FOBT 53:FCa
>
> BB: 2-digit product code (01 to 99)
>
> C: 1-digit bottle capacity (1: 20 mL)
>
> R: 1-digit reagent type (1: R1 2: R2 3: diluent)
>
> YYMMDD: 6-digit expiration date (YYMMDD)
>
> XXX: 3-digit lot number (000 to 999)
>
> NNNNN: 5-digit bottle number (00001 to 99999)
>
> M: Check digit

Switching between a reagent bottle and a diluent bottle is as follows.

・ Reagent

Before the first dispensing of each sample, compare the reagent test number and the number of sample replications. If the number of reagent tests in use is too small, a shortage is judged, and the bottle automatically changes. The detailed conditions for the bottle change vary for each reagent lot number.

Measurement	In case of the same lot number	In case of different lot numbers
Sample (retest)	The bottle changes.	
QC	The bottle changes.	The bottle does not change.
CC	The bottle does not change.	

(Note) It will not switch to a lot for which CC was not created. Set the reagent of the lot for which a CC has been created.

(Note) If the reagent test number becomes "0" due to trouble such as a detection failure of the reagent liquid level, further loading of the samples stops. Instead, the measurement results for the samples for which dispensing has completed are output.

・ Diluent

Bottles are switched automatically. However, if the liquid amount in a bottle becomes zero while creating the diluent system, the detailed conditions for the bottle change depending on the reagent lot numbers.

In case of the same lot number	In case of different lot numbers
The bottle changes.	The bottle does not change.

2.5.3 Preparing Purified Water

Fill the purified water bottle with purified water.

> ⚠ **Request**
>
> · Always use the provided purified water bottle.
> · Always dismount the bottle from the system, and then refill it.
> · Always check that the bottle is sufficiently filled.

(Note) Purified water bottle size: 500 mL.

1 Loosen the purified water bottle lid (white). Remove the hose.

2 Dismount the purified water bottle from the system.
Drain remaining purified water from the bottle.

3 Refill the purified water bottle.

4 Set the purified water bottle at the right-hand side ("Purified water") of the purified water installation system.

5 Insert the hose into the purified water bottle opening. Close the bottle lid.
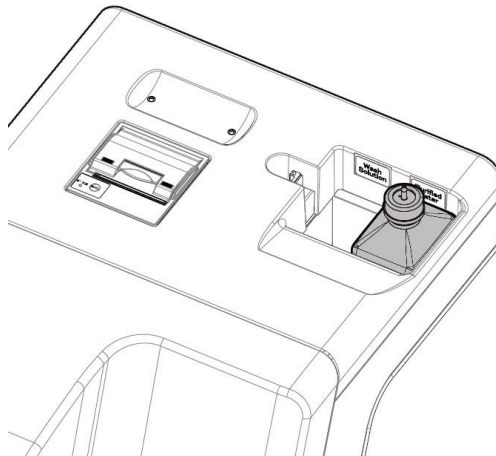
Preparation before the test

2.5.4   Preparing Washing Solution

Pour washing solution diluted to 3% into the washing solution bottle.

⚠	Request
	· Before using the system, always check that the washing solution is sufficient. · Always use the attached washing solution bottle (accessory). · Always remove the bottle from the system before refilling the washing solution.

⚠	Warning
⚠ Biohazard	· Wear protective gear (gloves, goggles, etc.) when handling the washing solution.

(Note)   Washing solution bottle: 500 mL.
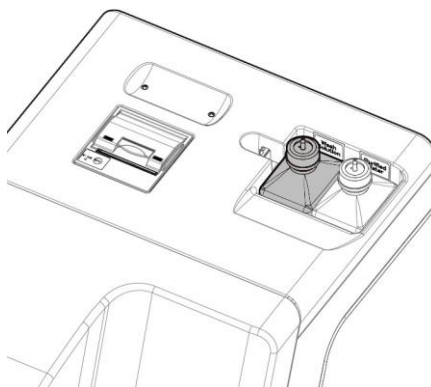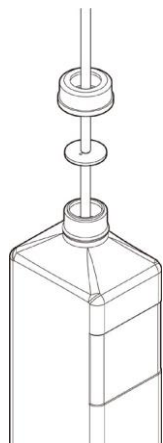
1 Loosen the washing solution bottle lid (yellow) and remove the hose.

2 Dismantle the washing solution bottle from the system.
Drain the remaining washing solution from the bottle.

3 Dilute the washing solution to a 3% concentration.
① Pour 15 mL of washing solution (undiluted) into the washing solution bottle.
② Pour purified water into the bottle to bring the total washing solution amount to 500 mL.

4 Set the washing solution bottle on the left side (washing solution) of the washing solution/purified water setting area.

5 Insert the hose into the washing solution bottle opening. Close the bottle lid.

(Note)   Washing solution without an indication of "(undiluted solution)" is the washing solution diluted to 3%.

2.5.5 Washing Solution and Purified Water Settings

Set up the washing solution bottle and the purified water bottle, and update the system.

Preparation before the test
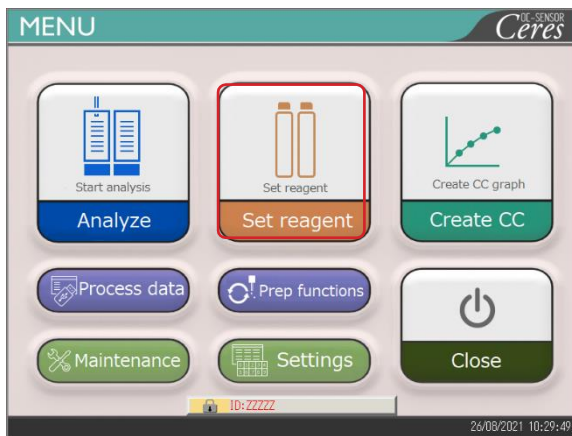
1 Touch {Set reagent} on the [MENU] screen.
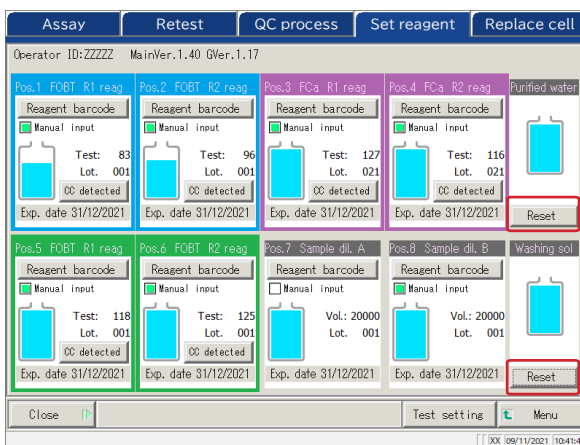
2 Touch {Reset} for the purified water and the washing solution.

* {Reset} turns to green.
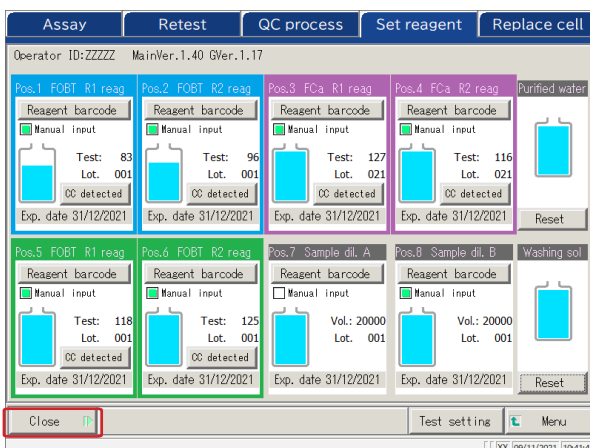
3 Touch {Close}.

* Information on the washing solution and purified water is updated.

2   Basic Operation

Preparation before the test

2.5.6   Setting Printer Sheets

Place the printer paper into the printer.

Paper cover

Paper cover open lever

STATUS LED
LED lamp   FEED button   Manual cutter
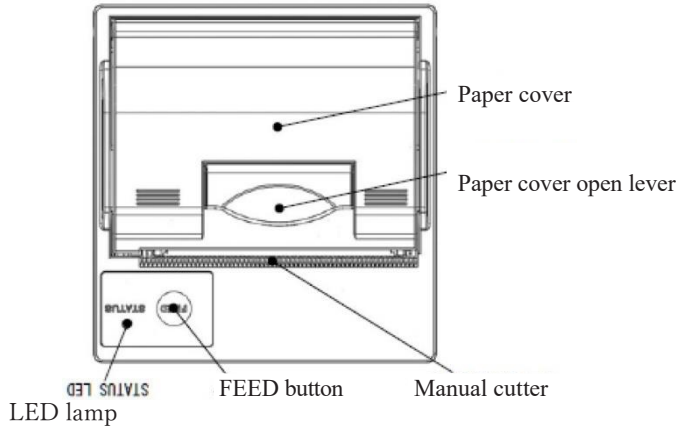
> ⚠ Caution
>
> ❗ Required
>
> · Pay close attention to the blade of the manual cutter.
>
>   Failure to observe this precaution may lead to injuries.

Paper cover

Paper discharge port

Manual cutter

FEED button
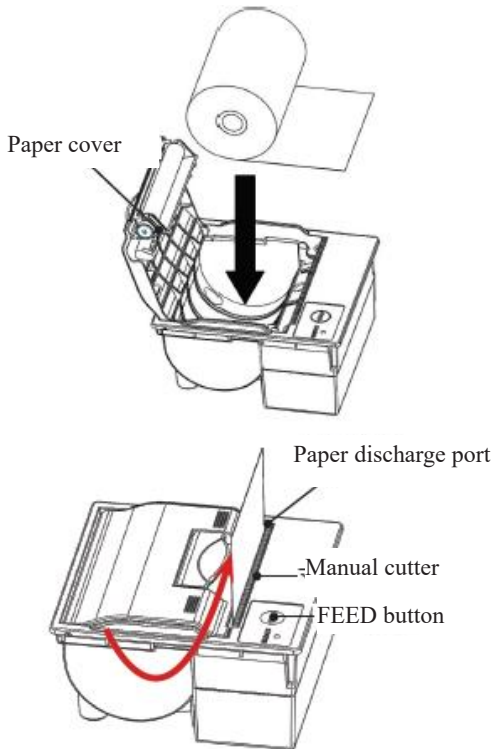
① Raise the paper cover open lever, and open the cover.

② Set the paper roll as shown in the drawing.
(If the roll is set upside down, printing is not possible.)

③ Draw out the end of the roll from the paper discharge port.

④ Bring down the paper cover.

⑤ Push down on both ends of the paper cover to close it. Check that the cover is locked.

⑥ Press the FEED button.

⑦ Cut the sheet with the manual cutter.

■ **Printer LED**

The LED on the printer indicates the printer status, including errors.

<Normal conditions>

LED	Printer condition
Green	Stand-by, ready for printing
Blinking green	Initializing

<Recoverable Errors>

LED	Printer condition
Red	Out of paper
Blinking red	Temperature abnormal (70 ℃ or higher)

<Unrecoverable Errors>

LED	Printer condition
Blinking red and green	Voltage too high
Blinking red and green	Voltage too low

2   Basic Operation

2.5.7   Checking the Drain Tank

(The tank connection with the system is set up by our service personnel.)
Check that the hose attached to the drain tank is connected to the system.

⚠	Warning
⚠ Biohazard	· Wear protective gear (gloves, goggles, etc.) when working with the drain tank. Failure to observe this precaution may lead to infection.

⚠	Caution
🛈 Required	· Before using the system, empty the drain tank. Failure to observe this precaution could cause waste liquid to overflow. · Install the drain tank at a position lower than the system. If the drain tank is installed at a position higher than the system, waste liquid may not drain properly.
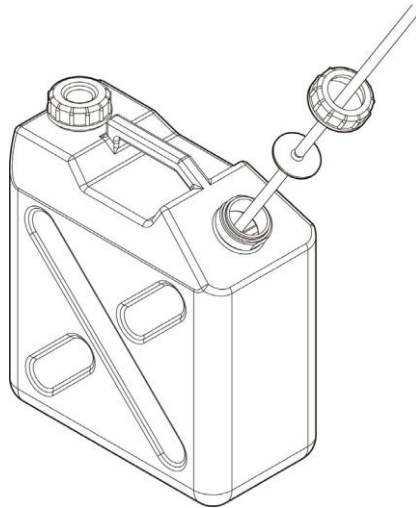
1 Connect the hose to the drain tank.
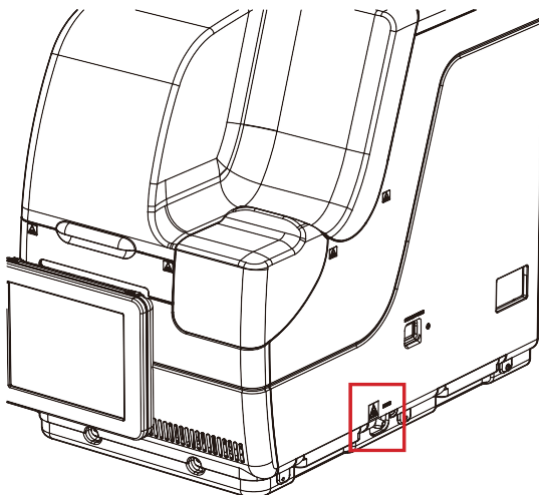
2 Check that the hose is connected to the drain connect or at the right side of the system.
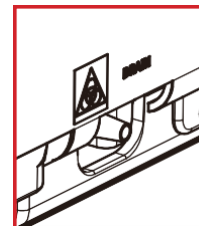
2.5.8 Creating CC

When R1 reagent, R2 reagent, and sample lots are newly installed, create a CC which corresponds to the lot.

⚠ Warning

☣

Biohazard

· Wear protective gear (gloves, goggles, etc.) when handling the calibrator and the QC samples.

Failure to observe this precaution may lead to infection.

---

1   Setting the STD Sample and QC Sample to the Rack

⚠ Request

· When pouring the calibrator and the QC sample into the sample cup, check that there are no bubbles.

(Note) When measuring the STD sample and the QC sample, use the "STD/QC rack." Set only the STD sample and the QC sample into the rack.
When measuring only QC, use the "QC process."

☞ Page 65 "2.5.12 Starting Analysis (QC Sample)"

Set the calibrator and the QC sample into the STD/QC rack.
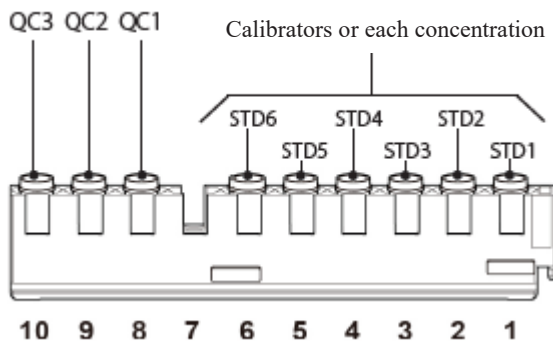
(Note) Numbers in the figure are rack positions. The rightmost position is No.1.

2   Setting the STD/QC Rack into the System
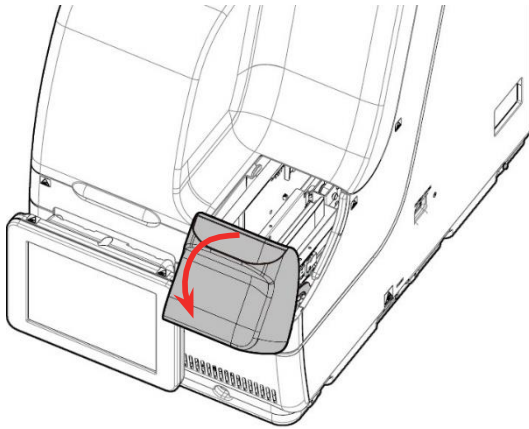
1 Open the rack lane cover.
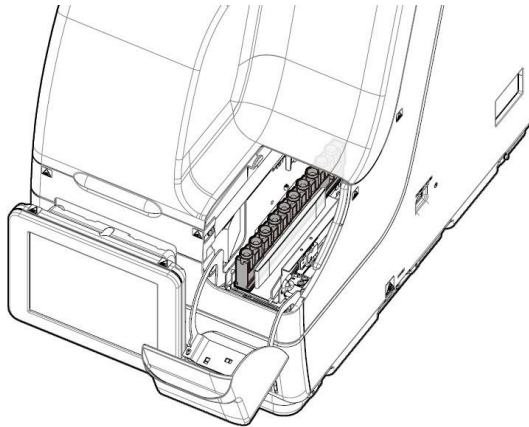
2 Set the rack into rack lane 1 or 2
with rack position No. 1 at the
inner-most side of the system.
Be careful set the rack in properly.

(Note)   When setting the rack, be careful with the
front/rear orientation. Push the rack in until
its end touches the inner section of the
system.
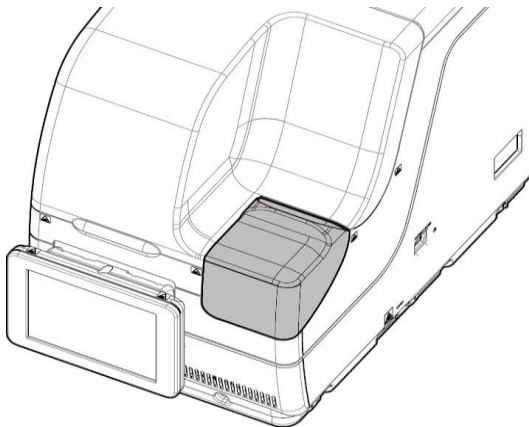
3 Close the rack lane cover.

⚠	Caution
🛇 **!** Required	· Set the rack in the system with rack position No. 1 at the innermost end. Failure to observe this precaution may cause problems.

3 Creating CC

Preparation before the test
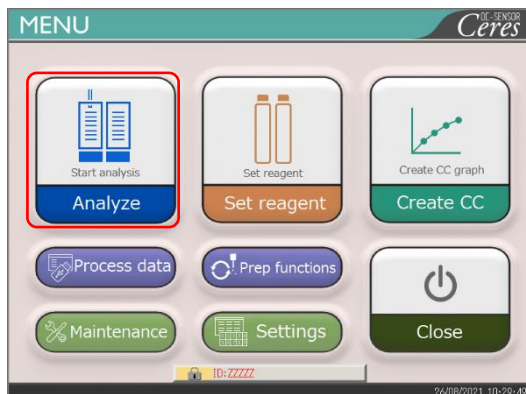
1 Touch {Analyze}
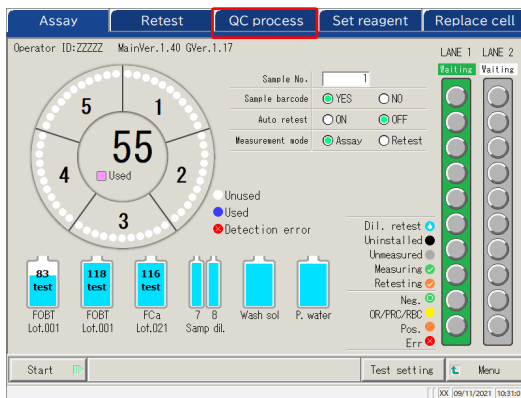
2 Touch the {QC process} tab.
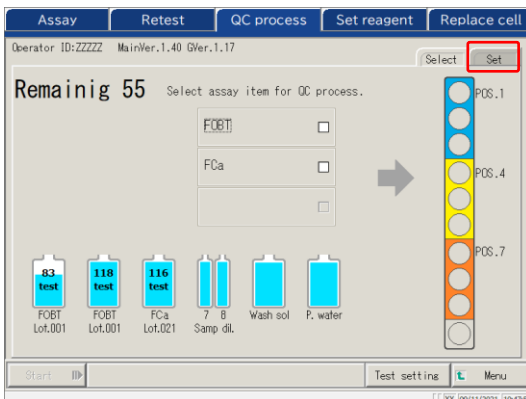
3 Touch the {Set} tab.
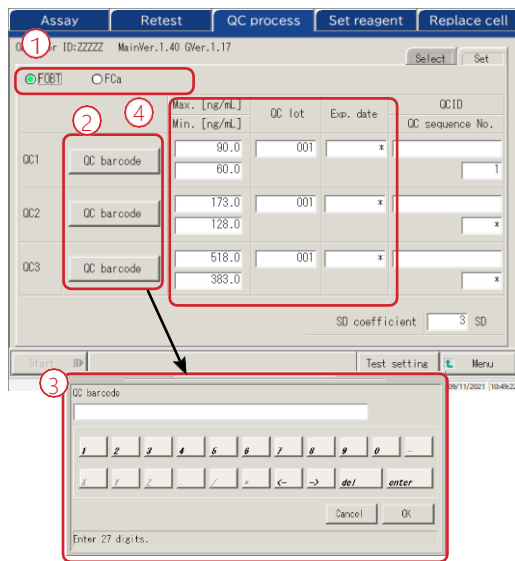
4 Set each QC item.
① Select a radio button (●) for the test item to create the CC.
② Touch {QC barcode}.
③ Read the QC barcode corresponding to the selected test item or QC1 – 3 using the handy barcode reader.
  When entering a barcode using the numeric keypad, enter the 27-digit QC barcode excluding the last digit (check digit).
④ Max./Min. values, QC lot, and expiration date are automatically entered from the barcode.
⑤ Enter the remaining settings.
  (See the table on page 68.)

(Note)　Expired QCs cannot be used.

⚠　Request

About QC barcode configuration

·　The QC barcode is a 27-digit ITF (excluding the check digit).

·　When entering a barcode, follow the configuration below.

KKKAABBCYYMMDDXXXYYYYYZZZZZM (barcode)

KKK: 3-digit manufacturer code (026)

AA: 2-digit item code (01 to 99)

　　　90:FOBT 53:FCa

BB: 2-digit product code (01 to 99)

C: Concentration type

YYMMDD: 6-digit expiration date (YYMMDD)

XXX: 3 digit lot number (000 to 999)

YYYYY:　Min. value of reference range (00001 - 99999)

ZZZZZ: Max. value of reference range (00001 - 99999)

M: Check digit

5 Touch {Menu}.
Returns to the [MENU] screen.
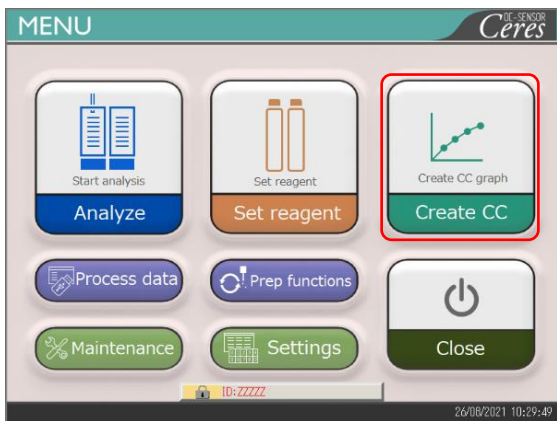
6 Touch {Create CC}.
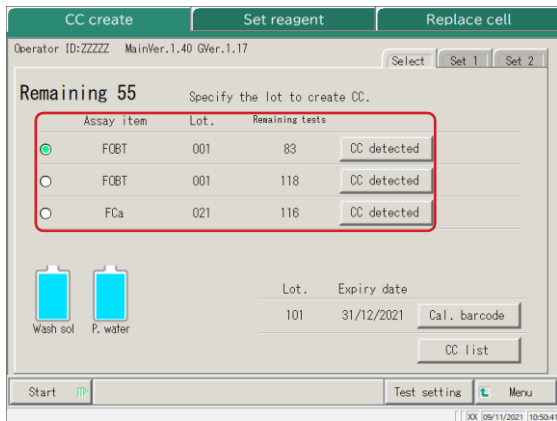
7 Touch a radio button ● to select the item/lot to create the CC.

Preparation before the test
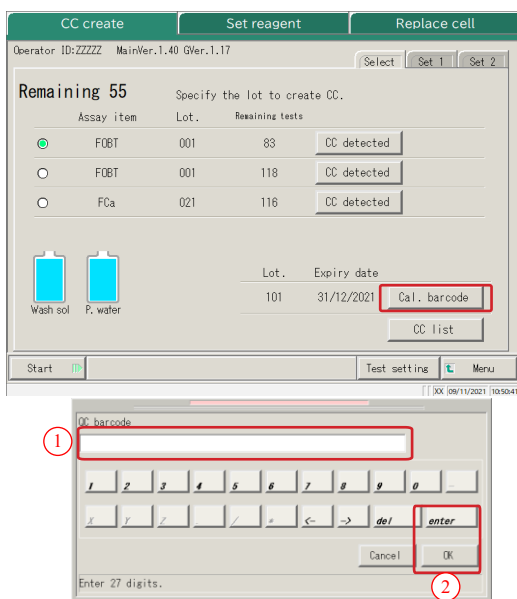
8 Touch {Cal. barcode} to enter the barcode of the calibrator.

{CC detected}: Displays the currently registered CC.

① Read the calibrator barcode with the handy barcode reader. When entering a barcode using the numeric keypad, enter a 17-digit calibrator barcode excluding the last digit (check digit).

② Touch {OK} or {enter}.
* The numeric keypad closes.
* The lot. and expiration date are displayed.

(Note) An expired calibrator cannot be used.

{CC list}: Displays a list of CCs.
☞   Page 57
{Test setting}: Sets the test item.
☞   Page 198
{Menu}: Returns to the [MENU] screen.

⚠ Request

Calibrator barcode configuration

·   The 17-digit barcode on the bottle is an ITF (excluding the check digit).

·   When generating a barcode, follow the configuration below.

KKKAABBYYMMDDXXXNM (barcode)

KKK: 3-digit manufacturer code (026)

AA: 2-digit item code (01 to 99)

　　90:FOBT 53:FCa

BB: 2-digit product code (01 to 99)

YYMMDD: 6-digit expiration date (YYMMDD)

XXX: 3-digit lot number (000 to 999)

N: Spare (O)

M: Check digit

Preparation before the test
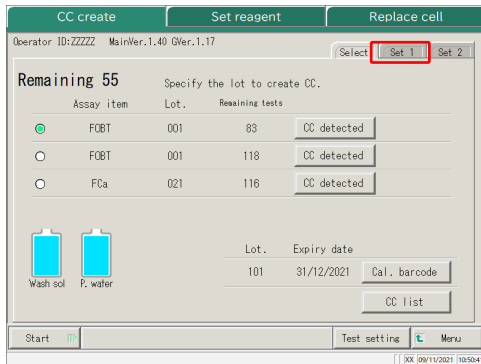
9 Touch the {Set 1} tab to set the number of replications for STD.

(Note) When the number of remaining cells is smaller than the number of STD measurement tests, a message about the cell shortage will appear.
Check the number of remaining cells before performing the STD tests.

(Note) Make settings other than those concerning STD replication on the {Set 1} and {Set 2} tabs as needed.
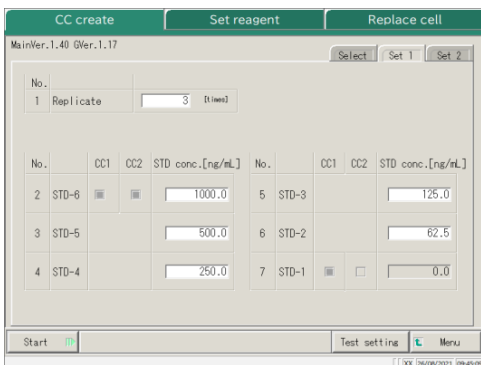
{Set 1} tab

☞For details on the settings, see page 224 "6.2.2 CC Protocol Setting" – {Page 1} tab.
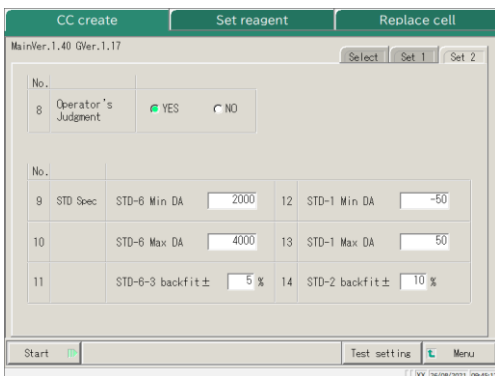
{Set 2} tab

☞For details on the settings, see page 224 "6.2.2 Protocol Settings" – {Page 2} tab.
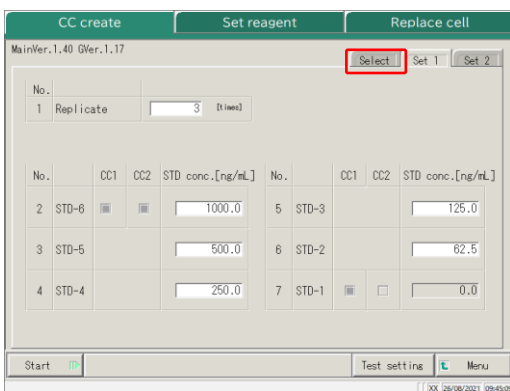
10 Touch the {Select} tab.

Preparation before the test
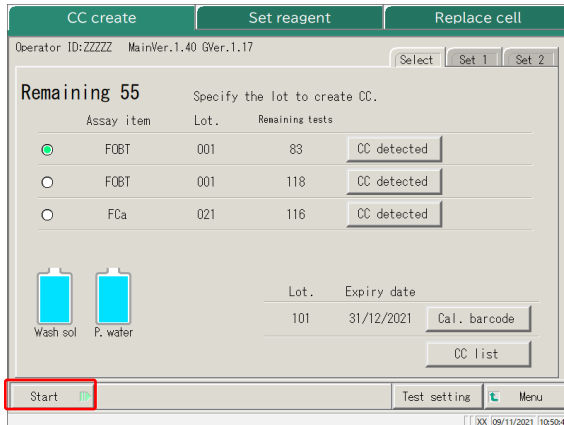
11 Touch {Start}.

* Start STD/QC measurement.
The screen shifts to the [CC create] screen.
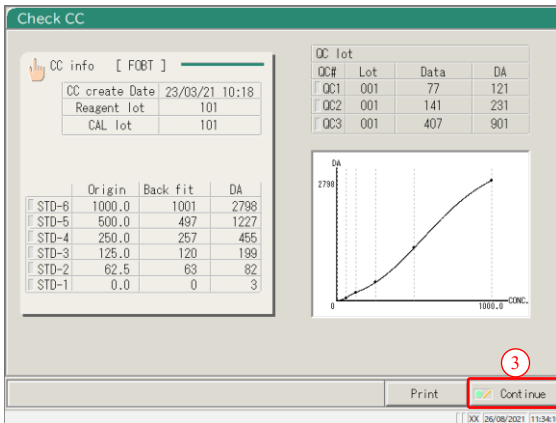
.**12** Register or cancel CC.

① When the test ends, the [Check CC] screen opens.
② Check the CC.
   ☞ For details on the [Check CC] screen, see page 56 "■CC check."
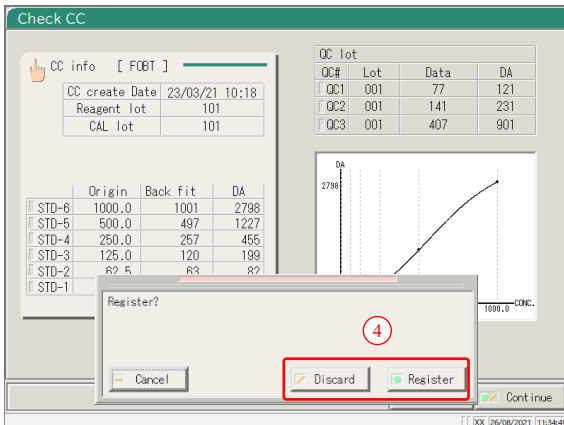
<When registering the CC >
③ Touch {Continue}.
④ Touch {Register}.
The tested CC is registered in the system.

< When not registering the CC >
③ Touch {Continue}.
④ Touch {Discard}.
Create the CC again.
   ☞ Page 47 "2.5.8 Creating CC"

* CC creation ends, and the screen returns to the [CC create] screen.

(Note) In the CC protocol setting, if "Operator's Judgment" after STD/QC test is set to "No," the tested CC is automatically registered in the system, and the [Check CC] screen does not open.
        ☞ Page 224 "6.2.2 CC Protocol Settings"

4 Removing a Rack
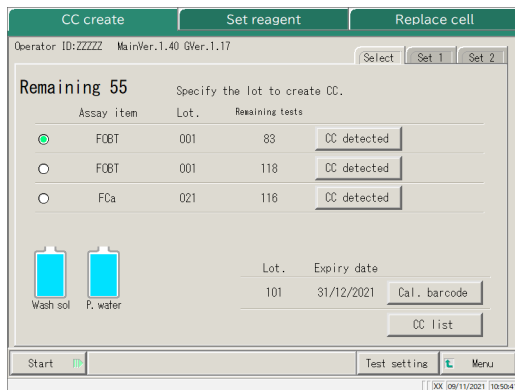
1 After the STD/QC test ends, the screen returns to the [Create CC] screen.
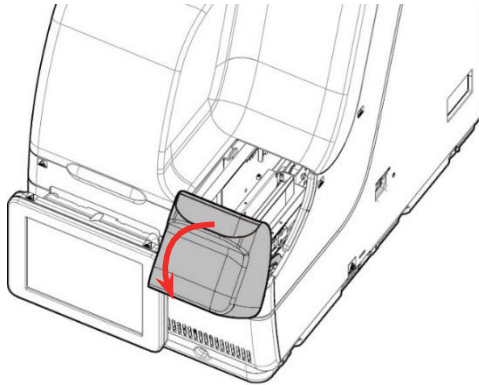
2 Open the rack lane cover.
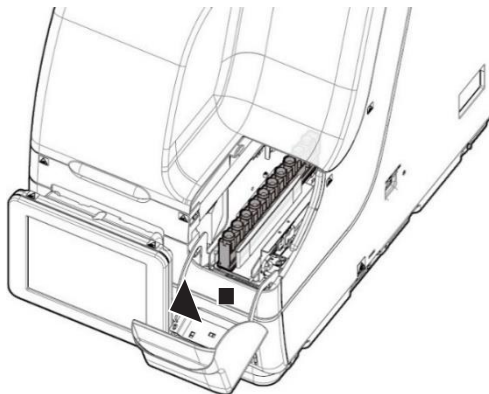
3 Remove the STD/QC rack.
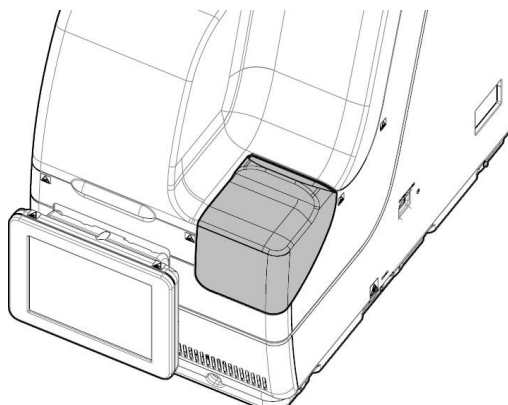
4 Close the rack lane cover.

Preparation before the test

Preparation before the test

■   CC check

If the CC has been created, touching {CC detected} on the [Create CC] screen or the [Set reagent] screen displays the CC information (test date and time, reagent lot, etc.) and the CC graph.
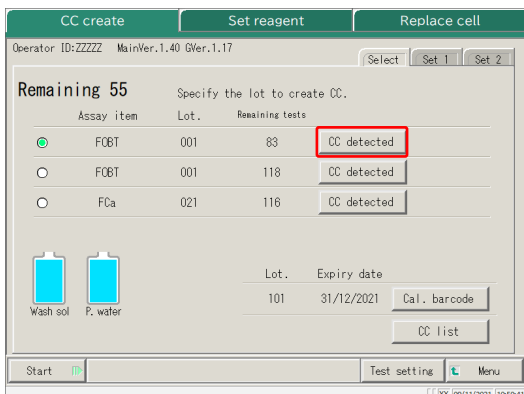
1 Touch {CC detected}.

2 Check the CC information and the graph.

{CC info}: Edit and recalculate the CC.
☞ Page 128
{CC list}: Display CC list.
☞ Page 57
{Print} : Print the CC information and the graph.
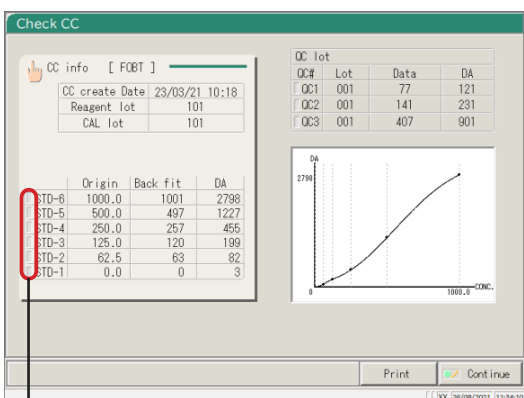
Turns red when the value is outside of the specified range.
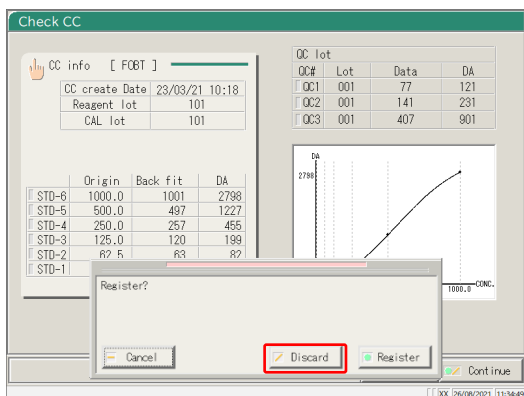
3 Touch {Continue}.
4 Touch {Discard}.
* The display returns to the previous screen.

(Note) Origin values and DA values can be changed on the [Edit and Recal CC] screen.
☞ Page 128 "3.3.8 Editing and Recalculating CC"
(Note) When the measurement result of the STD sample is out of the standard range, the box at the left side of the STD-# turns red.
☞ Page 224 "6.2.2 CC Protocol Settings"

■ CC list

When {CC list} is touched on the [Create CC] screen, the [CC list] screen opens. Detailed CC information can be referred from the list.

<div style="text-align:left">

Preparation before the test

</div>
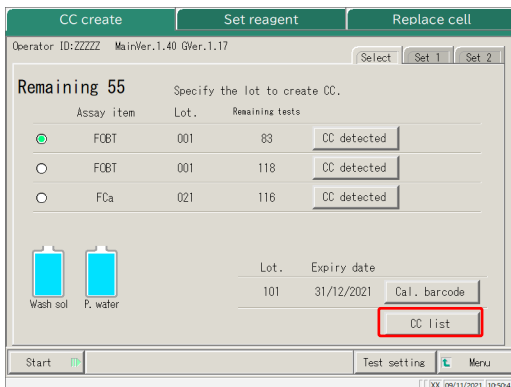
1 Touch {CC list}
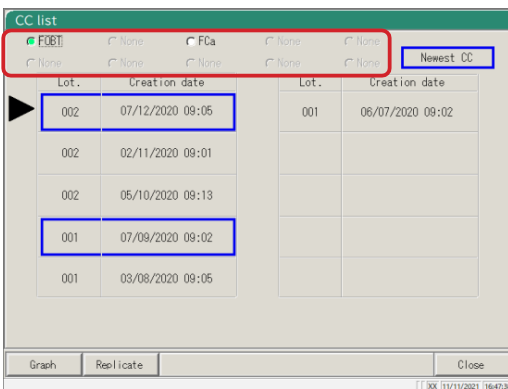
2 Select the test item

(Note) FOBT uses the common CC.

3 Check the CC list.

Items in blue frames □ are the latest CC or each lot.
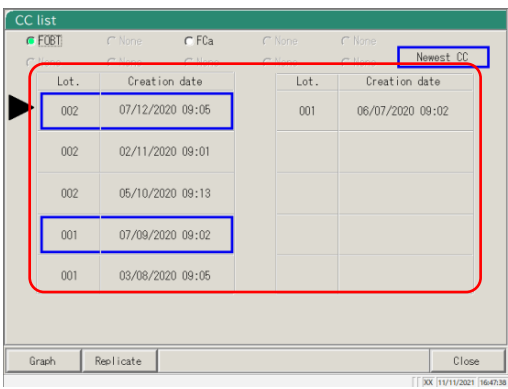
4 Touch "Lot" or "Creation date" of the CC to check the details.

The CC with the ▶ mark is the selected CC.

{Graph}: Displays the selected CC.

{Replicate}: Displays the STD replication.
☞Page 118
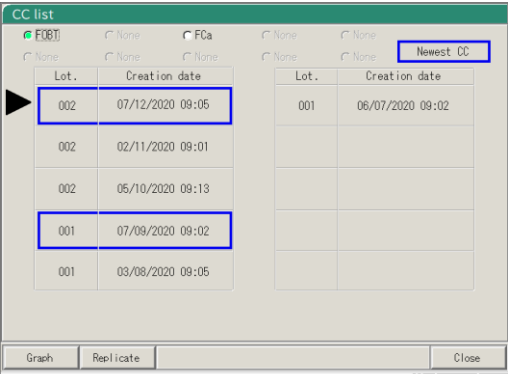
5 Touch {Close}.

* The display returns to the previous screen.

2.5.9   Setting Samples

Set the rack with the samples in the rack lane.

When racks are set in both Lanes 1 and 2, processing starts from Lane 1.

⚠	Warning
![Biohazard] Biohazard	・Wear protective gear (gloves, goggles, etc.) when handling the samples. Failure to observe this precaution may lead to infection.

1   Setting samples (sampling bottles, sample cups) in the rack

(Note) Set the sampling bottles vertically.

・   If a sampling bottle is set at an angle piercing might not be conducted properly.
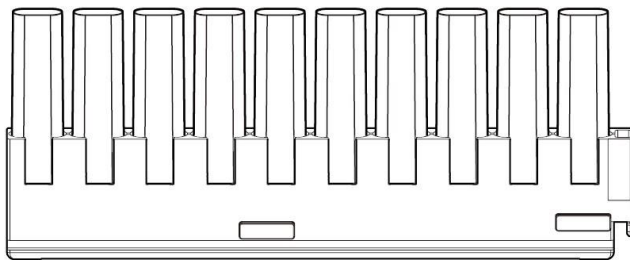
Up to ten sampling bottles or sampling cups can be set in one rack.

(Note)   Set the sampling bottles in the rack in a way that the barcodes face the user.

(Note)   Numbers in the figure are rack positions. No. 1 is on the right.

Preparation before the test

2   Setting a sample rack in the system
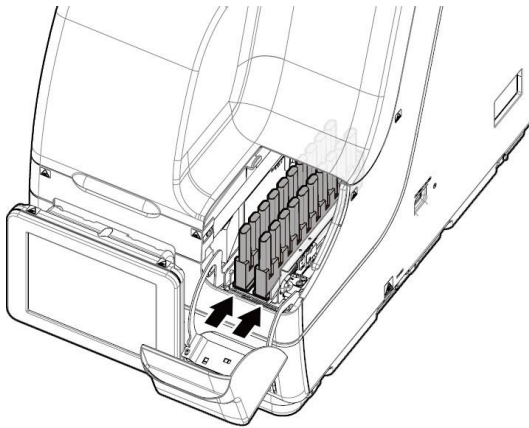
1 Open the rack lane cover.
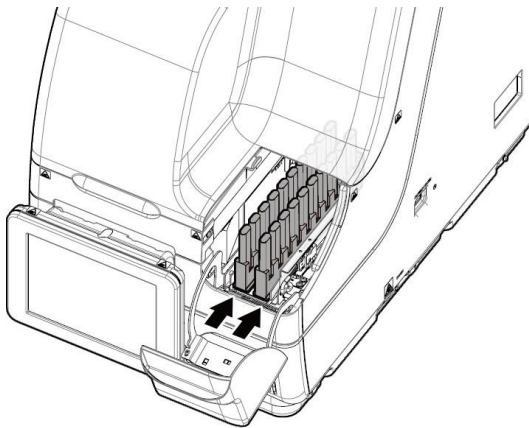
2 Set the rack into the rack lane with rack position No.1 at the innermost end. Pay close attention to set the rack properly.

(Note) When setting the rack, pay close attention to the front and rear orientation of the rack. Push the rack in until the rack contacts the innermost section of the system.
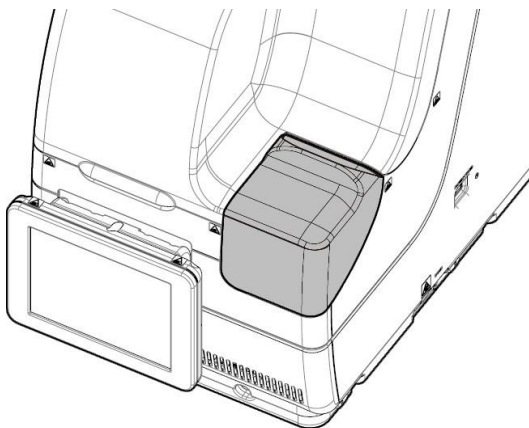
3 Close the rack lane cover.

⚠ Caution

🛑 **Required**
・Set the rack in the system with rack position No. 1 at the innermost end.

Failure to observe this precaution may cause problems.

<table>
<tr><td rowspan="4">2
Basic
Operation</td></tr>
</table>

2.5.10 Starting Analysis (Initial Test)

Before starting the first sample measurements, perform the initial inspection.
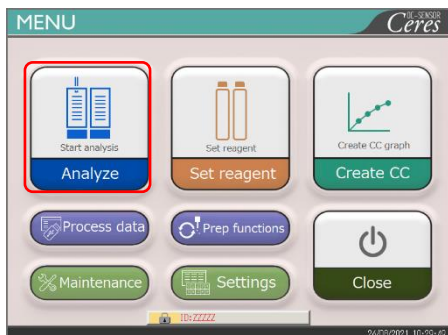
1 Touch {Analyze}.
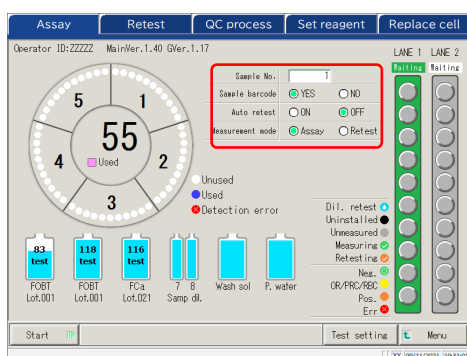
2 Set each item (see the following table).

{Test setting}: Sets the analyzing items.
　　　　☞ Page 198
{Menu}: Returns to the [MENU] screen.

　　　The changed settings are saved for each setting.

Item	Range/selection	Content
Sample No. (When the system power is turned off, the sample No. returns to the "Sample start No." set in [System Settings] - [Config.])	1 - 99999	The sequence No. of the first sample.
Sample barcode (Even when the system power is turned off, this setting is kept.)		Whether or not the sample barcode is used. ・ This setting is also reflected in [Settings] - [System Settings] - [Sample barcode settings].
	Yes :	The sample barcode is used.
	No :	The sample barcode is not used.
Auto retest (Even when the system power is turned off, this setting is kept.)		Whether or not automatic retest is performed for error samples. ☞ For error samples, see page 217 "6.2.1 Sample/QC Protocol Settings."
	On :	Automatic retest is performed for error samples.
	Off :	Automatic retest is not performed for error samples.
Measurement mode (This setting is kept until the system power is turned off.)		The measurement mode is selected.
	Assay:	Assay is selected when the test is conducted for the first time.
	Retest:	Retest is selected when the sample is retested.

(Note) Retest means testing a sample that was already tested. Piercing the sample bottle is not performed again. All of other operations will be the same as those of the "first test."

(Note) For automatic retest, the same sample sequence number is allocated for both the first test and the retest.

Test start

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3 Touch the {Start} button.
When the priming completes, dispensing of the sample starts.

2

Basic
Operation

Test start

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Basic
Operation
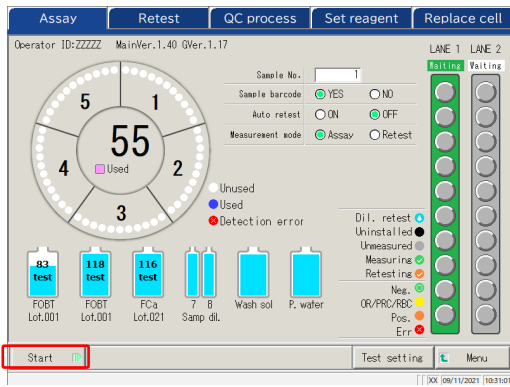
2.5.11 Start Analyzing (Retest)

When retesting a sample, the sample is re-analyzed. Set the dilution factor for each test item and perform the test.

Test start
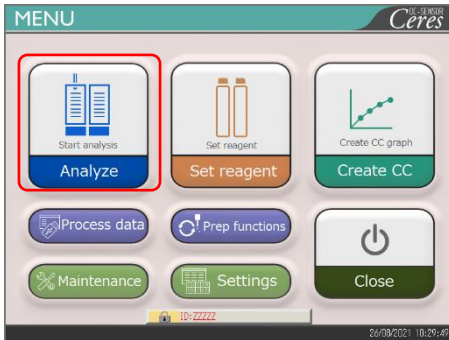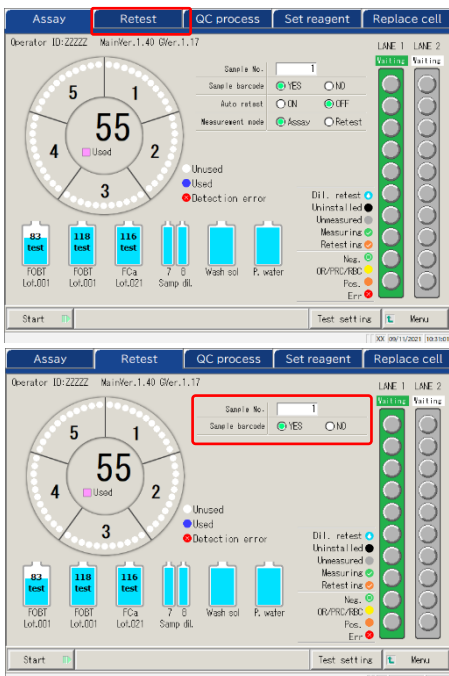
■1 Touch {Analyze}.

■2 Touch the {Retest} tab.

{Test setting}：Sets the item to be analyzed.
　　　　　☞　　Page 198
{Menu}：Returns to the [MENU] screen.
　　　　The settings are saved for each item.

■3 Set each item.

Item	Range/selection	Content
Sample No. (When the system is turned off, the sample No. returns to the "Sample start No." set in [System Settings] - [Config.].)	1 - 99999	The sequence No. of the leading sample.
Sample barcode (The setting remains even after the system is turned off.)	Yes: No:	Whether or not the sample barcode is used. ・　The setting is reflected to [Settings] - [System Settings] - [Samp barcode settings]. Use the sample barcode. Don't use the sample barcode.

Test start

(Note) To return to the [MENU] screen, touch {Menu}. The display returns to the [MENU] screen while the setting is unchanged.
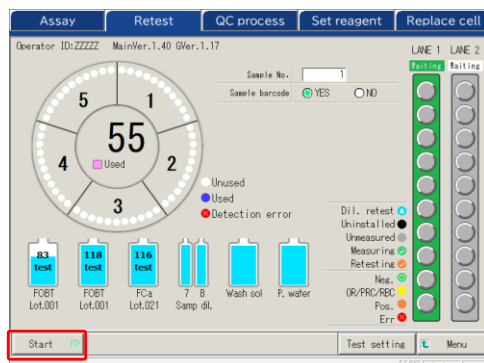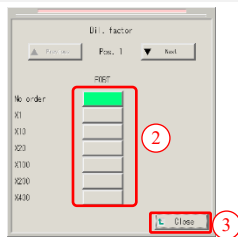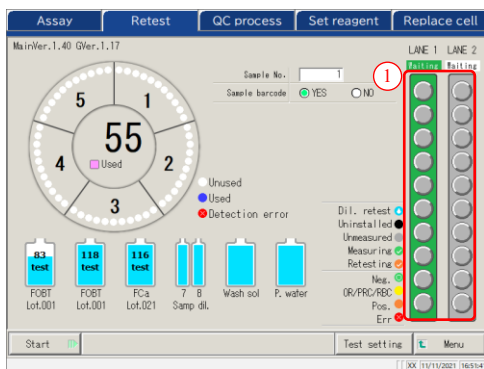
4 Set the sample dilution factor.

① Touch a sample position on the rack graphic. A dialog opens.

② Set the dilution factor.

In the drawing on the left, the following dilution factor is set.

FOBT : Diluted by a factor of 400

{▲Previous}: Selects the previous sample (moves up)

{▼Next}: Selects the next sample (moves down)

③ Touch {Close} to close the dialog. "Dil. retest ⬤ " is displayed for samples which the dilution factor is set.

5 Touch {Start}.

When the pre-test priming completes, sample dispensing starts.

2

Basic Operation

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Basic
Operation

Test start

■   Operation flow of the dilution retest

On the [Retest] screen, the "Dilution factor" is set. After the test starts, the sample is diluted in the cell, and the test starts.
The cell consumption is higher as compared to the regular tests.

Dispense the diluted sample	The reagent nozzle dispenses the diluent to the cells (for dilution).
↓	
Dispense sample	The sample nozzle dispenses the sample to the cells (for dilution).
Mix the sample	The mixer mixes the sample in the cell (for dilution).
↓	
Dispense R1 reagent	The reagent nozzle dispenses R1 reagent to the cell.
↓	
Dispense the diluted sample	The sample nozzle dispenses the diluted sample to the cell.
↓	
Mixing ①	The mixer mixes the liquid inside the cell.
↓	
Dispense R2 reagent	The reagent nozzle dispenses R2 reagent to the cell.
↓	
Mixing ②	The mixer mixes the liquid inside the cell.
↓	
Measurement	The transmitted light is measured.

The dilution count varies depending on the set magnification ratio

x10, x20: 1 time
x100, x200, x400: 2 times

One cell is used for one dilution.

2.5.12 Starting Analysis (QC Sample)

When testing the QC sample only, the QC process is used.

The [QC process] is configured on two pages. Switch pages by touching the {Select} tab and the {Set} tab.

> (Note)   If testing STD and QC at the same time, perform "CC create."
>   ☞ Page 47 "2.5.8 Creating CC"

⚠ **Warning**

	· Wear protective gear (gloves, goggles, etc.) when handling the QC samples.
Biohazard	Failure to observe this precaution may lead to infection.

---

1 Touch {Analyze}.

2 Touch the {QC process} tab.

2
Basic
Operation
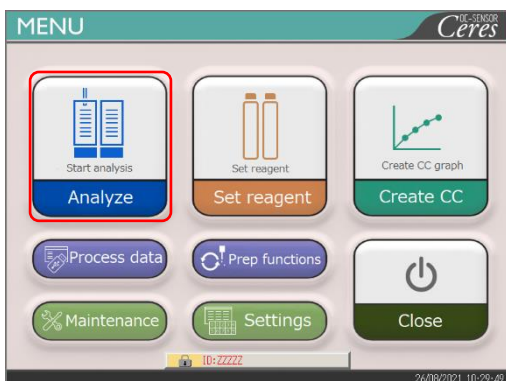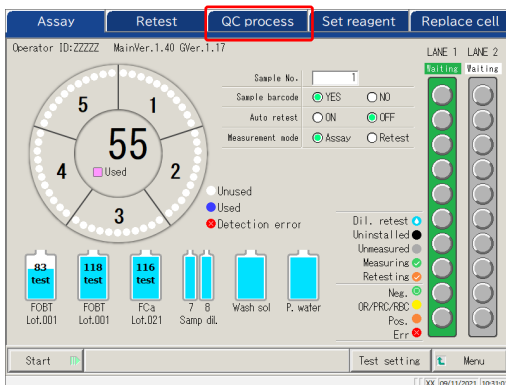
Test start
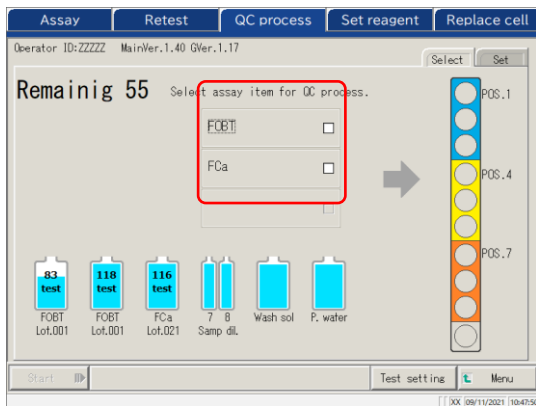
3 Set the QC sample.

① Select the test item to be measured (■).
   The QC sample setting positions in the rack
   are displayed in different colors.

{Test setting}: Sets the item to be analyzed.
                ☞   Page 198
{Menu}: Returns to the [MENU] screen.
        Changed settings are saved.

Note   Items for which R1 and R2 samples are set are displayed on the screen. If there is no item to be tested,
        set the reagent of the corresponding item.
        ☞   Page 37 "2.5.2 Setting the Reagent"
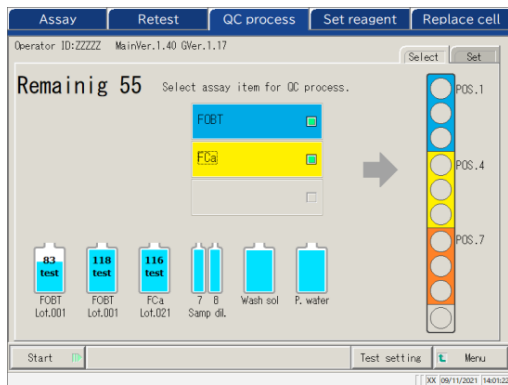
② Prepare the STD and QC racks.
③ Set the QC samples in the positions
   corresponding to the colours.
   In the case of the left figure, set the QC samples
   as follow.
   ・ FOBT for Pos. 1 - 3
   ・ FCa for Pos. 4 - 6

4 Touch the {Set} tab.

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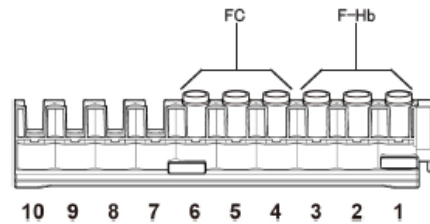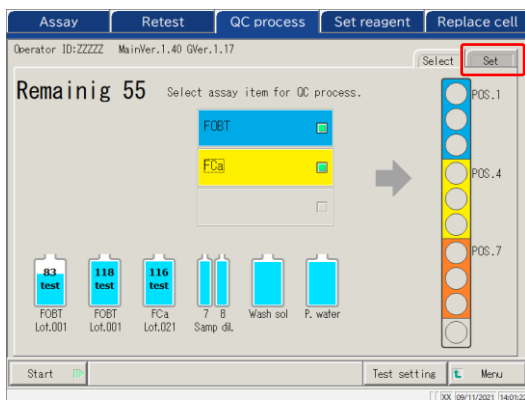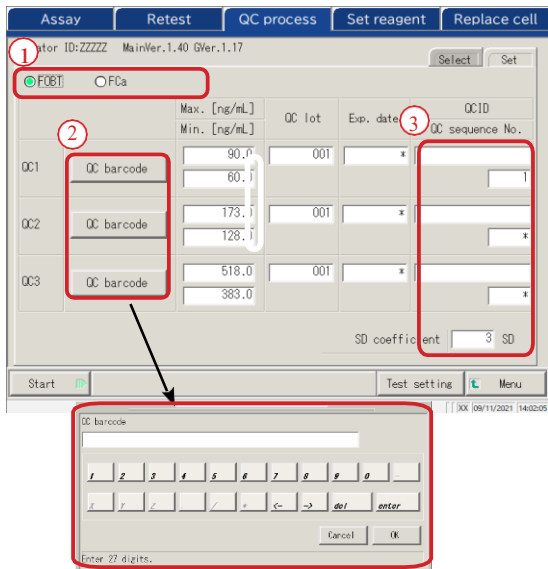
5 Set each item.

① Select the test item.

② Touch {QC barcode}.

Enter the QC barcode that corresponds to the selected test item or QC1-3.

☞ For QC barcode entry, see page 50.

③ Enter the remaining settings (see the table below.).

Test start

(Note) Be careful with the positions of the STD and QC racks and handling of QC1 - 3. In the following example, set as follows.

Pos.1 : [FOBT]-QC1
Pos.2 : [FOBT]-QC2
Pos.3 : [FOBT]-QC3
Pos.4 : [FCa]-QC1
Pos.5 : [FCa]-QC2
Pos.6 : [FCa]-QC3
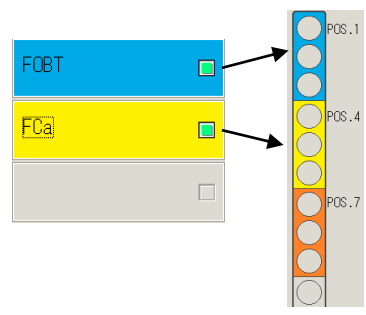
(Note) Set the QC replication on the [Protocol settings] screen.
☞ Page 217 "6.2.1 Sample/QC Protocol Settings"

(Note) If the number of remaining cells is smaller than the number of QC process tests, a message indicating insufficient cells is displayed. Before performing the QC process, check the number of remaining cells.

2
Basic
Operation

Test start

{Set} tab

Item	Range/selection	Content
Test item		Selects the test item to be set.
QC barcode	27 digits	Enter the QC barcode here. The max. value/min. value, QC lot, and expiration date are automatically set, and they can also be entered and edited manually.
QCID	0 – 9, X, Y, Z	As the tested QC1-3 ID, it is output to the external media, printer, and the high-order system. Can be omitted.
QC sequence No.	1 – 99999, *	QC sequence No. When a numerical value is entered for QC1 and "*" is entered for QC2-3, a serial number from the QC1 value is automatically allocated every time the QC is measured. Ex) If QC1 = 3, QC2 = *, and QC3 = *, the tested QC → QC sequence No. QC1 → 3 QC2 → 4 QC3 → 5 QC1 → 6 QC2 → 7 QC3 → 8 When numerical values are entered for each of QC1-3, the sequence number is allocated in a fixed way every time QC is measured. Ex.) If QC1 = 3, QC2 = 10, QC3 = 15, the tested QC → QC sequence No. QC1 → 3 QC2 → 10 QC3 → 15 QC1 → 3 QC2 → 10 QC3 → 15
SD coefficient □ SD	1-9	Sets the SD coefficient used for the calculation of $\overline{X}$-R control drawing for the accuracy control process.

(Note) Expired QCs will not be analyzed.

(Note)   When the QC lot is *, the expiration date, max./min. control limit values are hidden, and the corresponding QC is not tested.

2

Basic
Operation

Test start
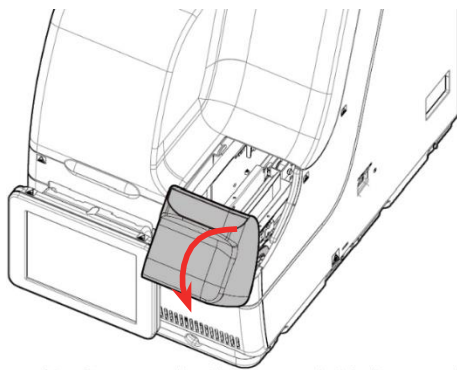
6 Open the rack lane cover.
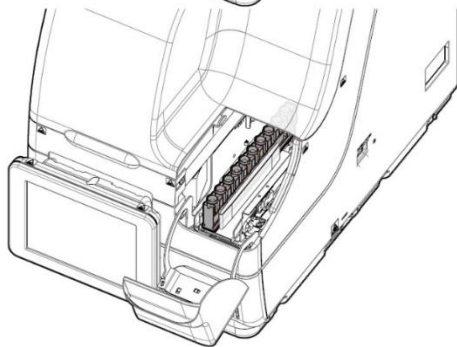
7 Set the rack at lane 1 or lane 2 with rack position 1 innermost. Pay attention to set the rack properly.
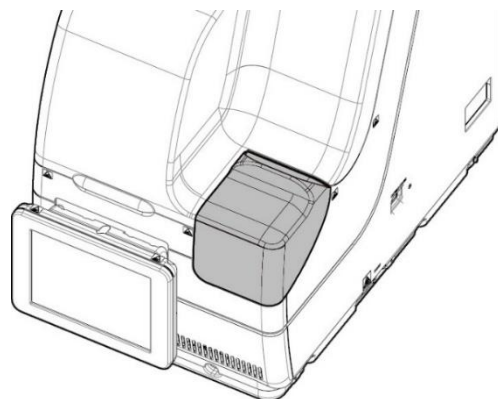
8 Close the rack lane cover.

⚠	Request
🛈 Required	· When setting the rack in the lane, rack position 1 must be innermost.

Failure to observe this precaution may lead to trouble.
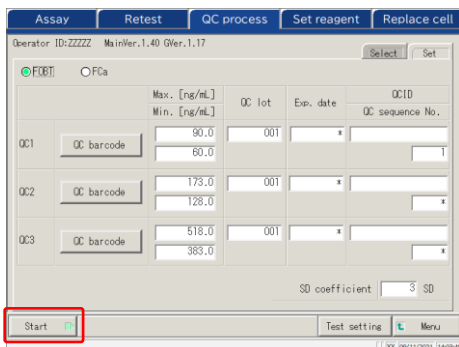
9 Touch {Start}.
When the pre-set priming completes, dispensing of the sample starts.

2.5.13　Additionally Setting the Sample

While executing the initial analysis, the procedure to additionally setting the rack is explained.

| ⚠	Warning
🔰 Biohazard	・Wear protective gears (gloves, goggles, etc.) when handling the samples. Failure to observe this precaution may lead to infection.

The lane status consists of three types: "In use," "Replace," and "Waiting." (See page 74.) For lanes displaying something other than "In use" while testing, new setting or replacement of the rack is possible.

However, after an "In use" rack is discharged to the rack lane, if a new rack and/or replacement is performed while there is no rack "In use," the test of the set rack does not start until a new test starts.
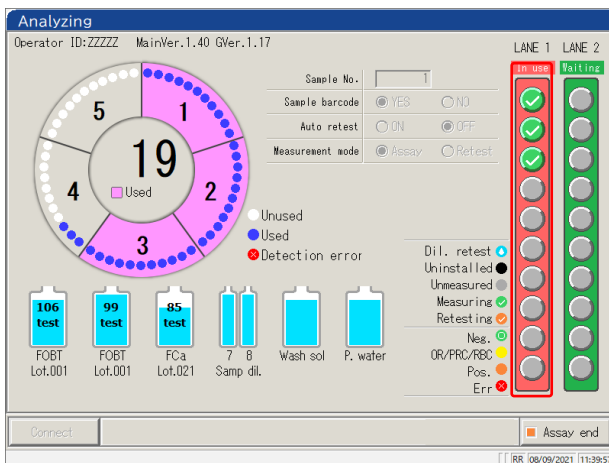
1 Check that there is a rack displaying "In use" in red in the lane information.
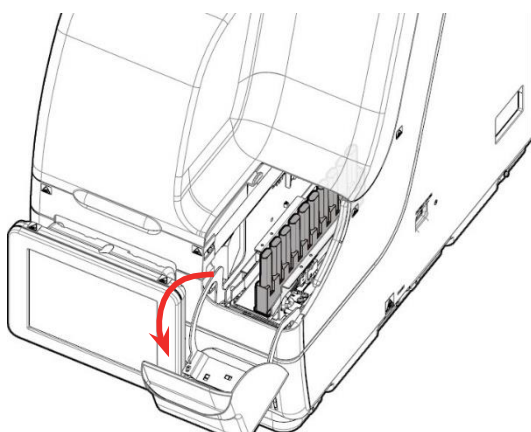
2 Open the rack lane cover.

(Note) In the following cases, the rack lane cover is locked; therefore, inserting a new rack or replacement of a rack cannot be done:
- ・　Initializing
- ・　Priming before analysis
- ・　Rack discharging from the transfer lane to the rack lane
- ・　Retest measuring
- ・　Auto retesting
- ・　QC processing
- ・　CC creating

*For Retest, QC test, and CC create, the rack lane cover is unlocked and the rack can be removed from the lane when all dispensing processes are completed and the rack is discharged.

Testing
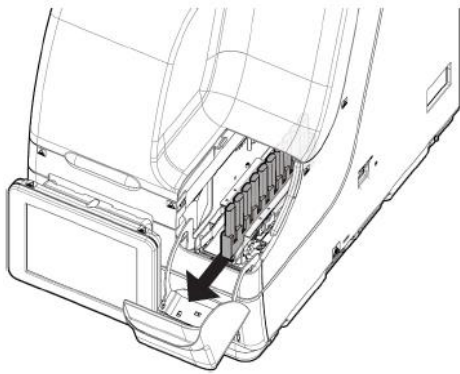
3 Remove the rack from the rack lane for which the lane information is "Replace" or "Waiting."
However, if no rack is set, unloading is not necessary.
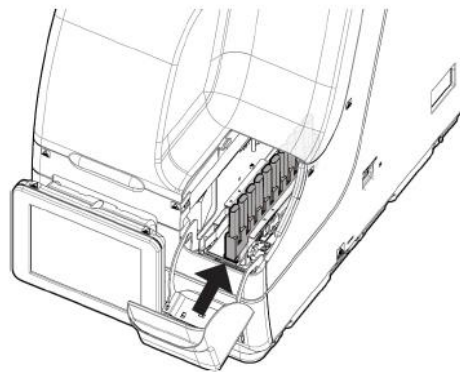
4 Set the rack to be added to the rack lane.

Be careful to set the rack properly.

(Note) When setting the rack, put the rack in with position 1 innermost, and push it in until the rack contacts the innermost section of the system.

(Note) Replace the rack as quickly as possible. Otherwise, dispensing could fail for some cells, and efficient cell use is hindered.

(Note) For lanes indicated as "In use," do not set a rack.

⚠	Required
🛈 Required	・ Set the rack in the system with rack position No. 1 at the innermost end. Failure to observe this precaution may lead to troubles.

5 Close the rack lane cover.

*Dispensing starts automatically.

2.5.14 Checking the Analysis Information

■   Checking the reagent volume

On the [Assay] screen, the [Retest] screen, the [QC process] screen, and the [Analyzing] screen, remaining volumes of the washing solution, purified water, and regent are displayed.
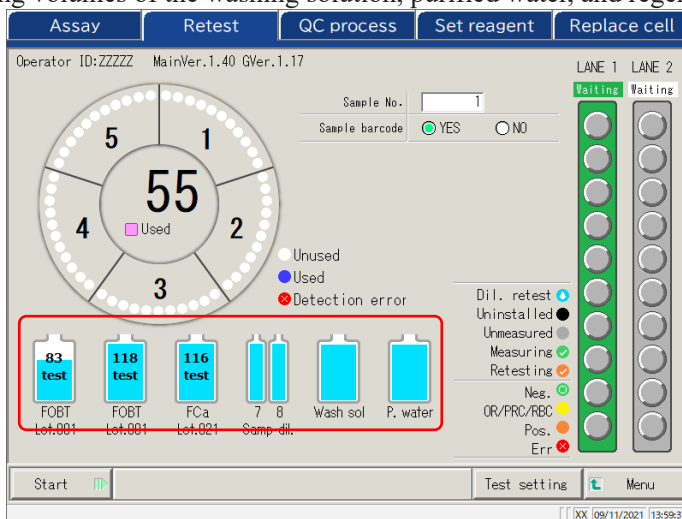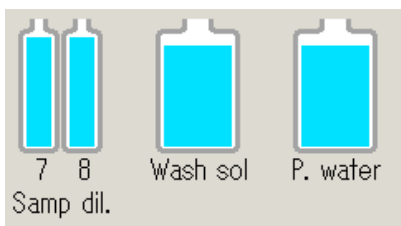
For the diluent, washing solution, and purified water, the remaining volumes are displayed using a bottle graphic.
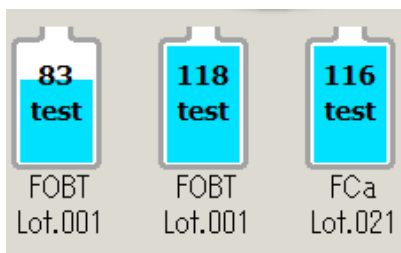
For the R1 and R2 reagents, the remaining volume is displayed with bottle graphics. In addition, the test item, lot number, and available test count are displayed.

* On the [Set reagent] screen, only reagents for which pairing is established are displayed.

     Lot.XXX : Lot numbers of R1 and R2 reagents (3 digits)

     XX test : Process-able test count
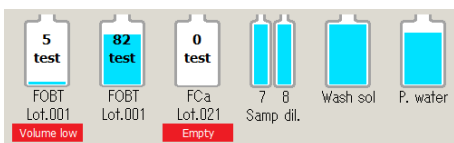
If an error occurs, the error information is displayed under the bottle.

 (Red)

 (Red) remaining volume≦5%

 (Yellow) remaining volume≦10%

 (Red)

■   Checking the rack info

Rack info is displayed on the [Assay] screen, [Retest] screen, and [Analyzing] screen. The conditions of the sample rack and the samples in the system can be checked.

<Sample information>
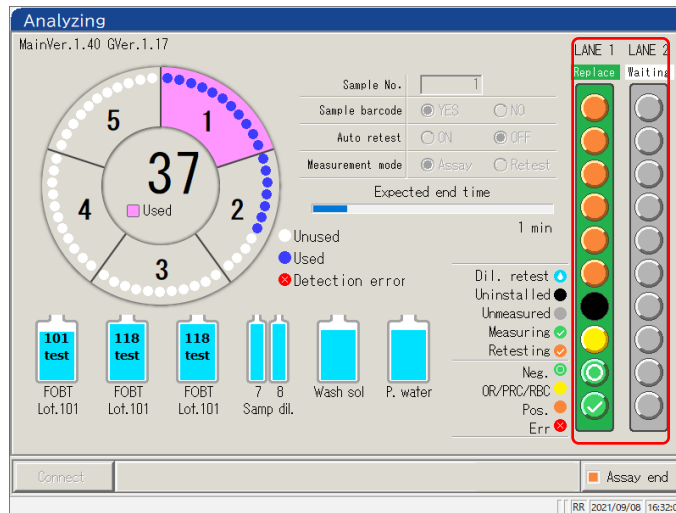
The request condition and analysis result of each sample.

(Light blue)	Re-specification of diluting	Dilute retest is set. Displayed only on the [Retest] screen.
(Black)	Not set	Sample not set.
(Gray)	Not measured	Not measured
(Green)	Measuring	Currently measuring. Displayed only on the [Analyzing] screen.
(Orange)	Remeasurement	Currently retesting. Displays only on the [Analyzing] screen.
(Green)	Normal	Measurement result: Negative
(Yellow)	OR/PRC/RBC	Measurement result, OR/PRC/RBC.
(Orange)	Positive	Measurement result: Positive
(Red)	Error	Error occurred during the measurement, and the result was not output.

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<Rack info>

Request condition and analysis result of Lanes 1 and 2 rack status are displayed.

	Waiting	
Waiting	(Gray)	The rack is not set or the state before the sample is dispensed.
Waiting	(Green)	Rack replacement is available
In use	In use	
	(Red)	Dispensing the sample
Replace	Replace	
	(Green)	Dispensing the sample on the rack completed. Rack replacement is available.

<div style="border:1px solid black">

2.5.15 Ending the Analysis

</div>

When testing all of the set samples is finished, the analysis automatically ends. This section describes other ways to finish the analysis.

■   Normal ending of the analysis

After finishing the tests of all dispensed samples, the test ends.

Samples not dispensed when the normal end is selected remain as "Not measured.".

When selecting "Abort" for the analysis, see "■ Abort analysis."
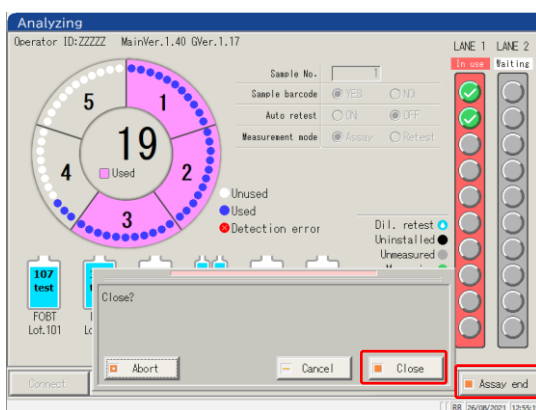
1 Touch {Assay end}.

2 Touch {Close}.
* Results of the measured samples are printed.

{Abort}: Ends the testing in the middle of the process.
{Cancel}: Closes the dialog box.
{Close}: Ends the testing.

■   Abort analysis

The analysis is aborted.
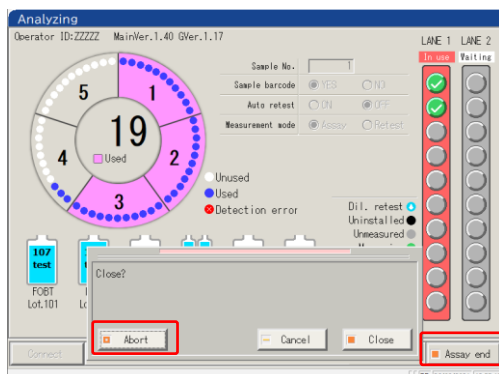
1 Touch {Assay end}.

2 Touch {Abort}.
* Results for the samples are discarded.

{Abort}: Ends the test in the middle of the process.
{Cancel}: Closes the dialog box.
{Close}: Ends the test.

Test finish

2
Basic
Operation

Test finish

■   Aborting the testing

If an error occurs during testing, a popup window for aborting opens. The testing of all dispensed samples is finished, and then the test ends.
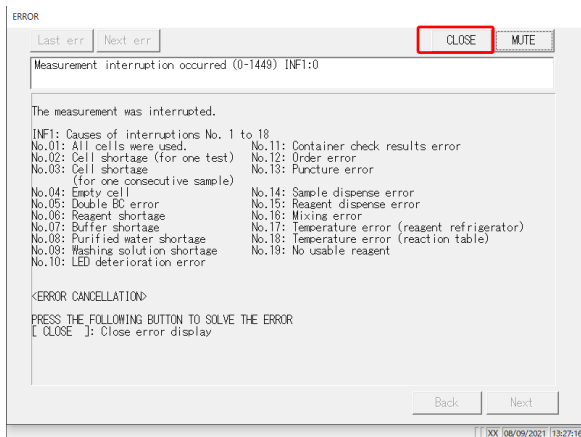
1 Close the screen with {Close}.

■   Resuming the test

Only when the testing was ended or ended by aborting the sample measurement, pressing [Start] on the [Assay] screen resumes the testing from the position after the measurement result output. When the Start button is pressed, the following dialog box opens. Starting a new test or resuming the testing can be selected.
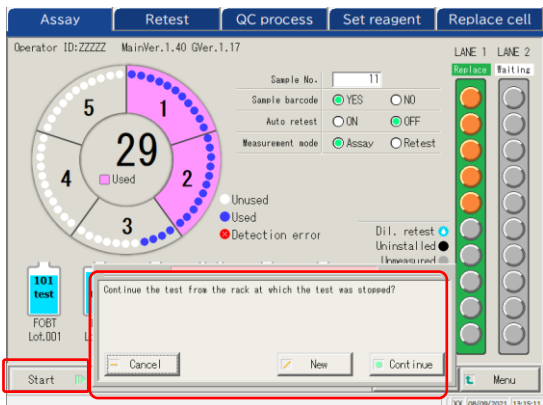
1 Touch {Start}.

{Cancel}: Closes the dialog box.
{New}: Begins testing from Lane 1 Position 1.
　　　* Pierced samples will be pierced again.
{Continue}: Continues testing from the position next to the one for which the measurement results have been output.
　　　* Pierced samples are not pierced again.

(Note) ・ When a discharged rack is removed, the rack info is cleared. In that case, resuming the testing is not possible.

　　　　 ・ When the test mode is changed before resuming, resuming the testing is not possible.

　　　　 ・ When automatic retest is set to "Yes," resuming the testing is not possible.

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2.6 Inspection and Cleaning After Use

2.6.1 Removing the Racks

The racks are removed after the testing is finished.

⚠	Warning
☣ Biohazard	・Wear protective gear (gloves, goggles, etc.) when handling the samples. Failure to observe this precaution may lead to infection.

Inspection and cleaning

1 Open the rack lane cover.
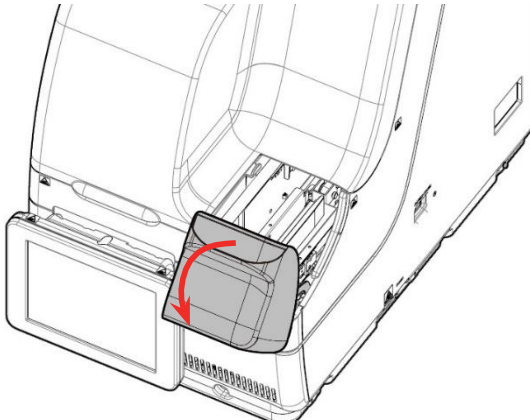
2 Remove the racks which testing is finished.
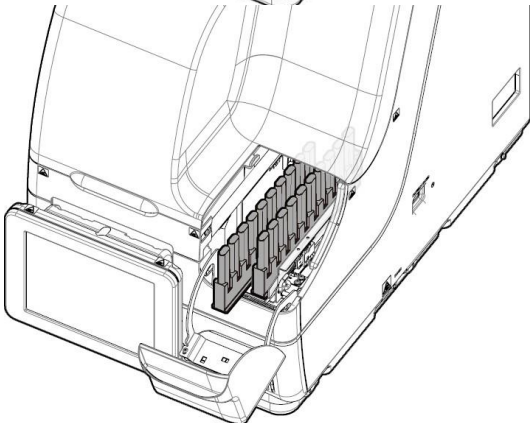
3 Close the rack lane cover.
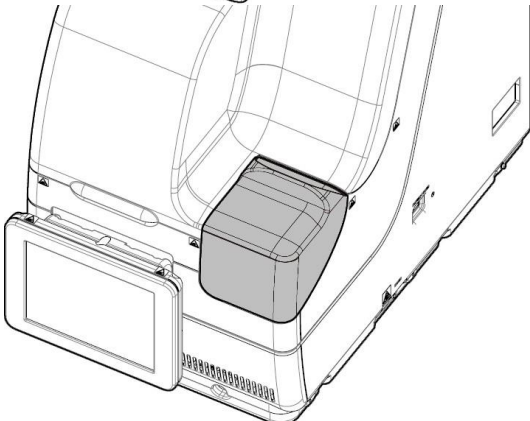
2.6.2 Replacing Cells

The used test cells are replaced.

⚠	Warning
☣ Biohazard	· Wear protective gear (gloves, goggles, etc.) when handling the used cells. Failure to observe this precaution may lead to infection.
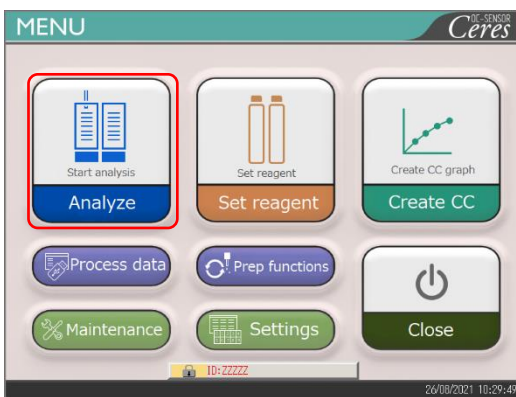
1 Touch {Analyze}.
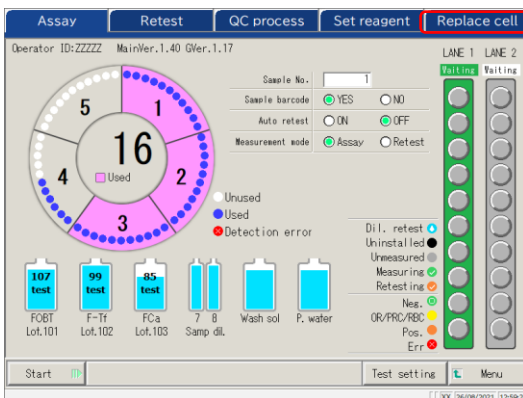
2 Touch the {Replace cell} tab.
The [Replace cell] screen opens.
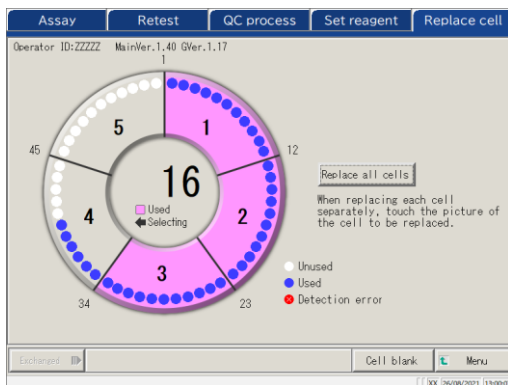
{Cell blank}: Displays the cell blank value of the cell which is currently set.
☞ Page 83
{Menu}: Returns to the [MENU] screen.

Inspection and cleaning

3 Open the safety guard.
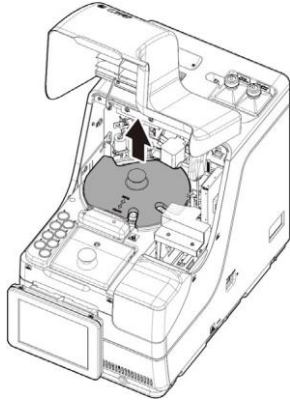
4 Remove the Light-shielding cover.
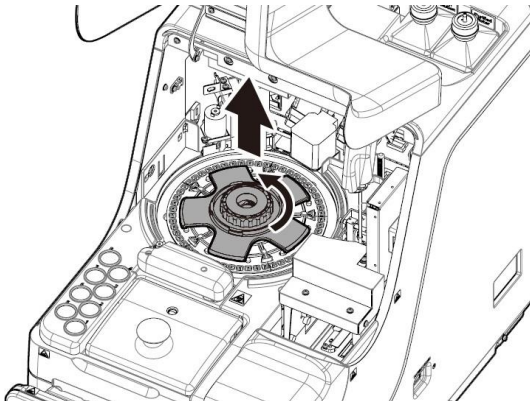
5 Remove the cell retainer.

Rotate the center handle counterclockwise and align the ▼ mark with the unlock mark .
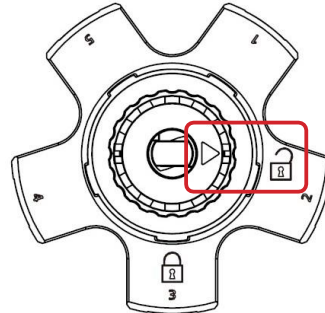
6 Remove the used cell and replace it.

<Replace one by one>

① Remove the cell and replace it with a new one.
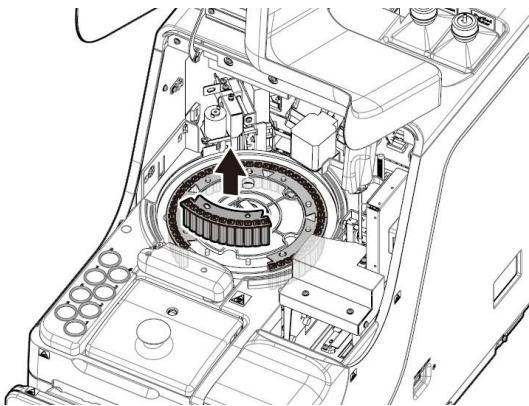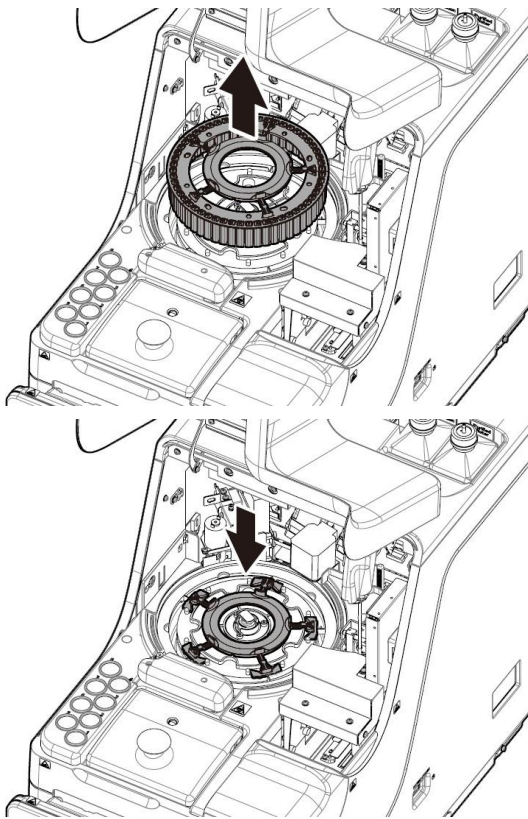
<Replacing five cells in a batch>
① Pull up the cell batch replacement tool. All five cells can be removed with the tool.

② Remove the cells from the cell batch replacement tool.

③ Attach the cell batch replacement tool to the system.

④ Attach five new cells to the system.

Request	
![Required icon] **Required**	・When setting a test cell, check that the cell legs are not floating. After setting the test cell, rotate the reaction table by hand. Check that the cell and the reaction chamber are not contacting. If they are contacting, an abnormal sound can be heard. After setting the test cells, if any abnormal sound occurs, immediately stop the operation and check the test cell condition. The test cell might not be properly set.

Test cell   Test cell leg

Test cell leg is not floating.

Reaction table

Reaction chamber
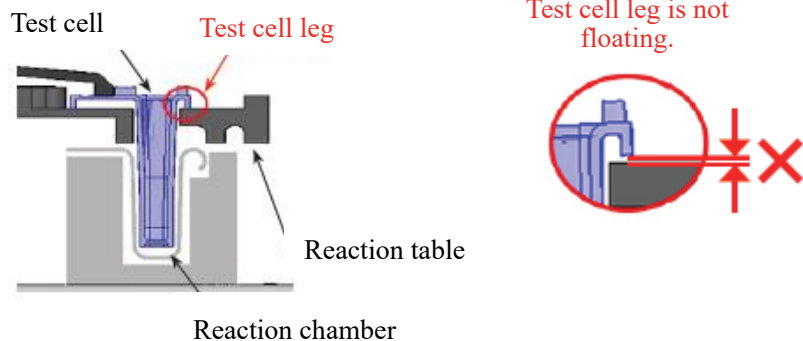
This can cause trouble.
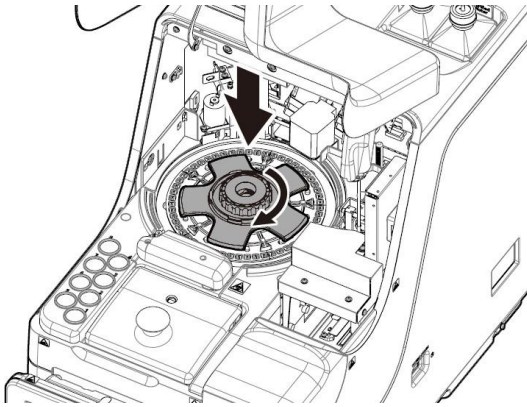
7 Return the cell retainer.

Turn the center handle counterclockwise and align the ▼ mark with the lock mark.
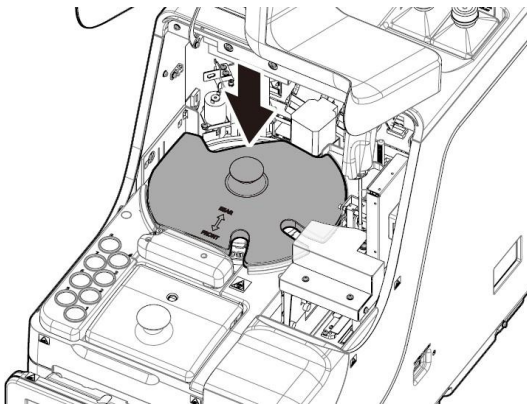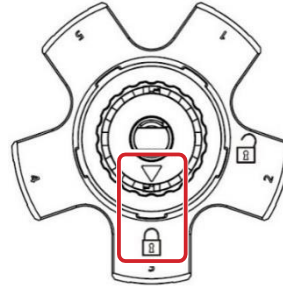
8 Replace the Light-shielding cover.
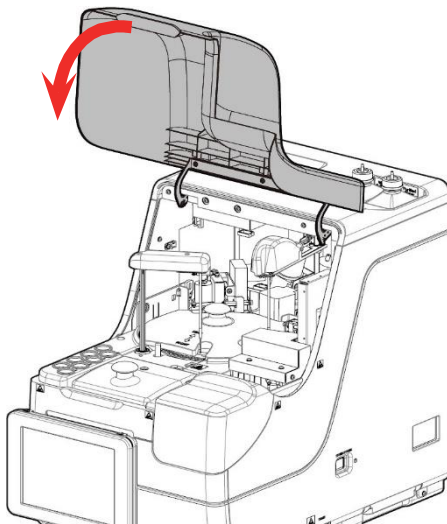
9 Close the safety guard.
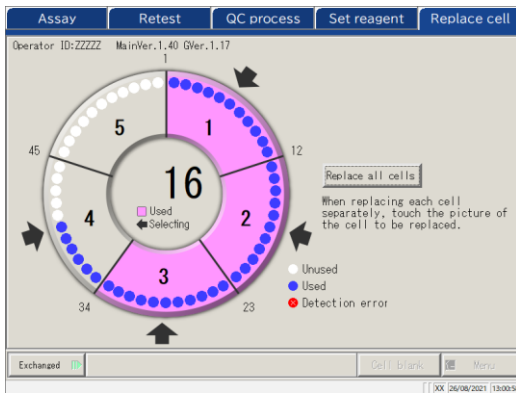
10 Touch the replaced cells.
If all cells have been replaced, touch the {Replace all cells} button. The arrows ➡ are displayed.

* Touching the selected cell again cancels the cell selection.
* Touching {Cancel all cells} cancels selection of all the cells.
* Buttons at the lower section of the screen cannot be operated while any cells are selected.
（Buttons become inactive.）
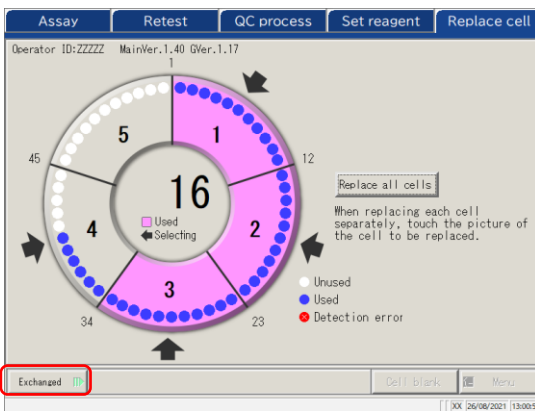
11 Touch {Exchanged}.

* The cell blank test starts.
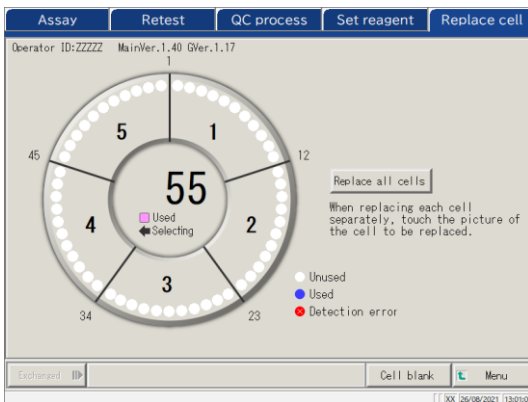
12 Cell replacement is completed.

13 Discard the used cells.

■ Checking the cell blank value

Testing the cells without dispensing is called cell blank testing.

This value is used for the calculation of measured data. In addition, it is also used to judge whether or not the cells can be used without problems. This section describes the way to check the cell blank values.
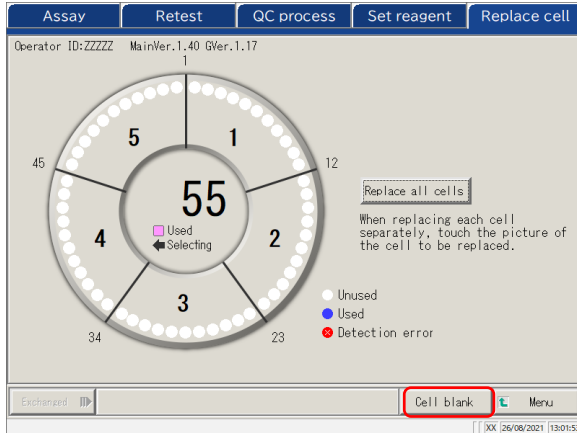
1 On the [Replace cell] screen, touch {Cell blank}.
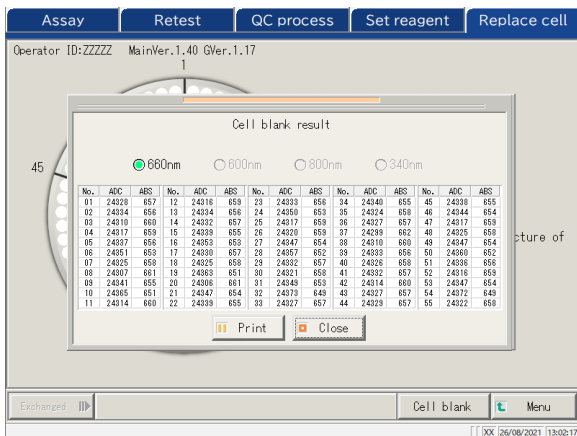
2 Check that no errors are output. The cells with an error is displayed in red.

*Cells with an error cannot be used for testing. If there are many error cells, replace the cells again.

● 660 nm / ● 600 nm / ● 800 nm / ● 340 nm
: Switches the cell blank test wavelength.
* Usually, it is checked at 660 nm.

{Print}: Prints the test result.
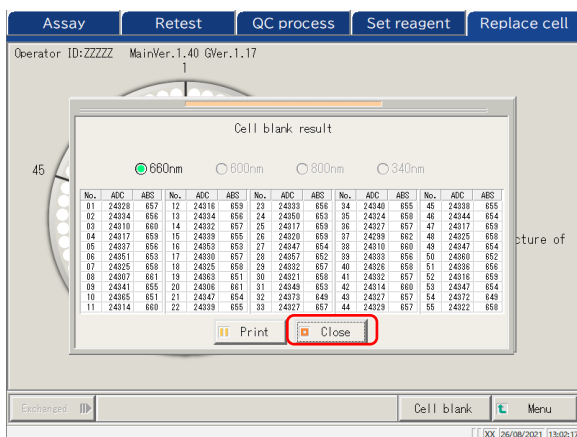
3 {Close} closes the Cell blank result screen.

Inspection and cleaning

2.6.3 Cleaning Various Sections

On the [MENU] screen, touching {Maintenance} opens the [Maintenance] screen.

"Inspection and cleaning" items are displayed. Follow the instructions on the screen to clean each section.

⚠	Warning
☣ Biohazard	· Wear protective gear (gloves, goggles, etc.) when cleaning the system. Failure to observe this precaution may lead to infection.
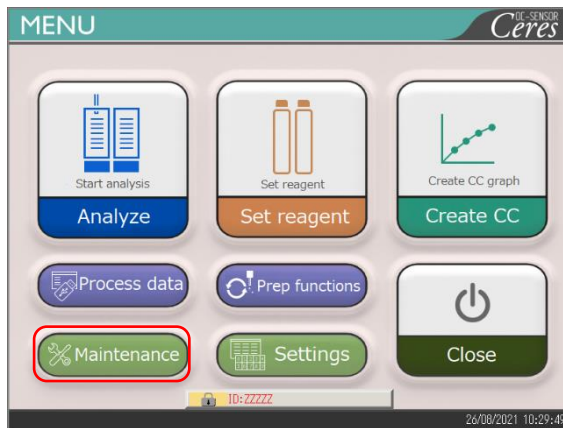
1 Touch {Maintenance}.
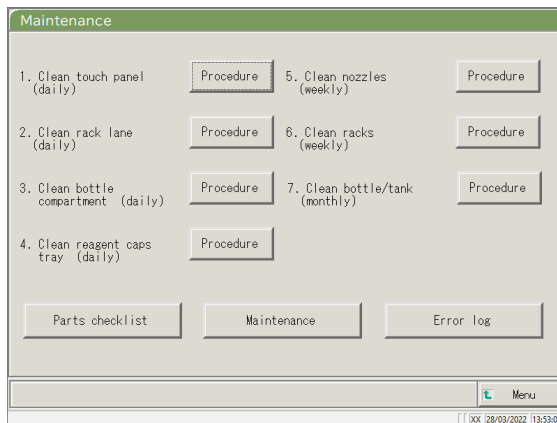
2 The [Maintenance] screen opens.

Clean each section.

Sections to be cleaned are as follows.

1. Touch panel (daily)
2. Rack lane (daily)
3. Washing solution and purified water setting positions (daily)
4. Reagent cap space (daily)
5. Nozzle (weekly)
6. Rack (weekly)
7. Clean bottle/tank (monthly)
   ☞ For details, see page 170 "5.1 Inspection and Maintenance"

(Note) When there is a part for which the replacement date has passed, a message appears explaining this, with instructing to check the Parts checklist screen.
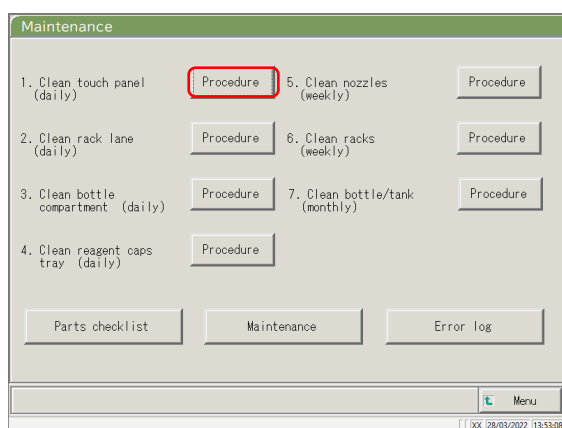
3 If the cleaning procedure is unknown, touch each {Procedure}. The cleaning procedure is displayed. After cleaning completes, touch {Close} to close the cleaning procedure screen.

{Parts checklist}: List of parts required for inspection and replacement is displayed.

☞ Page 86 "2.6.4 Opening Parts Checklist"

☞ {Maintenance}: Adjust the system and/or checks the performance (for service personnel)

{Error log}: Display the error log. A maximum of 1000 error logs can be checked.

☞ Page 88 "2.6.5 Opening the Error Log"

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

Inspection and cleaning

2.6.4　Opening Parts Checklist

On the [Parts checklist] screen, part names, last replaced date, and number of months used (maximum use count) are displayed.
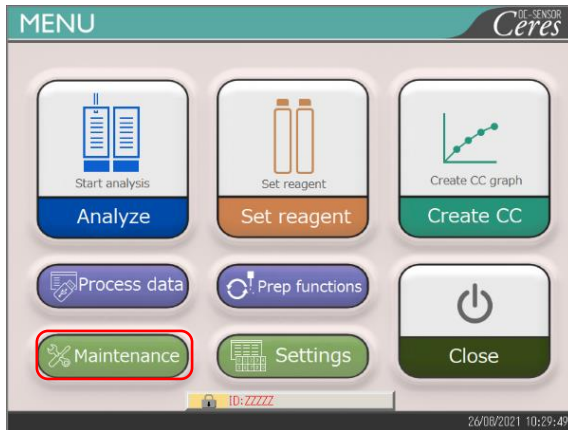
1 Touch {Maintenance}.
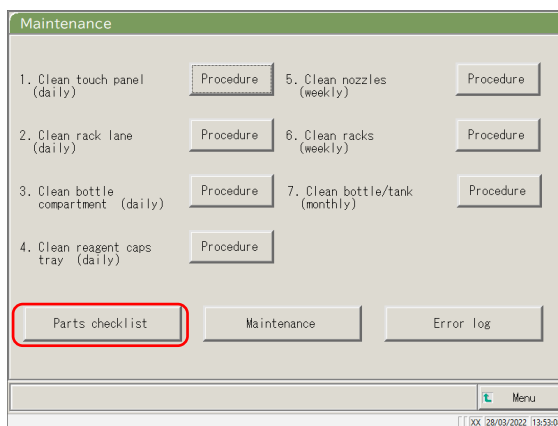
2 Touch {Parts checklist}.
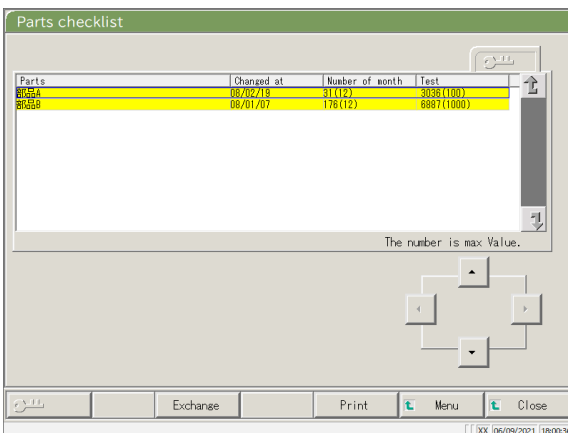
3 Check if there are any parts which require replacement. Displayed content as the table on the next page.

If there are any parts or which the number of month or tests has exceeded the max. value, the line becomes yellow.

No.	Item	Content	Remarks
①	Part	Name of the part	Max. of 15 digits of half size alphanumeric characters or 7 digits of full size characters
②	Changed at	Date when the part was replaced (YY/MM/DD)	
③	Number of months	Number of months from the latest replacement to the current date	
	( )	Max. number of months	
④	Test	Number of tests from the latest replacement to the current date	
	( )	Max. number of use	

Inspection and cleaning
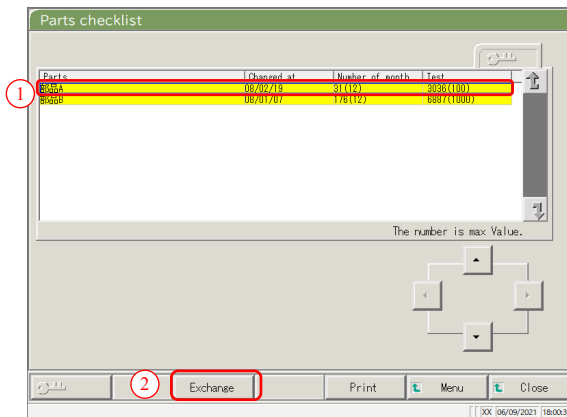
4 Replace the parts.

① Select the part (yellow line) to be replaced.
② Replace the part.
③ Touch {Exchange}.

> * A dialog box asking "Exchange parts?" opens.

{Exchange}: Touch this button after replacing the part.
{Print}: Print a list of parts for inspection and replacement.
{Menu}: Return to the [MENU] screen.
{Close}: Return to the [Maintenance] screen.
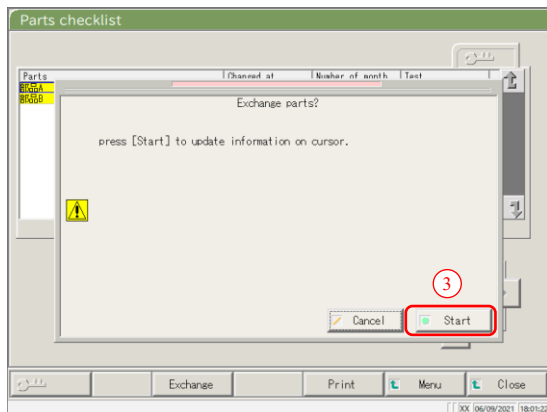
④ Touch {Start}.

> * The latest replacement date is updated to today.
> * The number of months and use count are reset to "0."
> * Closes the dialog box.

{Close}: Close the dialog box.

{Start}: Update the parts replacement information.

(Note) Parts replacement is also available for lines not colored in yellow.

2.6.5   Opening the Error Log

On the [Error log] screen, the date and time of errors, error codes, and error names (content) are displayed. A maximum of 20 errors can be displayed on one screen. A maximum of 1000 errors can be displayed in the entire list. If there are more than 20 errors, use the scroll bar to move through the list.
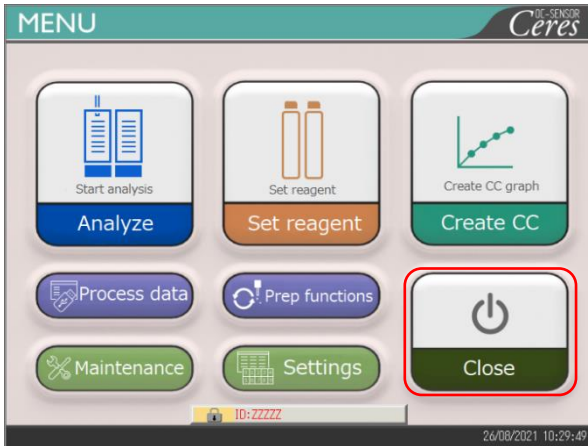
1 Touch {Maintenance}.
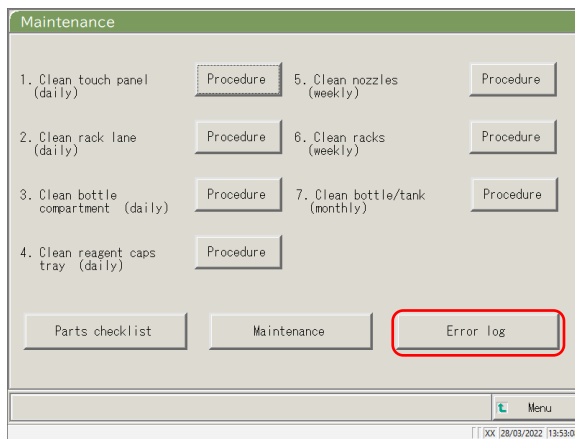
2 Touch {Error log}.
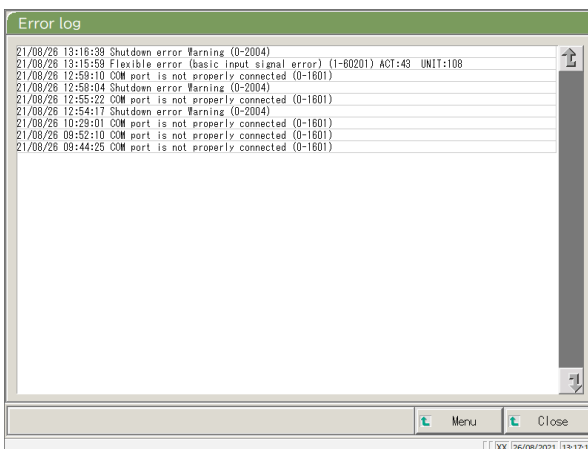
3 Check the error information.

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

{Close}: Return to the [Maintenance] screen.

2.7 Shutting Down the System

To properly shut down the system, use the "shut down mode." The System switch turns off automatically (the primary power switch does not turn off.)
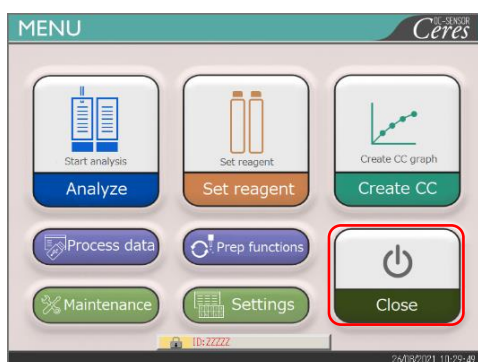
1 Touch {Close}.
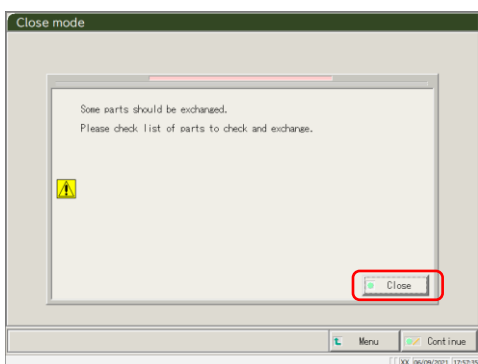
2 The [Close mode] screen opens.
If there are any expired items, a message appears saying "Some parts should be exchanged. Please check the list of parts to exchange" is displayed.

Touch {Close} and then {Menu} to return to the [MENU] screen.

☞ Page 86 "2.6.4 Opening Parts Checklist"
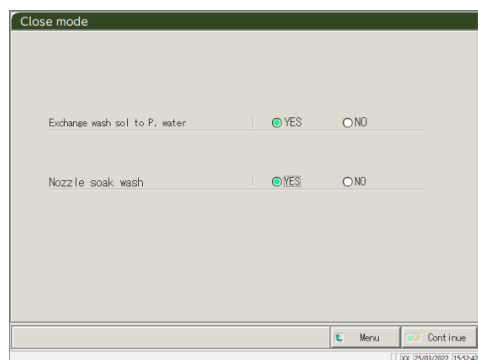
3 If there are no expired parts, select an operation to be conducted at the end of the operation.

Item	Range/selection		Content
Exchange wash sol to P. water	Yes :		Replace the purified water.
	No :		Do not replace the purified water.
Nozzle soak wash	Yes :		Soak for storage.
	No:		Do not soak for storage.
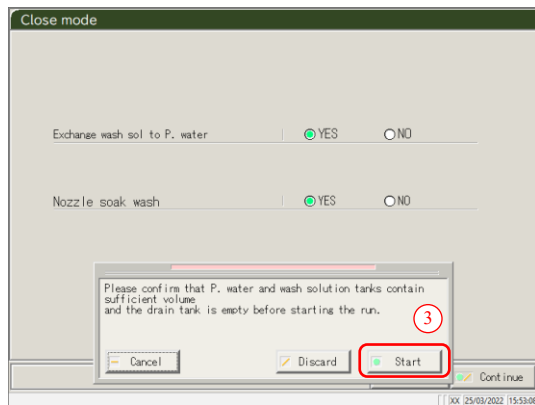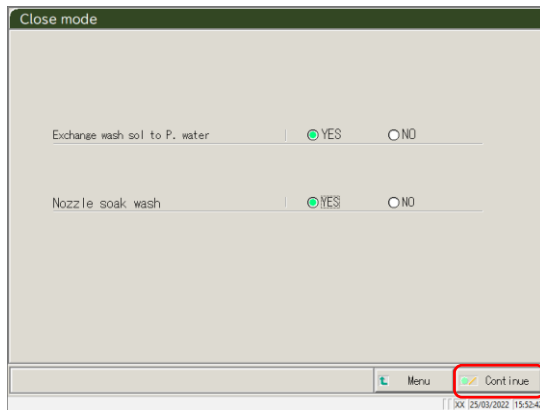
4 Touch {Continue}.

5 Executes the Close mode.
　① Check that the purified water bottle and the washing solution bottle are not empty.
　② Check that the "drain tank" is not full.
　③ Touch {Start}.

{Cancel}： Close the dialog box.

{Discard}： Abort the closing mode and returns to the [MENU] screen.

{Start}： Execute the Close mode.

6 Replace the washing solution pipe inside the purified water bottle (when "Exchange buffer and wash sol to P. water" is set to "Yes").

　① Remove the pipes connected to the washing solution bottle.
　② Connect the pipe in ① to the container filled with purified water.

7 The nozzle is stored with the nozzle tip soaking (when "Yes" is selected for "Nozzle/cell soak wash")

　＊ The System switch shuts off.

　＊ The setting which was executed in the Close mode is saved.

8 The system power turns off.

2.8　Processing the Drain Tank

Disconnect the hose attached to the drain tank and drain the waste liquid from inside the tank.

⚠	Warning
🔶 Biohazard	· Wear protective gear (gloves, goggles, etc.) when handling the drain tank. Failure to observe this precaution may lead to infection.
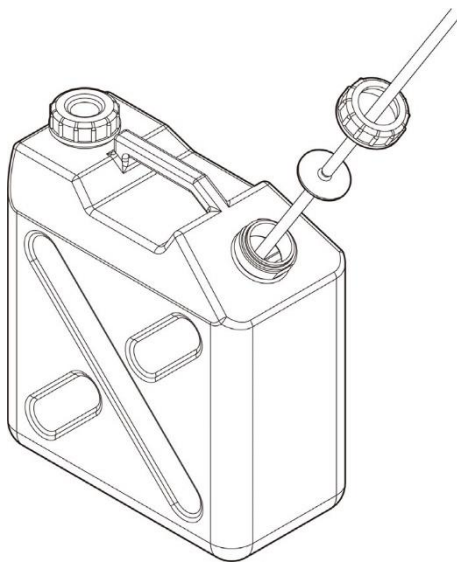
1 Remove the hose from the drain tank.

2 Drain the waste liquid from the drain tank.

3 Connect the hose to the drain tank.

System shutdown

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3.1 Processing Test Data

On the [Process data] screen, test data can be selected, edited, and deleted.

(Note)
- Test data are saved for each item.
- Samples for up to 5000 tests can be saved on the hard disk for each test item. If the number of tests exceeds 5000, the old data are overwritten.
- Up to 1000 tests of the QC samples for each control can be saved on the hard disk. If the number of tests exceeds 1,000, the old data are overwritten.

3.1.1 Opening the [Process Data] Screen

The [Process data] screen can be opened by touching {Process data} - –Process data} on the [MENU] screen.
If a password has been set in Config., the password will be required.

1 Touch {Process data}.

2 Touch {Process data}.

2   If a password has been registered in [System settings] - –Config.], or if {Process data} is used for the first time with the currently logged in account, enter the password.

① Touch the entry field for the password.
② Enter a password from the keyboard.
③ Touch {OK} or {enter}. The dialog closes.
④ Touch {Continue}.
⑤ Touch {Start}.

{Cancel}   : Closes the dialog box.
{Discard}   : Returns to the [Select data processing] screen.

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3   [Process data] screen opens.

* {Samp} tab is selected.
* The list of test date and time is displayed.

(Note)   The test date and time are when the system was started up.

If no data was processed, the date and time are not displayed.

3.1.2 Opening the [Test Data] Screen

The test data are selected by switching between the {Samp} and {QC} tabs on the [Process data] screen. When {Test data} is touched after specifying the test date, the specified data is displayed. (the [Test data] screen is different when the {Samp} tab is selected and when the {QC} tab is selected.)

(Note) The displayed date and time are the ones when the System switch is turned on (time when the system is started up).

(Note) The data measured until the System switch is turned off are saved on the hard disk.
When displaying the [Process data] screen, see page 94 "3.1.1 Opening the [Process Data] Screen."
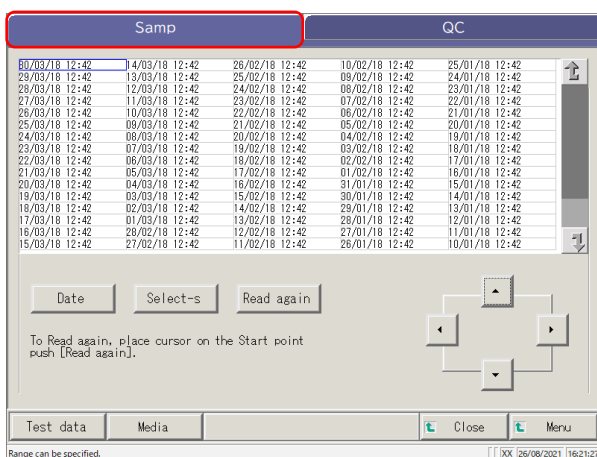
1 Touch the displayed test data tab.
{Samp} tab
{QC} tab
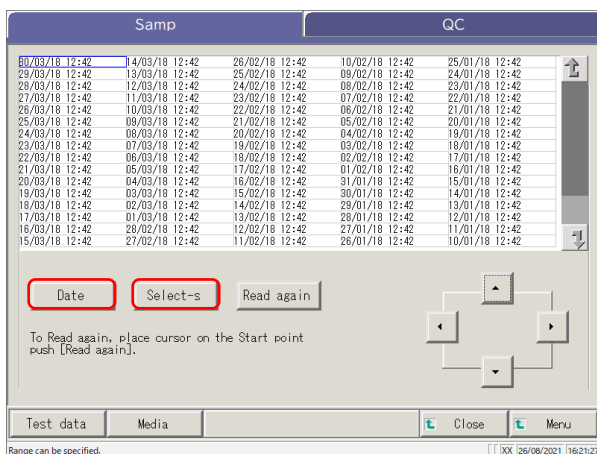
2 Specify the test data by date and time or by range.

<When specifying by the test date and time>

Touch {Date} to specify the test date.

☞ Page 100 "3.1.3 Specifying a {Date} for the Test Data" **2**

<When specifying by range>

Touch {Select-s} and specify the test date range.

☞ Page 102 "3.1.4 Selecting {Select-s} for Test Data" **2**

(Note) When {Date} or {Select-s} is not selected, all displayed test data becomes the target of data processing. (max. 5,000 data).

3 Touch {Test data}.

{Close}   : Returns to the [Select data
processing] screen.
{Menu}   : Returns to the [MENU] screen.

When the {Samp} tab is selected
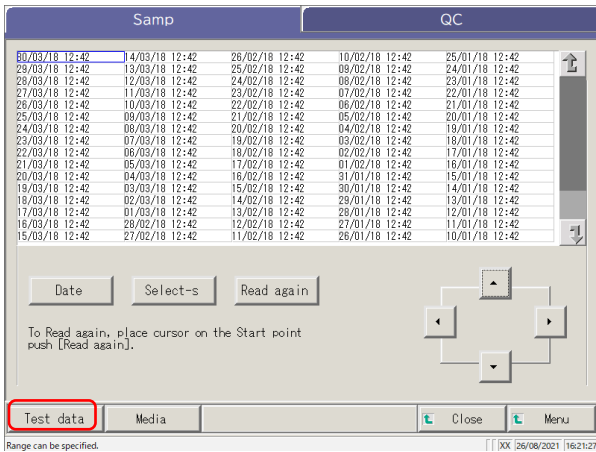
4 The test data is displayed.
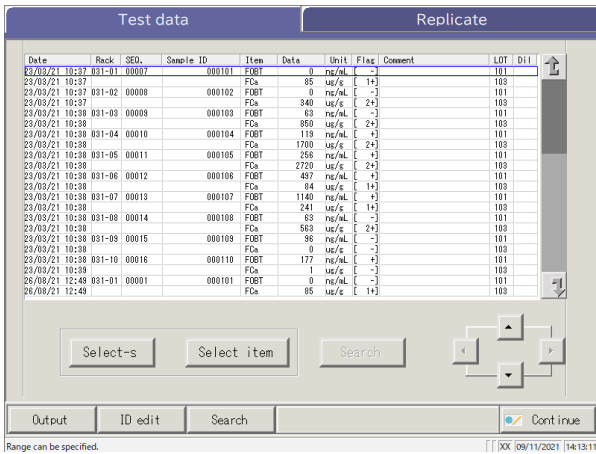
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When the {QC} tab is selected
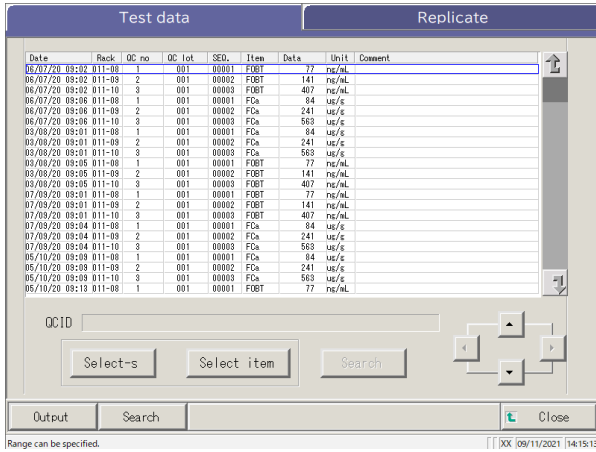
Contents displayed on the [Test data] screen

Display item	Content		Remarks
Date	Date and time of the sample test		
Rack	Rack No.- Tack Position No.		
SEQ.	Sample sequence number		
Sample ID	Barcode on the sample bottle		
Item	Test item		
Data	Test result (concentration)		
Units	Units of test data FOBT : ng/mL FCa : µg/g		
Flag	-, +, 1+, 2+, 3+		
Comment	Error information (excluding read errors)		
	UR	Under range	Outputs a blank for the measured data and the flag
	OR	Over range	Outputs a flag only
	PRC	Prozone	Outputs a flag only
LOT	Lot of the sample used for the test		
Dil	Dilution information		
	Space	No dilution (Analyze, retest)	
	A	No dilution (retest)	
	A10	Dilution by a factor of 10 (retest)	
	A20	Dilution by a factor of 20 (retest)	
	A100	Dilution by a factor of 100 (retest)	
	A200	Dilution by a factor of 200 (retest)	
	A400	Dilution by a factor of 400 (retest)	

Content of the [Test data] screen (QC)

Display item	Content		Remarks
Date and time	Date and time of the sample test		
RACK	Rack No.- Rack Position No.		
QC No.	QC No.1 - –		
QC lot	QC lot (3 digits)		
Seq.	QC sequence No.		
Item name	Test item		
Measured data	Test result (concentration)		
Units	Units of test data FOBT: ng/mL FCa: µg/g		
Comment	Error information (excluding the read errors)		
	UR	Under range	
	OR	Over range	
	PRC	Prozone	
QC ID	ID of QC sample at the cursor position		

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3.1.3 Specifying a {Date} for the Test Data

The date of the test data to be displayed is specified on the [Process data] screen.

> (Note) If a part of the year, month, and date is omitted when entering the test date, a search is conducted. The latest test data that matches the entered conditions are extracted. ☞ Next page **3** (Example)

> (Note) If a part of the year, month, and date is omitted when entering the test date, a search is conducted. The latest test data that matches the entered conditions are extracted.
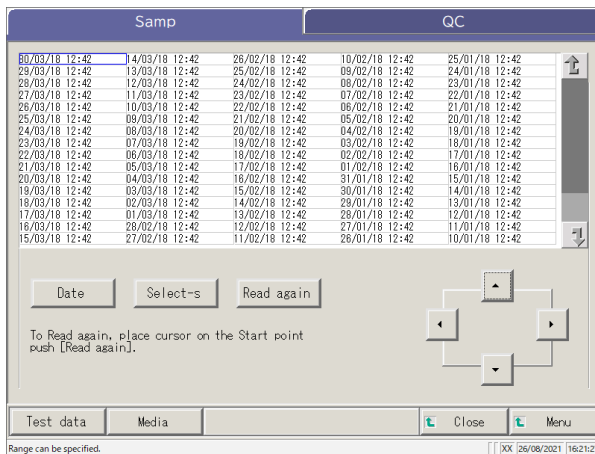
1 Touch the tab of the test data to be displayed.

{Samp} tab
{QC} tab
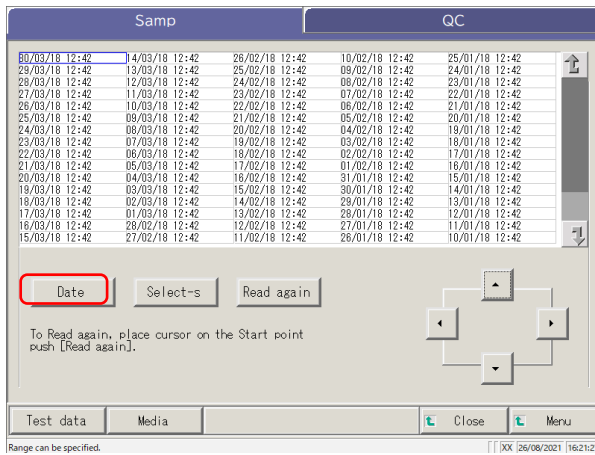
2 Touch {Date}.
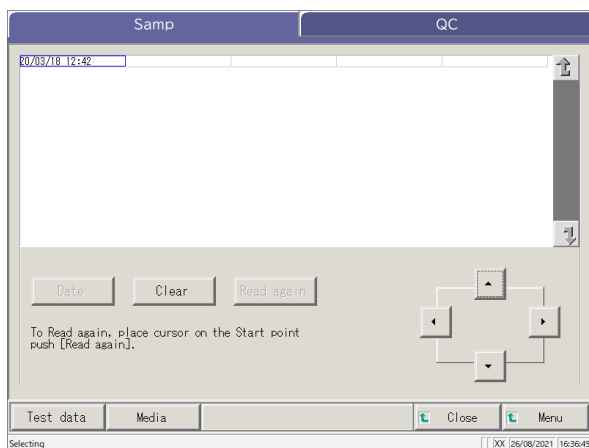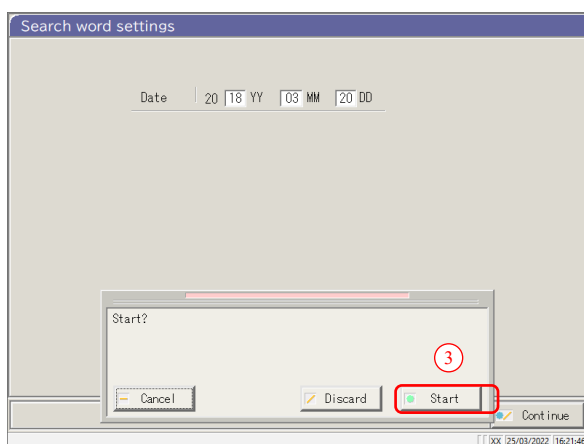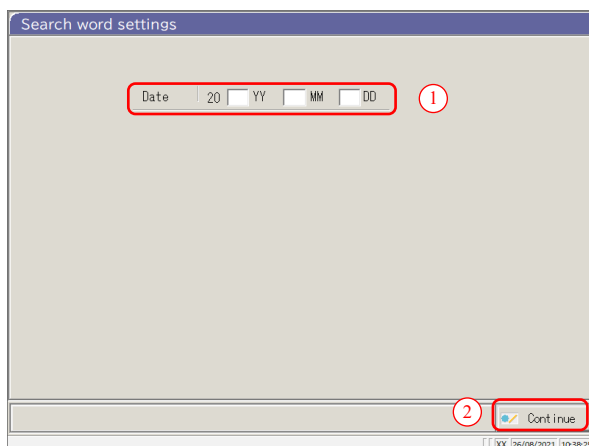
3   Specify the Date.
① Touch the entry field and enter the year, month, and date.

If a part of the year, month, and date is omitted, a search is conducted. The latest test data that matches the entered conditions are extracted.

(Example) If October 5 is entered while omitting the year, only data of the current year are displayed. For example, if the current year is 2020, the displayed data will be as follows.

2020/10/05 10:10 (displayed)
2020/10/05 10:15 (displayed)
2020/10/05 10:20 (displayed)
.
.
.
2019/10/05 14:25 (not displayed)
2019/10/05 14:30 (not displayed)
2019/10/05 14:35 (not displayed)
② Touch {Continue}.
③ Touch {Start}.

{Cancel}   : Closes the dialog box.
{Discard} : Returns to the [Select data processing] screen.
{Start}   : The data is searched within the specified date range.

4   The data of the specified test date are displayed.

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(Note)   To re-specify the test date, touch {Clear}.

All tests are displayed. and the displayed condition returns to the condition when no range is specified.

<table>
<tr><td>

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</table>

3.1.4 Selecting {Select-s} for Test Data

The test data to be displayed are specified within a test date range (starting point and ending point).

The range is specified by touching test dates on the [Process data] screen or by operating the cursor buttons.

When the starting point is specified and {Select-s} is touched, the test data starting point is set. Then, when the ending point is specified and {Select} is touched, the test data ending point is set. When the starting and ending points are finalized, the test data in-between becomes the range.

(Note) When opening the [Process data] screen, see "[3.1.1 Opening the [Process Data] Screen" on page 94.

(Note) When not specifying the range, all data (max. 5000) becomes the target of processing.
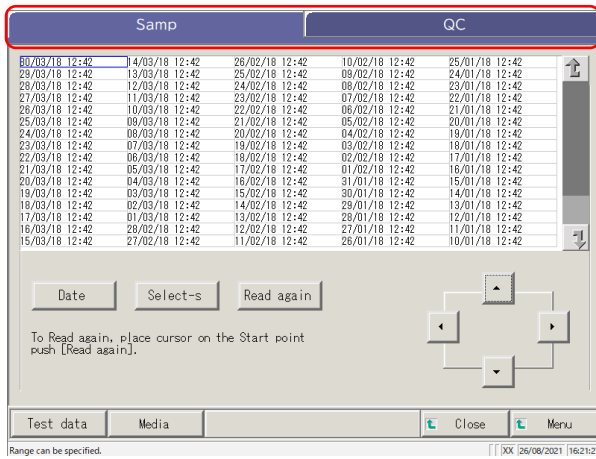
1 Touch the tab of test data to be displayed.

{Samp} tab
{QC} tab
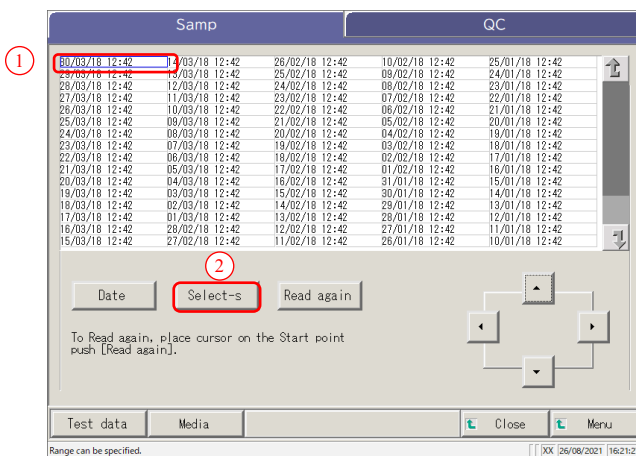
2 Specify the test date of the starting point.

① Touch the date to be used as the starting point.

② Touch {Select-s}.

*The test date of the starting point has been specified. (The letters turn blue.)

* When the starting point is finalized, {Select-s} changes to {Select}.

(Note) The starting and ending points can also be specified using the cursor buttons.

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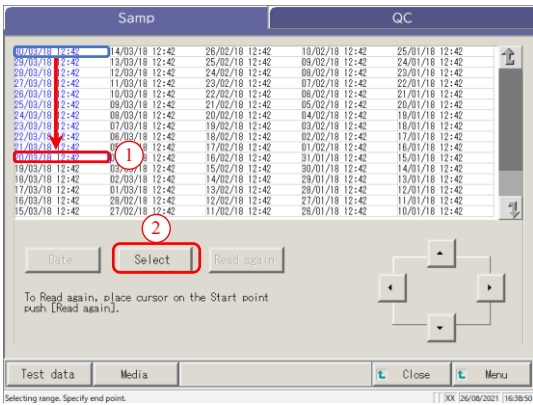
3   Specify the test date and time of the ending point.
①   Touch the date and time to be used as the ending point.
②   Touch {Select}.
  * The test date of the end point is finalized.
  * When the end point is finalized, {Select} changes to {Clear}.

{Clear}: Clears the range specification.
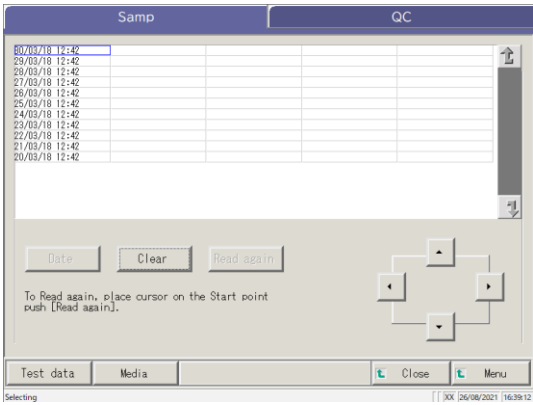
4   The test data within the specified range are displayed.

(Note)   ·   When the same dates are specified for the starting point and ending point, only one test data is specified.

·   To respecify the range, touch {Clear}.

All test data are displayed, and no range is specified.

<div style="border:1px solid">

3.1.5   Reading "Test Data" Not Displayed in the List (Re-reading)

</div>

The maximum number of sample data sets that can be displayed and edited in the list is 5,000.

To edit sample data not displayed in the list, it is necessary to read the data.

Specify the date to use as a starting point. Select a former date or a later date to read the data to be edited.

(Note)   When opening the [Process data] screen, see "3.1.1 Opening the [Process Data] Screen" on page 94.
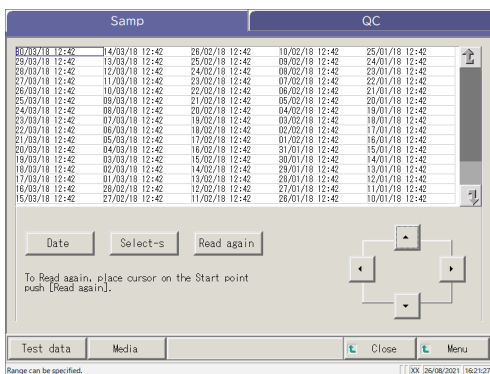
1   {Samp} tab is displayed.
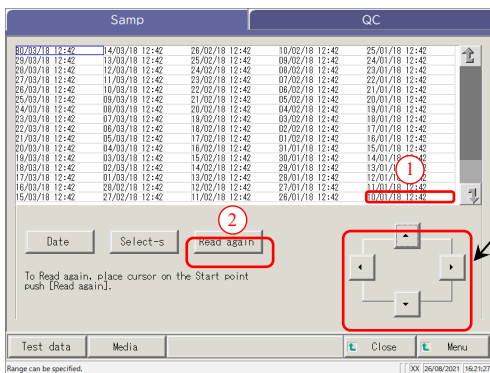
2   The test data is read by specifying the starting point.

① Touch the test date and time to be used as a starting point.
(Selecting is also possible using the cursor buttons at the bottom right of the screen.)

② Touch {Read again}.

③ Select the reading method (see the following table).
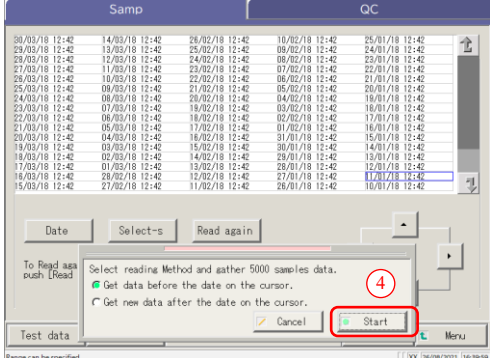
④ Touch {Start}.
*   Starts reading the test data.

{Cancel}: Closes the dialog box.

{Close}: Returns to the [Select data processing] screen.
Or returns to the [Analyzing] screen.
(When the {Test data} button is touched on the AssayMainView screen)

{Menu}: Returns to the [MENU] screen.

Select	Content
● Get data before the date on the cursor.	The data is acquired before the date of the cursor position (date and time at the cursor position are not included).
● Get new data after the date on the cursor.	Reads the data before the date and time of the cursor position (date and time at the cursor position are not included).

<div style="border:1px solid black; padding:10px;">

3.1.6   Reading "Test Data" in External Media (Switching the External Media)

</div>

Test data saved on external media can be read and displayed on the screen. This is not possible for QC sample test data.

(Note)   When displaying the [Process data] screen, see "3.1.1 Opening the [Process Data] Screen" on page 94
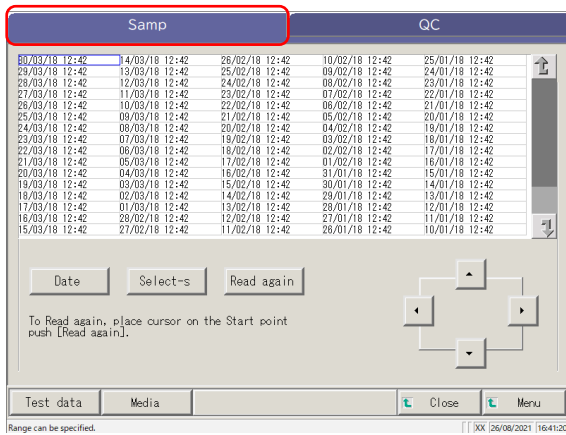
1   Touch the {Samp} tab.

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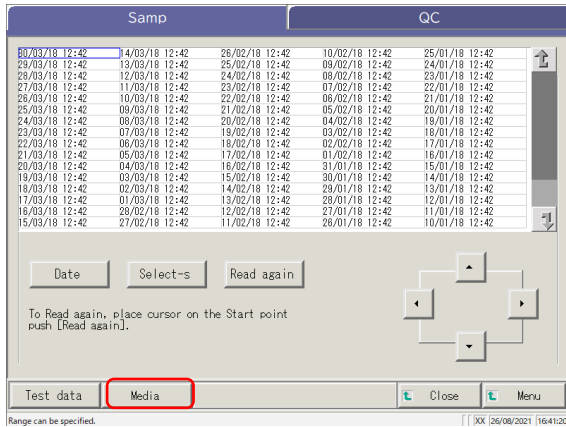
2   Touch {Media}.

{Media} changes to {HD change}.

* The data is read from the external media.
* The test data saved on the external media are displayed (max. 5000).
* The data are displayed from the latest date back.
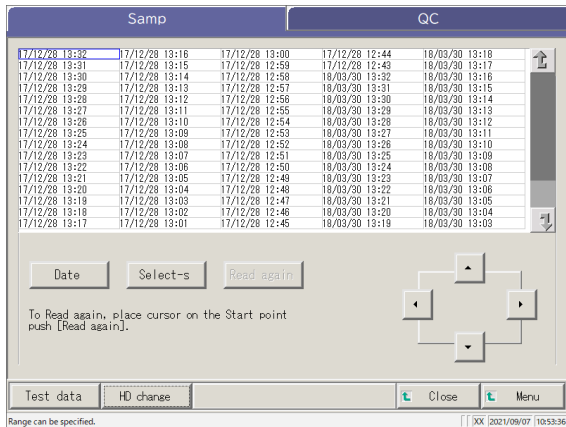
{HD change}: Returns to the display of test data saved on the system hard disk.

3.1.7   Searching the Test Data

The test data can be searched by Sample ID, Sample sequence No., Rack No., and test date.

(Note)   The test data cannot be searched by rack position No.

(Note)   When displaying the [Process data] screen, see "3.1.1 Opening the [Process Data] Screen" on page 94.
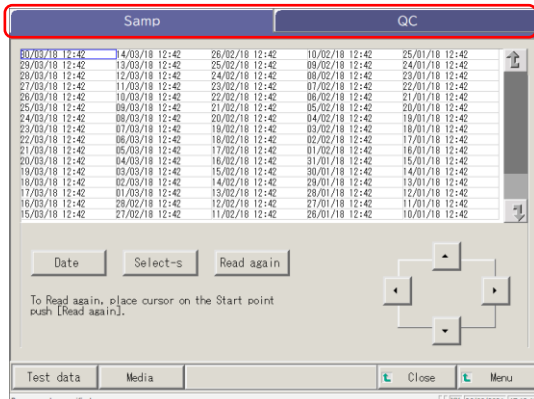
1 Touch the test data tab to be displayed.

   {Samp} tab
   {QC} tab
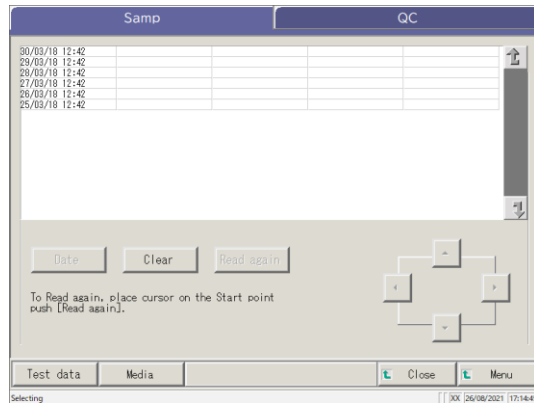
2 Specify the test data by test date or range.

<When specifying by test date>

   Touch {Date} to specify the test date.

   ☞ Page 100 "3.1.3 Specifying a {Date} for the Test Data" 2

<When specifying by range>

   Touch {Select-s} to specify the test date range.

   ☞ Page 102 "3.1.4 Selecting {Select-s} for Test Data" 2
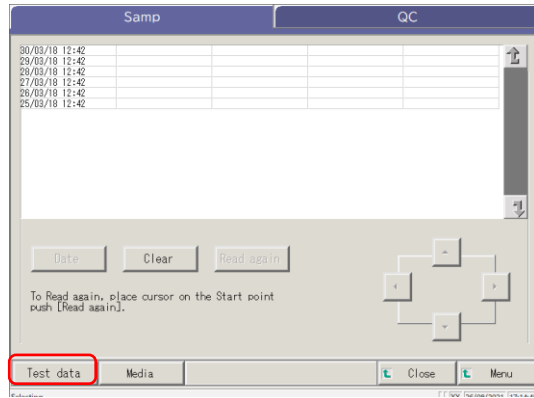
3 Touch {Test data}.
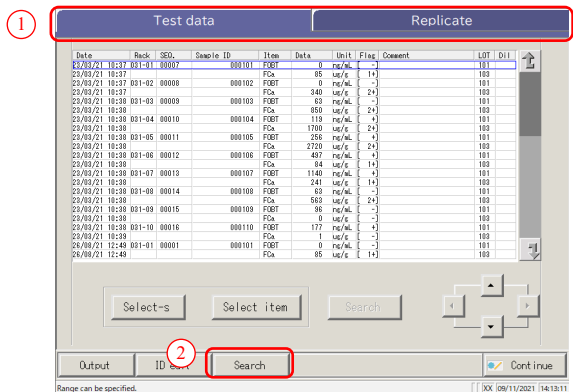
4 Search the target sample.

① Touch the corresponding tab.

② Touch [Search].
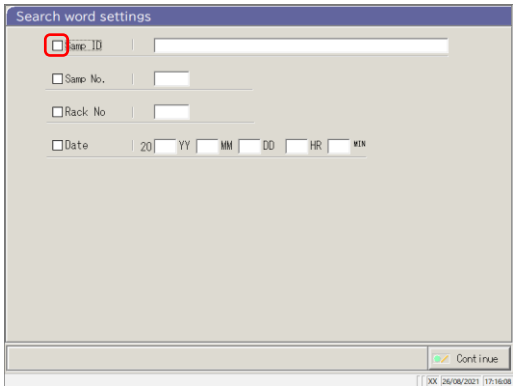
5 Select a keyword type to be searched.

☐ Samp ID (only for the {Samp} tab)

☐ Samp No.

☐ Rack No.
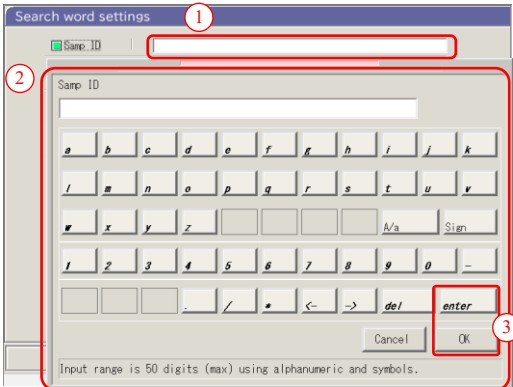
☐ Date

6 Enter a keyword.

① Touch the entry field next to a keyword.

② Enter a value using the keyboard.

③ Touch {OK} or {enter}.

{A/a} : Switches between large/small letters.

{Sign} : Enters symbols.

(Note) When the test date is selected, the year, month, date, hour, or minute must be entered.
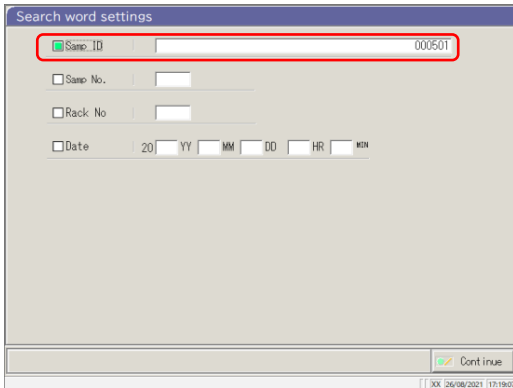
7 The search condition has been entered in an entry field.
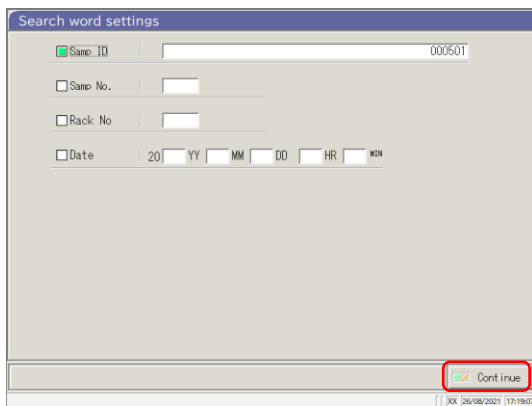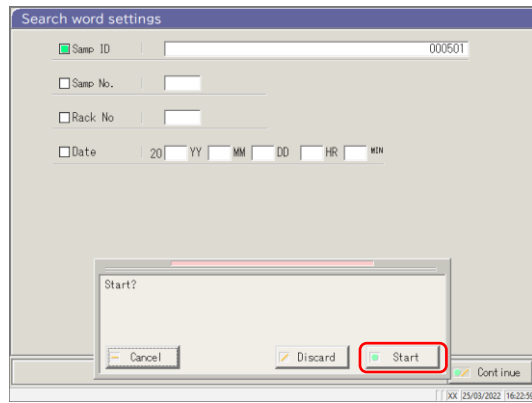
8 Touch {Continue}.

9 Touch {Start}.

        * Searching starts.
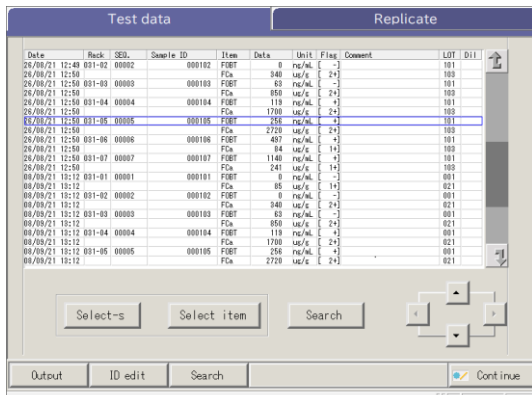
10 The search results are displayed.

{Search}: Continues searching.

3.1.8 Outputting Test Data

The specified test data is output to the selected destination.

- ・ Prints the test data
- ・ Saves the test data on external media.
- ・ Outputs the test data to the host computer.
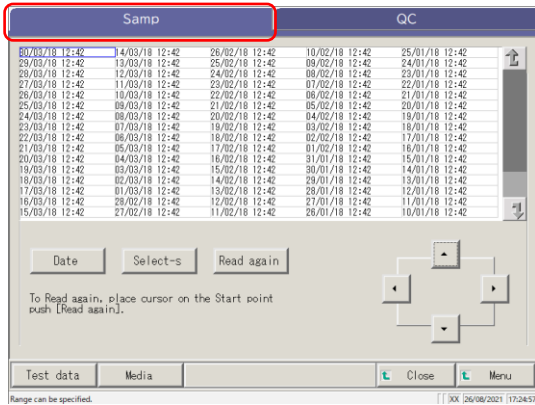
1 Touch the tab for the test data to be output (printed).

{Samp} tab
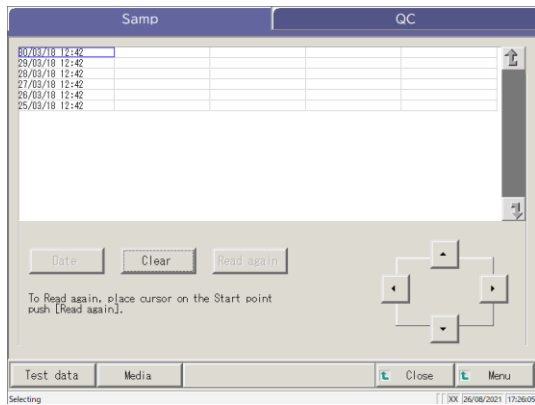
2 Specify the test data by date or range.

<When specifying by test date>

Touch {Date} to specify the test date.

☞ Page 100 "3.1.3 Specifying a {Date} for the Test Data" **2**

<When specifying by range>

Touch {Select-s} to specify the test date range.

☞ Page 102 "3.1.4 Selecting {Select-s} for Test Data" **2**

3 Touch {Test data}.

3

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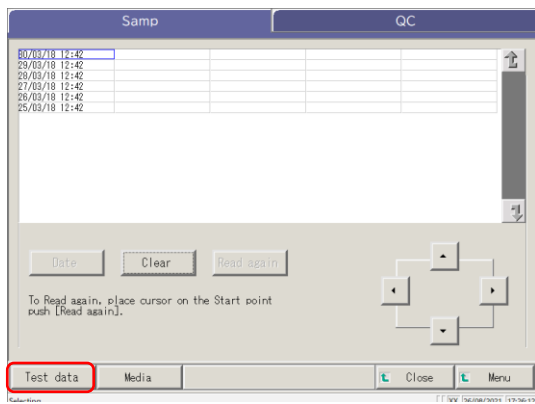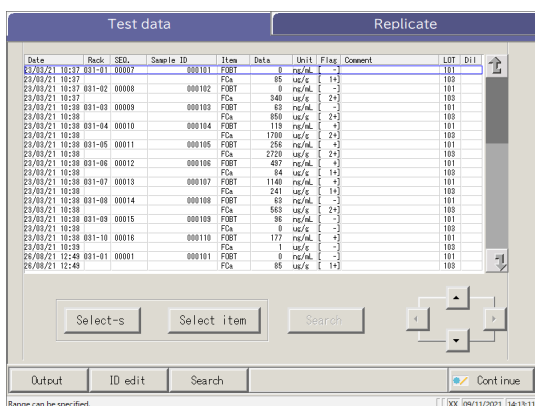
4 Specify the output range.

The procedure is the same as for the screen for selecting data.
☞ Page 102 "3.1.4 Selecting {Select-s} for Test Data" **2**
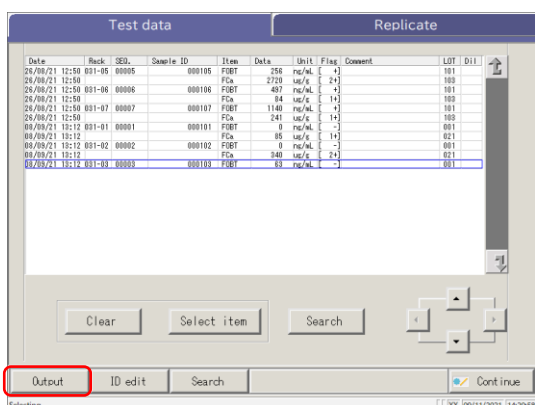
5 Touch {Output}.
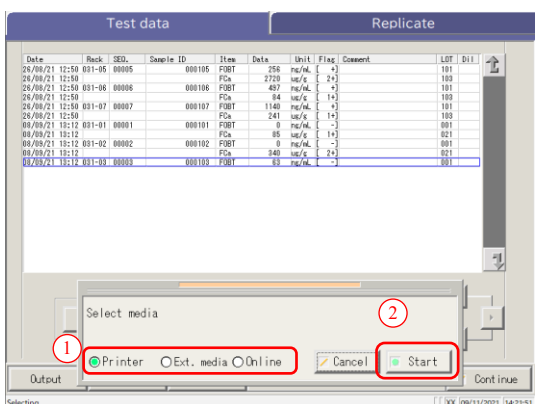
6 Outputs the test data.
① Select the destination.
- ○ Printer
- ○ Ext. media
- ○ Online
② Touch {Start}.

{Cancel}: Closes the dialog box.

(Note) If an error occurs in the test result communication, selecting "Network" in the [Select media] dialog is unavailable.

⚠ Request	
❗ Required	・ If the external media becomes full in the course of outputting the data, replace it with another external media and touch {Retry}.
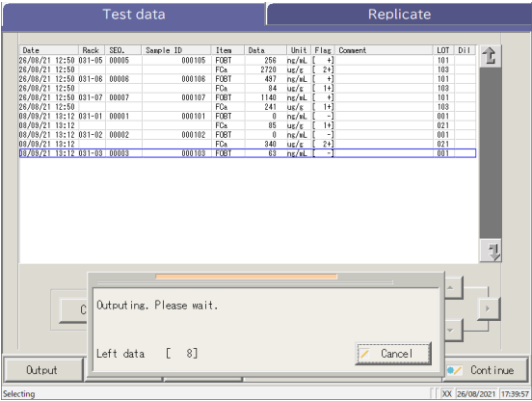
* During output, the [Output] dialog opens.
* When the output completes, the [Output] dialog closes.

3

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3.2 Editing a Sample ID

The sample ID of the data selected on the [Test data] screen can be edited.

(Note) In [System Settings] - –Samp barcode settings] screen - –Sample barcode], if [Duplicated check] is set to "YES," a
redundancy check on the Sample IDs is conducted.

However, if the sample ID of Retest data is edited, the redundancy check is not conducted.
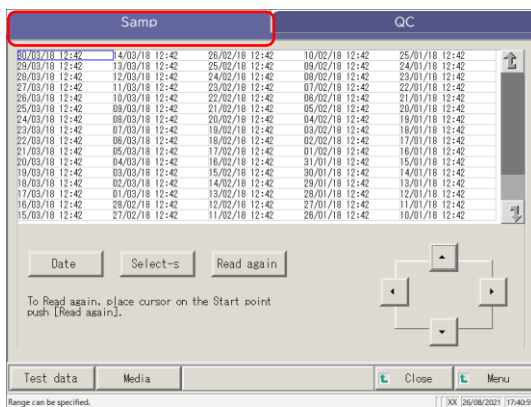
1 Touch the {Samp} tab.
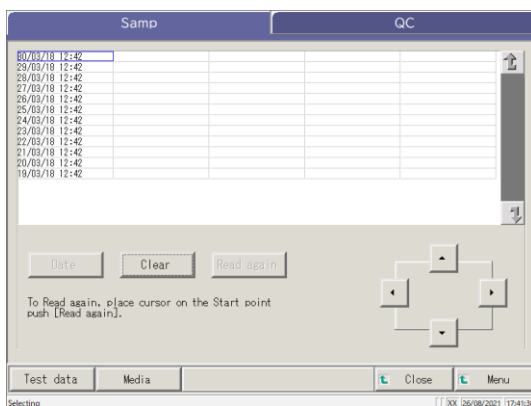
2 Specify the test data by date or range.

<When specifying by test date>

Touch {Date} to specify the test date.

☞ Page 100 "3.1.3 Specifying a
{Date} for the Test Data" **2**

<When specifying by range>

Touch {Select-s} to specify the test date
range.

☞ Page 102 "3.1.4 Selecting {Select-
s} for Test Data" **2**
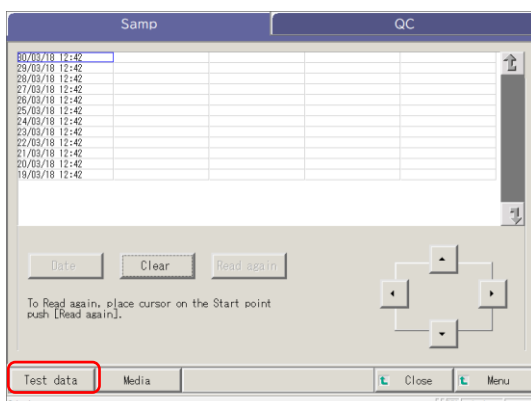
3 Touch {Test data}.
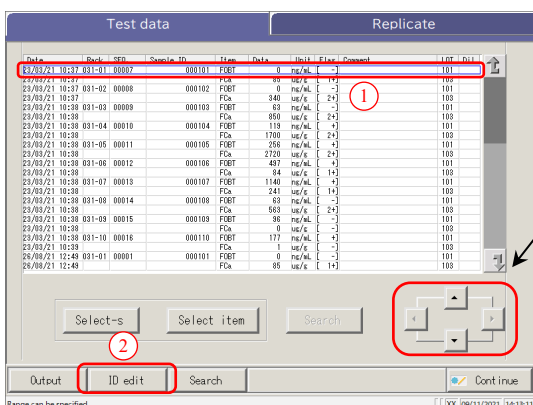
4 Select a sample ID.

① Touch the sample ID to be edited.
   (The sample ID can also be selected
   also by moving the cursor with the
   buttons.).

② Touch {ID edit}.

(Note) When the cursor is on a sample ID with 16 or more digits in the 2D code, the ID edit function becomes unavailable.
([ID edit] becomes inactive.)
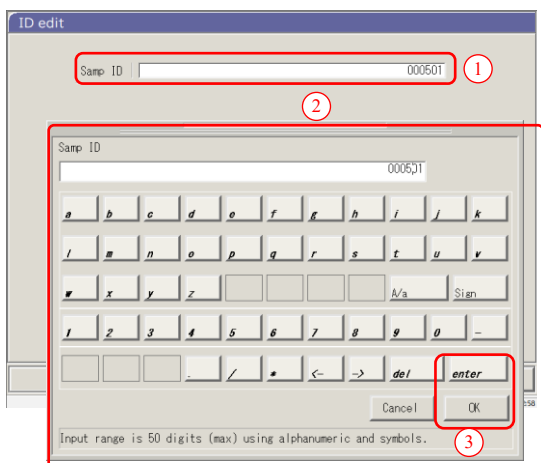
5 Enter a sample ID.

① Touch the entry field for the sample ID.
   The Samp ID dialog opens.

② Enter a sample ID using the keyboard.

③ Touch {OK} or {enter}.

{A/a}   : Switches between large/small letters.
{Sign}   : Enter symbols.
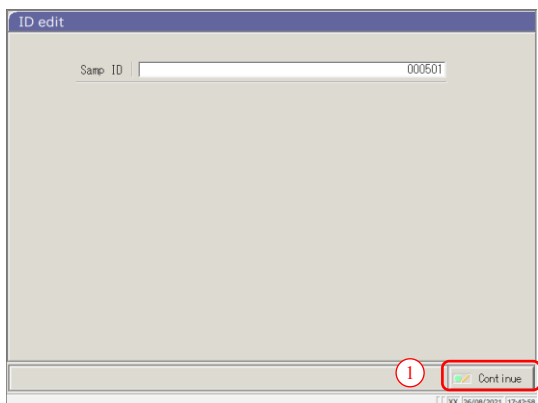
6 Update the sample ID.

① Touch {Continue}.

② Touch {Start} on the dialog box.
   * The edited sample ID is recorded.
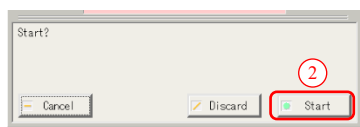
{Cancel}: Closes the dialog box.

{Discard}: Aborts editing of the sample ID, and returns
           to the [Test data] screen.

3.3 Replication

The replication data of the test data specified on the [Test data] screen is displayed.

3.3.1 Displaying the [Sample Replication] Screen (Sample)

The replication data of the sample is displayed.

(Note) If the range is not specified or the item is not selected, all data are displayed.
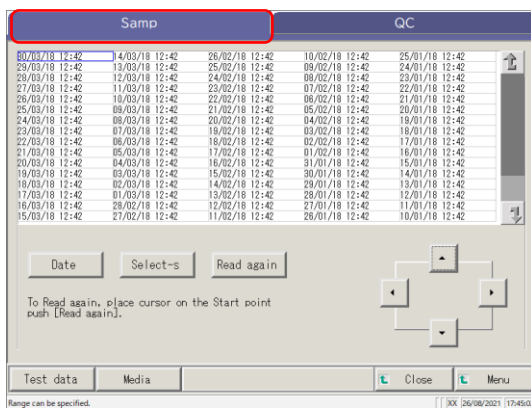
1 Touch the {Samp} tab.
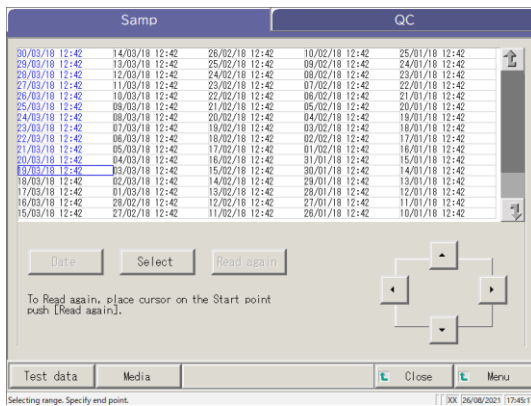
2 Specify the test data by date or range.

<When specifying by test date>

Touch {Date} to specify the test date.
☞ Page 100 "3.1.3 Specifying a {Date} for the Test Data" **2**

<When specifying by range>

Touch {Select-s} to specify the test date range.
☞ Page 102 "3.1.4 Selecting {Select-s} for Test Data" **2**

3 Touch {Test data}.

3
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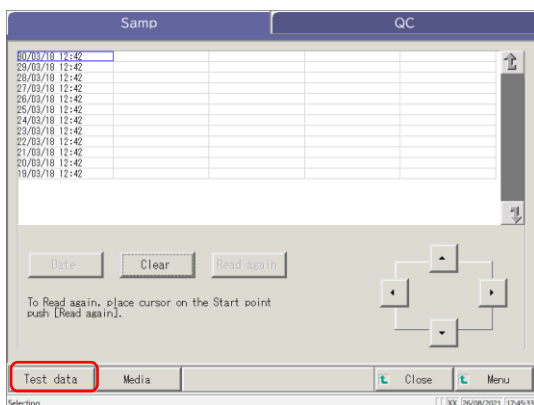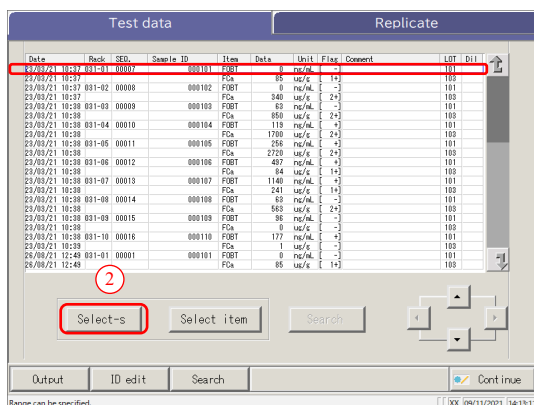
4 Specify the test data within the test date range.

① Touch the test date of the starting point (the cursor buttons at the bottom right of the screen can also be used).

② Touch {Select-s}.

* The line of the specified date changes to blue (starting point)

* {Select-s} changes to {Select}.
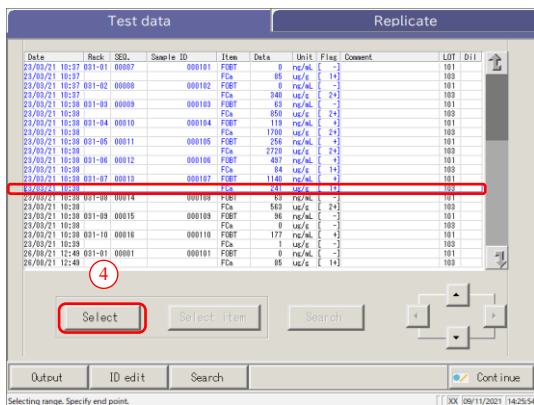
③ Touch the test date of the ending point (the cursor buttons at the bottom right of the screen can also be used).

* The lines of the specified range changes to blue (ending point).

④ Touch {Select}.

* The data in the specified range is displayed.

* When the ending point is finalized, {Select} changes to {Clear}.

{Select-s} : Finalizes the starting point data for range specification.

{Select} : Finalizes the ending point data for range specification.

{Clear} : Clears the specified range.
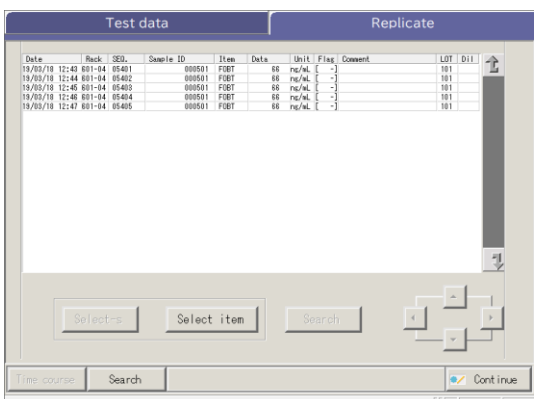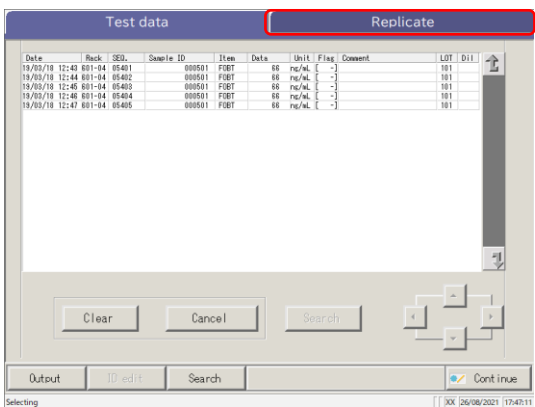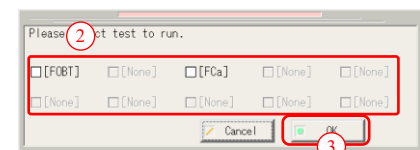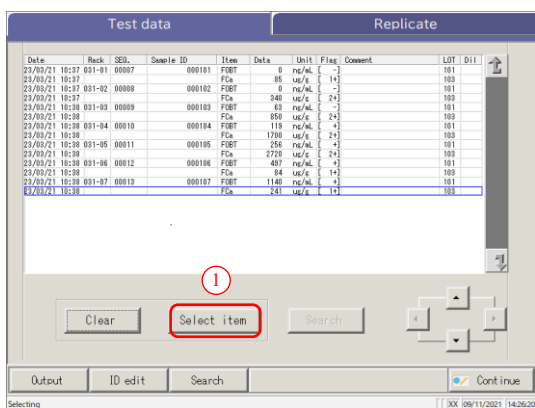
5 Select an item of test data.
   ① Touch {Select item}.
      The item select dialog is displayed.

   ② Select an item on the dialog.

   ③ Touch {OK}.
     * {Select item} changes to {Cancel}.

{Cancel}: Clears the range specification and item
            selection.

6 Touch the {Replicate} tab.

7 The [Replicate (sample)] screen opens.

> {Time course}: Displays the time course data.
>
>   ☞Page 131 "3.3.9 Displaying and Printing Time Course (Sample)"
>
> {Search}: Searches the sample by the sample ID, sample No., rack No., and test date.
>
>   ☞Page 126 "3.3.7 Searching Replication Data"

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Content of the [Replicate] screen

Display item	Content		Remarks
Date	Date and time of the sample test		
Rack	Rack No.- Rack Position No.		
SEQ.	Sample sequence No.		
Sample ID	Barcode on the sample bottle		
Item	Test item		
Data	Test result (concentration)		
Units	Units of measured data FOBT: ng/mL FCa: µg/g		
Flag	-, +, 1+, 2+, 3+		
Comment	Error information (excluding read errors)		
	UR	Under range	Outputs a blank for the measured data and the flag (displayed for dilution retest)
	OR	Over range	Outputs a flag only
	PRC	Prozone	Outputs a flag only
LOT	Lot of the sample used for the test.		
Dil	Dilution information		
	Space	No dilution (analyze, retest)	
	A	No dilution (retest)	
	A10	Dilution by a factor of 10 (retest)	
	A20	Dilution by a factor of 20 (retest)	
	A100	Dilution by a factor of 100 (retest)	
	A200	Dilution by a factor of 200 (retest)	
	A400	Dilution by a factor of 400 (retest)	

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3.3.2 Displaying [Replicate (STD)] Screen

STD replication data is displayed.
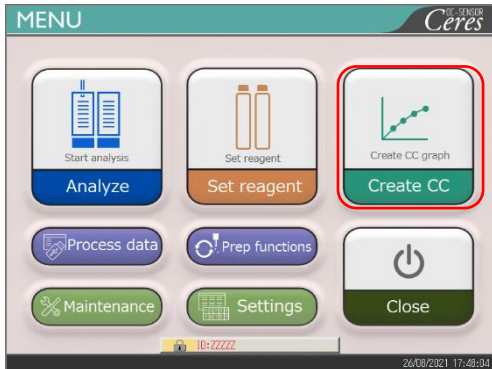
1 Touch {Create CC}.
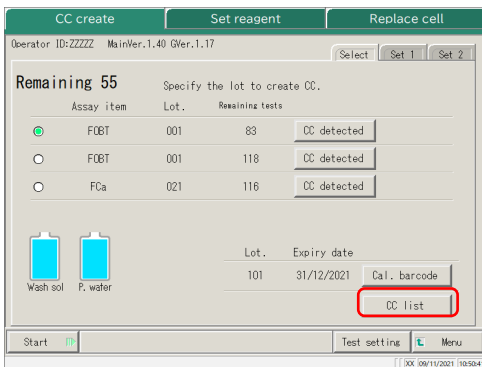
2 Touch {CC list}.

  * The [CC list] screen opens.
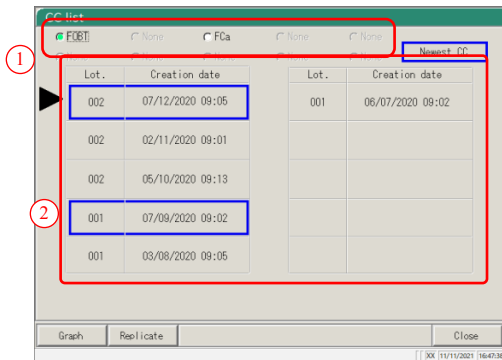
3 Select CC.

  ① Select an item.

  ② Touch the lot or creation date of the
     CC to be edited or recalculated.

   *The selected CC is indicated by the ▶ mark.
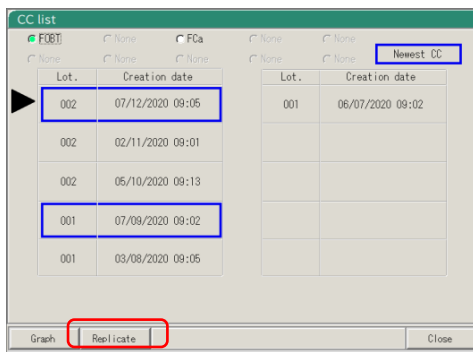
4 Touch {Replicate}.
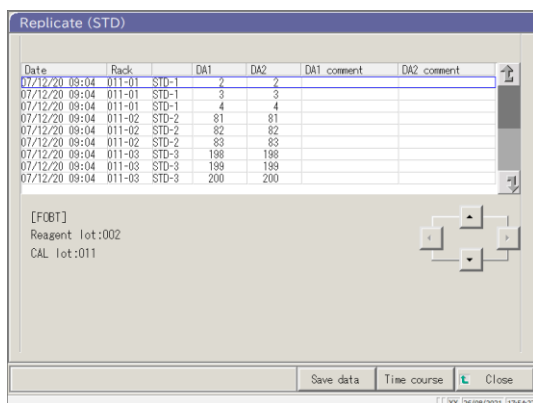
4 Data of the selected CC are displayed.

Content of the [Replicate (STD)] screen

Display item	Content	Remarks
Date	Date and time when STD was measured	
Rack	Rack No.- Rack Position	
(Blank)	STD concentration (STD-1 - –TD-6)	
DA1	ABS (A#) change amount A3-A1	☞ Page 236 "1.2 DA Value Calculation"
DA2	ABS (A#) change amount A2-A1	
DA1 comment	DA1 comment	
DA2 comment	DA2 comment	

{Save to media}: Saves the replicate data to an external media.

☞Page 120 "3.3.3 Saving Replicate Data (STD) to External Media"

{Time course}: Opens the [Time course data] screen.

☞Page 132 "3.3.10 Displaying and Printing Time Course (STD)"

☞Page 135 "3.3.12 Changing the Time Course Range (STD)"

{Close}: Returns to the [Select data] screen.

3.3.3   Saving Replication Data (STD) to External Media

By opening the [Replicate (STD)] screen, the replication data displayed on the screen can be saved to external media.

The explanation starts from the condition at which the [Replicate (STD)] screen is displayed.

☞   Page 118 "3.3.2 Displaying [Replicate (STD)] Screen"
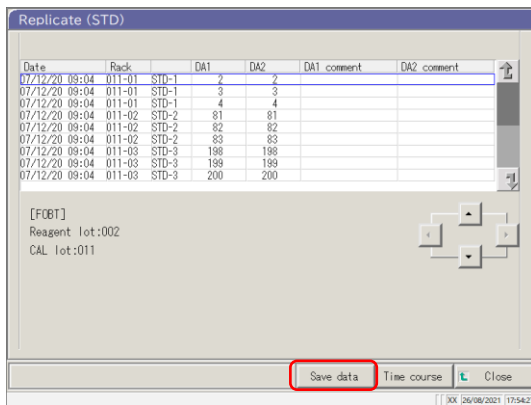
1   On the [Replicate (STD)] screen, touch the {Save data} button.

* The STD replication data is saved on the external media.

Note   If external media is not connected, the "External media is not connected" message will be displayed. Connect external media and touch {Retry}.

<div style="border:1px solid black">

3.3.4 Displaying the [Replicate (QC)] Screen

</div>

The QC replication data is displayed.

(Note) If a range is not specified, all data are displayed on the screen.
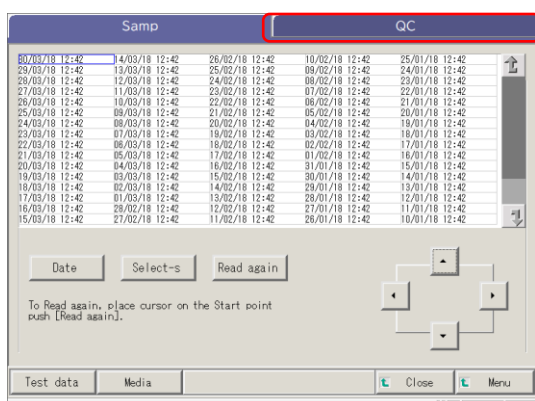
1 Touch the {QC} tab.
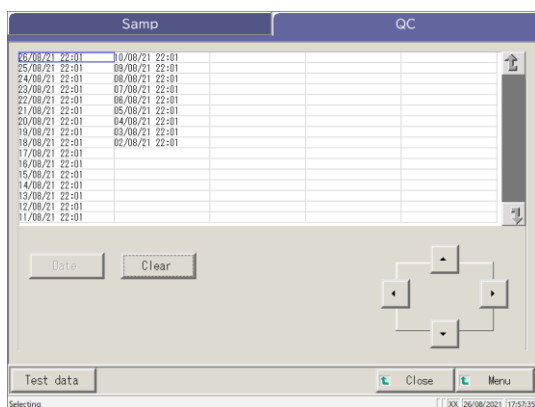
2 Specify the test data by date or range.

<When specifying by test date>

Touch {Date} to specify the test date.

☞Page 100 "3.1.3 Specifying a {Date} for the Test Data" **2**

<When specifying by range>

Touch {Select-s} to specify the test date range.

☞Page 102 "Selecting {Select-s} for Test Data" **2**
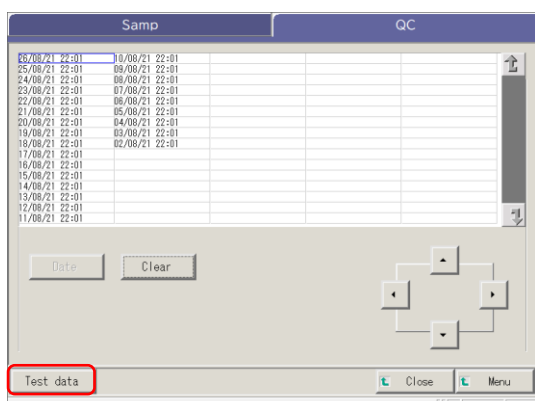
3 Touch {Test data}.
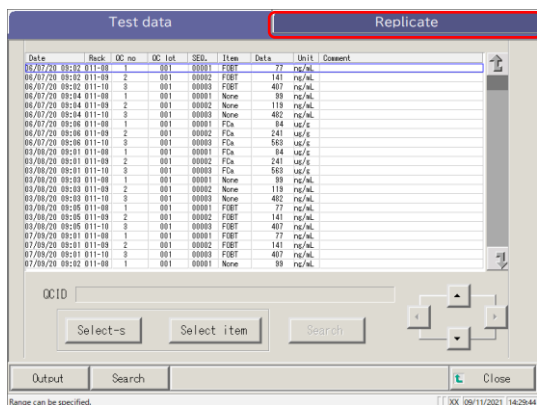
4 Touch the {Replicate} tab.
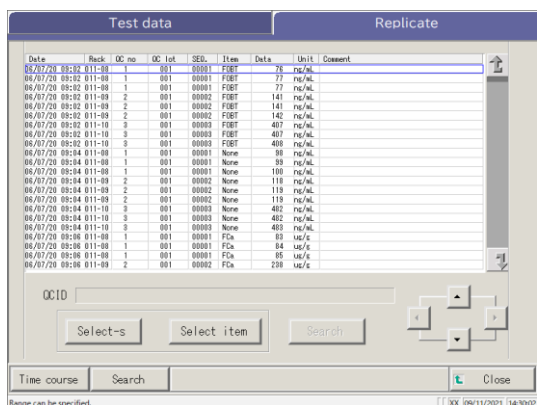
5 The [Replicate (QC)] screen is displayed.

    * QC IDs are displayed.

{Close} : Returns to the process data start screen.

Content of the [Replicate (QC)] screen

Display item	Content	Remarks
Date	Date and time when QC was measured	
Rack	Rack No.- Rack Position No.	
QC no.	QC sample No.	
QC lot	QC sample lot number	
SEQ.	QC sequence number	
Item	Test item	
DATA	QC sample measured data	
Units	Units of measured data FOBT: ng/mL FCa: µg/g	
Comment	Barcode read error	
QC ID	QC ID of the QC sample at the cursor position	

(Note) When the QCID has 16 or more digits of 2D code, only 15 digits from the beginning are displayed.

{Time course} : Displays the time course data.

    ☞Page 131 "3.3.9 Displaying and Printing a Time Course (Sample)"

{Search} : Searches the sample by the sample ID, sample No., rack No., and test date.

    ☞Page 126 "3.3.7 Searching Replication Data"

3
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Operations

3.3.5 Specifying {Select-s} for Replication Data

The replication data can be specified within a test date range (from starting point to ending point) by touching the test date or by operating the cursor buttons on the [Replicate] screen.

Specifying the starting point and touching {Select-s} sets the replication data starting point.

When the ending point is specified and {Select} is touched, the replication data ending point is set.

When both starting point and ending point are finalized, the replication data between the starting and ending points are specified.

The explanation starts from the condition at which the [Replicate] screen is displayed.

☞   Page 114 "3.3.1 Displaying the [Sample Replication] Screen (Sample)"   **1** - **5**
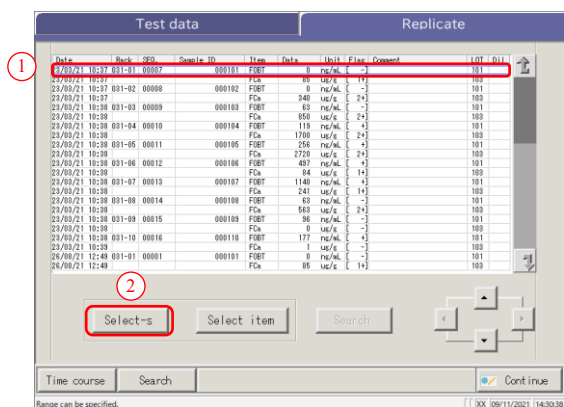
1 Specify the replication data starting point.
  ① Touch the date and time to be used as a starting point.
  ② Touch {Select-s}.
    * The starting point is set. (The line of specified date turns blue.)
    * When the starting point is set, {Select-s} changes to {Select}.
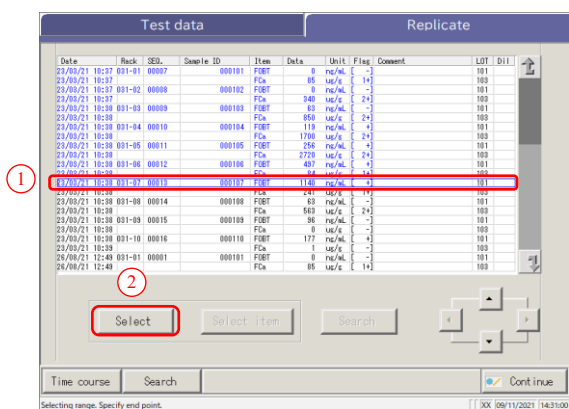
2 Specify the replication data ending point.
  ① Touch the date and time to be used as an ending point.
    * The line of the specified range turns blue.
  ② Touch {Select}.
    * The data of the specified range is displayed.
    * When the ending point is specified, {Select} changes to {Clear}.

{Select-s}: Finalizes the starting point of the range specification.

{Select}: Finalizes the ending point of the range specification.

{Clear}: Clears the specified range.

3.3 Replication

(Note) When the dates and times specified as the starting point and ending point are the same, only one test data set is specified.

(Note) To redo the specification of the replication data range, touch {Clear}. All replication data are displayed, and no range is specified.
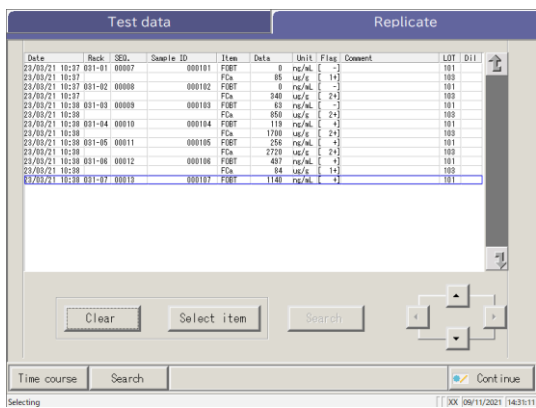
3 The replication data is specified.

* The specified replication data is displayed.

}

To further limit the test items to be processed on the [Replicate] screen, select an item.

The explanation starts from the condition at which the [Replicate] screen is displayed.

☞ Page 114 "3.3.1 Displaying the [Sample Replication] Screen (Sample)" ▮1▮ - ▮5▮
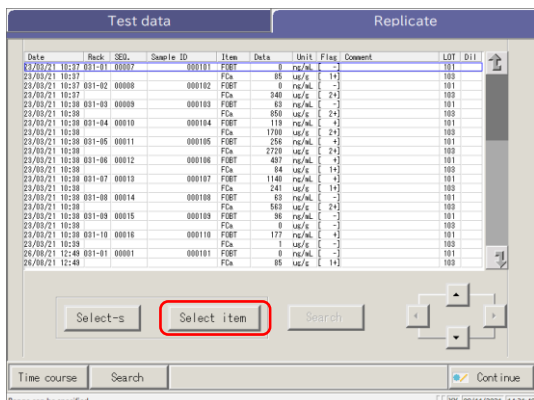
1 Touch {Select item}. The item selection dialog opens.
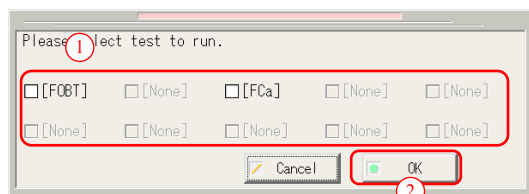
2 Select a test item.
① Select an item in the dialog.
② Touch {OK}.
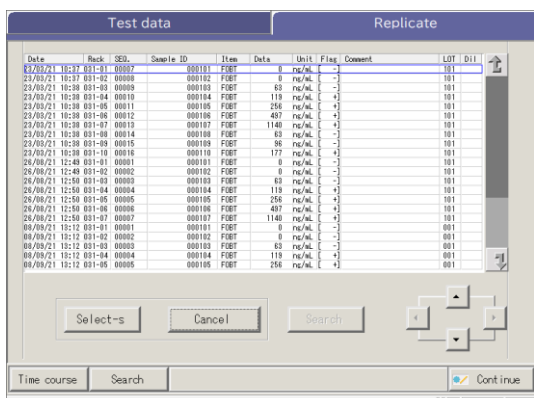
3 The selected item data are displayed.
* {Select item} changes to {Cancel}.

{Cancel} : Clears the range specification and item selection.

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Applied
Operations

3.3.7 Searching Replication Data

The replication data can be searched by sample ID, sample number, rack number, and test date.

The explanation starts from the condition at which the [Replicate] screen is displayed.

☞ Page 114 "3.3.1 Displaying the [Sample Replication] Screen (Sample)" **1** - **5**

(Note) When a range is not specified, all error samples do not become the target of the error sample search.

The replication data cannot be searched by rack position number.

(Note) The replication data range can also be specified by {Select-s} on the [Replicate] screen. The procedure is the same as "3.3.5 Specifying {Select-s} for Replication Data" on page 123.
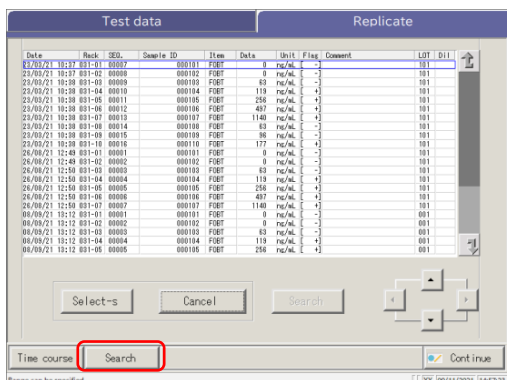
1 Touch {Search}.
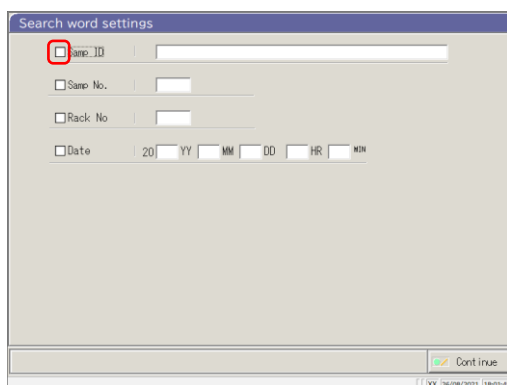
2 Select the keyword to be searched.

- ☐ Samp ID (only for the {Samp} tab)
- ☐ Samp No.
- ☐ Rack No.
- ☐ Date
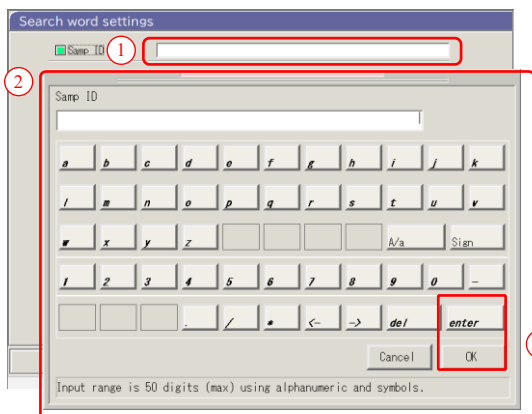
3 Enter a value.

① Touch inside the "entry field" next to a keyword.

② Enter a value using the keyboard.

③ Touch {OK} or {enter}.

{A/a}: Switches between large/small letters.

{Sign}: Used to enter symbols.

(Note) If "Test date" is selected, the year, month, day, hour, or minute must be entered.

(Note) The search range is the range specified on the [Test data] screen.
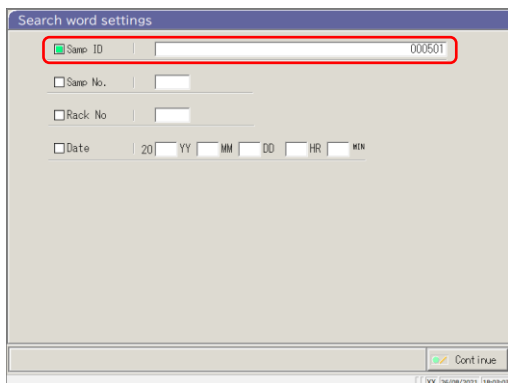
4 A search condition is entered in the entry field.
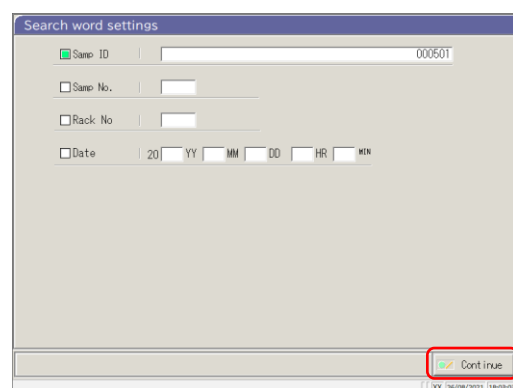
5 Touch {Continue}.
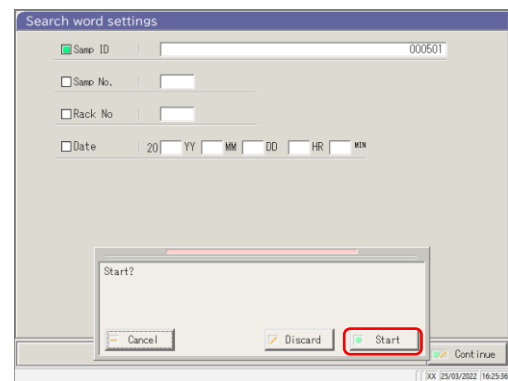
6 Touch {Start}.
  * The search starts.
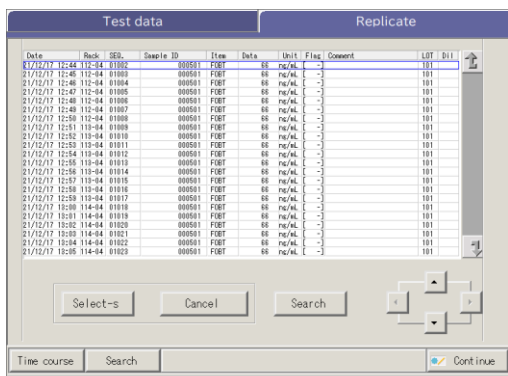
7 The search results are displayed.

3.3.8 Editing and Recalculating CC

Recalculation of CC origin value and DA value by editing and saving the recalculated CC in the hard disc are available.

(Note) While logging in with an administrator ID or when "NO" is set to Operator mode, editing and recalculation are available.

The explanation starts from the condition which the [CC list] screen is displayed.

☞ Page 57 "■ CC list"
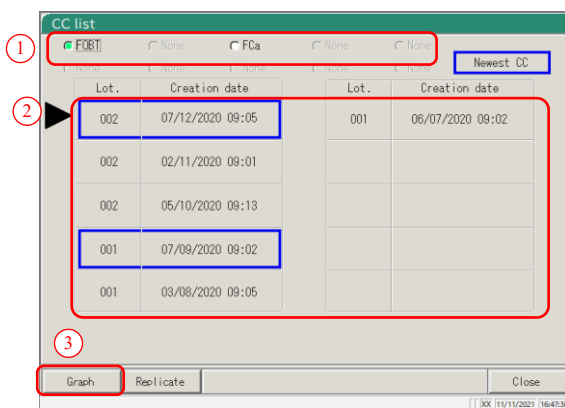
1 Select CC.

① Select an item.
② Touch the lot or creation date of the CC to be edited/recalculated.
* The selected CC is indicated by the ▶ mark.

2 Touch {Graph}.

3 Touch {CC info}.

4 Edit CC.
① Touch the entry field of the item to be edited.
The keyboard is displayed.
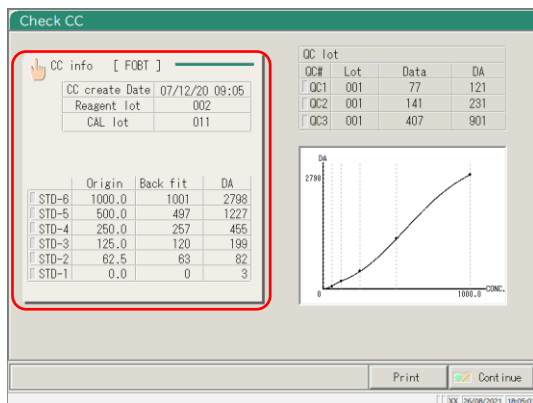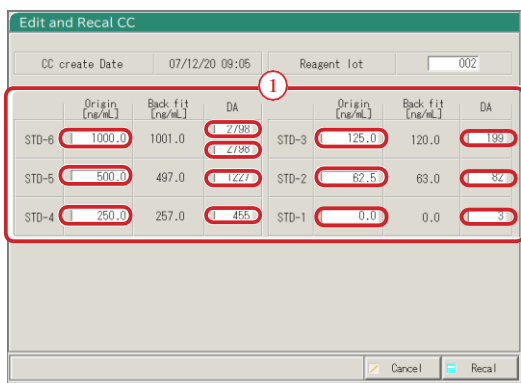
(Note) The DA1 values of STD-1 - –TD-5 should be entered in DA fields.
The DA values of STD-6 are the entered value of DA1 for the upper level and the entered value of DA2 for the lower level.

(Note) DA2 for STD-6 is referred to for the PRC method check.
☞ Page 238 "1.4 Prozone Check"
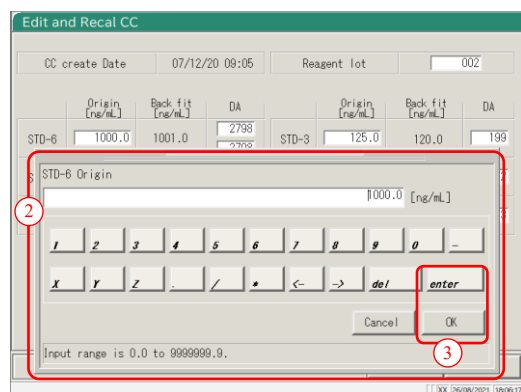
② Enter a number.

③ Touch {OK} or {enter}.
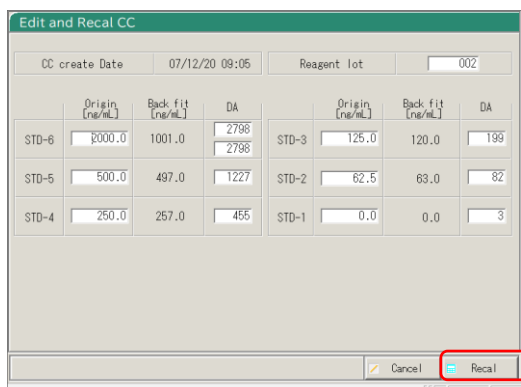
5 Touch {Recal}.

* The recalculated CC will be displayed.

3
Applied Operations
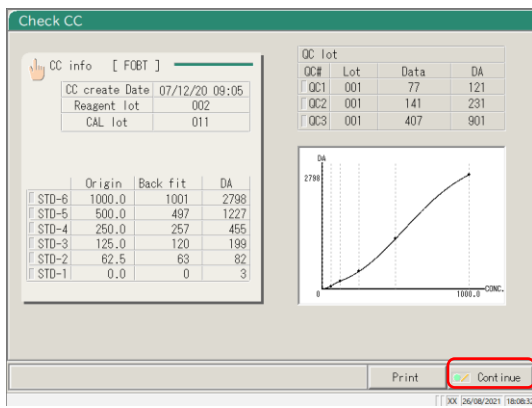
6   Touch {Continue}.
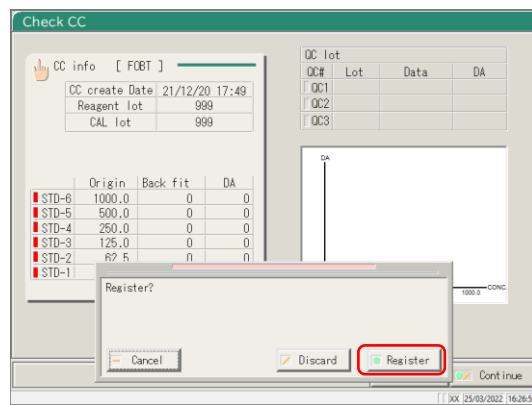
7   Touch {Register}.

   * The CC is registered as the latest CC.

{Register}: Registers the CC data.

{Discard}: Aborts registration and returns to the [Check CC] screen.

{Cancel}: Closes the dialog box.

3.3.9   Displaying and Printing a Time Course (Sample)

The time course of the replication data (sample) can be displayed. On the screen, the time course (graph), the number of cycles (Cycle), and the absorbance (ABS) are displayed.

The explanation starts from the condition at which the [Replicate] screen is displayed.

☞ Page 114   「3.3.1 Displaying the [Sample Replication] Screen (Sample)"   **1** - **3**
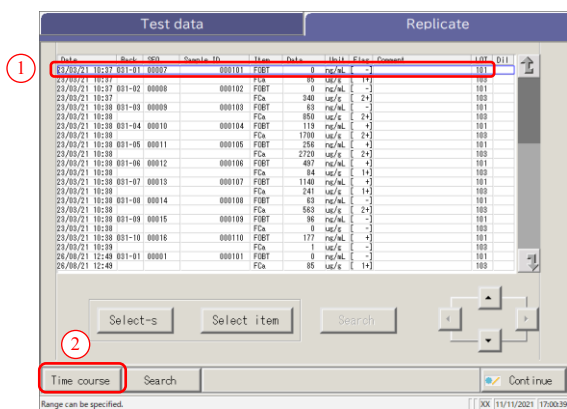
1   Display the time course.
①   Touch the date field.

* The specified data is encircled by a blue frame.

②   Touch {Time course}
* The time course of the specified data is displayed.

3

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2   The time course is displayed.

When printing the time course, touch {Print}.

{Print} : Prints the time course.
{Range change} : Changes the time course range.
{Close} : Returns to the [Replicate] screen.
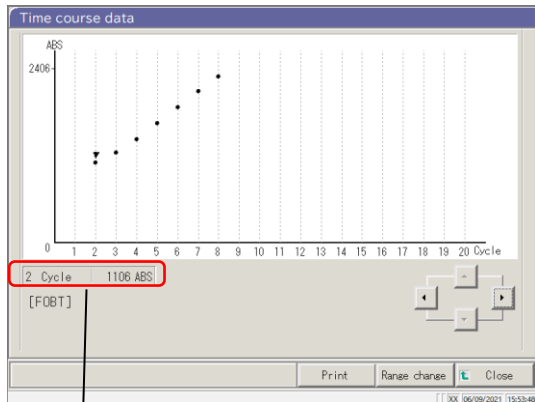
(Note)   The "▼" mark on the screen can be moved by the cursor buttons.
The numeral information of the cursor is displayed in ⬭
Each item indicates the following meanings.

# Cycle	#ABS		
↑	↑	a:	Number of cycles
a	b	b:	ABS (Test value – Cell blank value)

<div style="border:1px solid black; padding:10px;">

3.3.10 Displaying and Printing a Time Course (STD)

</div>

The time course of the replicate data can be displayed.

On the screen, the time course (graph), the number of cycles (Cycles), and the absorbance (ABS) are displayed.

The explanation starts from the condition at which the [Replicate (STD)] screen is displayed.

☞ Page 118 "3.3.2 Displaying [Replicate (STD)] Screen"
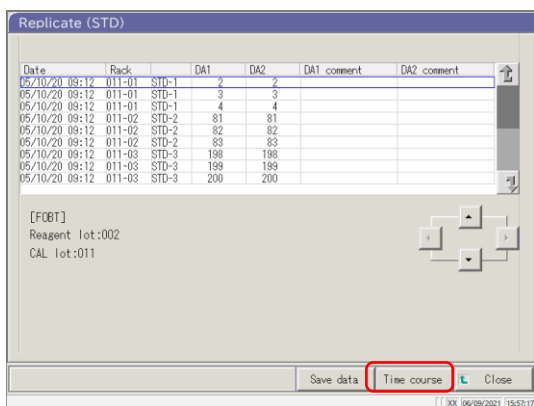
1 Touch {Time course}.

* The time course of the specified data is displayed.
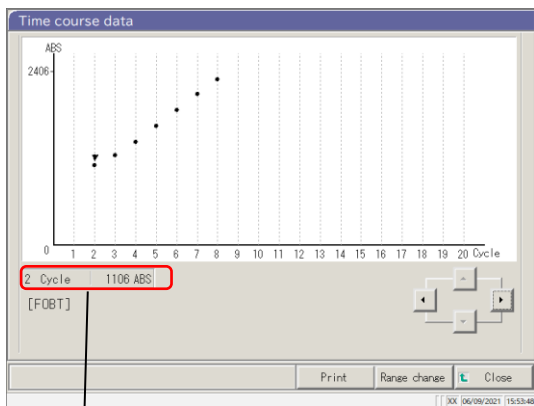
2 The time course was displayed.

When printing the time course, touch {Print}.

{Print} : Prints the time course.
{Range change} : Changes the time course range.
{Close} : Returns to the [Replicate] screen.

(Note) The "▼" mark on the screen can be moved by the cursor buttons.

The numeral information of the cursor is displayed in ⬭

Each item indicates the following meanings.

# Cycle	#ABS		
↑	↑	a:	Number of cycles
a	b	b:	ABS (Test value – Cell blank value)

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3.3.11 Changing the Time Course Range (Sample)

On the [Time course data range change] screen, the range can be changed by entering "Max Value" and "Min Value."

The explanation starts from the condition at which the [Replicate] screen is displayed.

☞ Page 114 "3.3.1 Displaying the [Sample Replication] Screen (Sample)"　▐1▌ - ▐3▌

(Note) The time course data for which the range was changed is not saved to the hard disk.

3
Applied
Operations
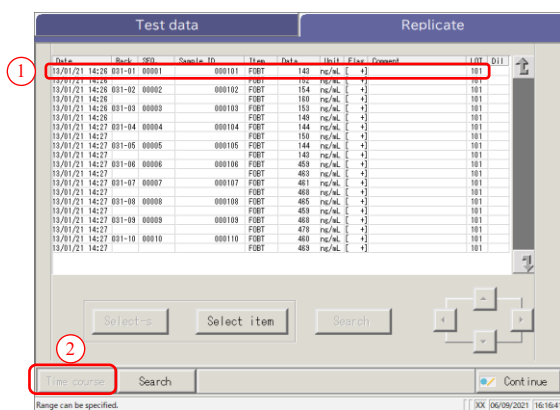
▐1▌　Display the time course.
① Touch a Date field.
　　* The specified data is encircled by a blue frame.

② Touch {Time course}.
　　* The time course of the specified data is displayed.
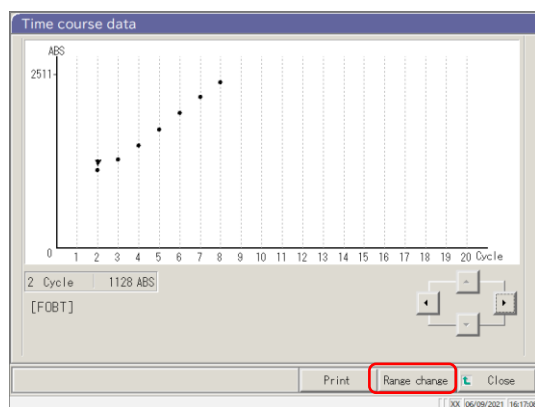
▐2▌　Touch {Range change}.

{Print}　　　: Prints the time course.
{Range change}: Changes the time course range.
{Close}　　　: Returns to the [Replicate] screen.
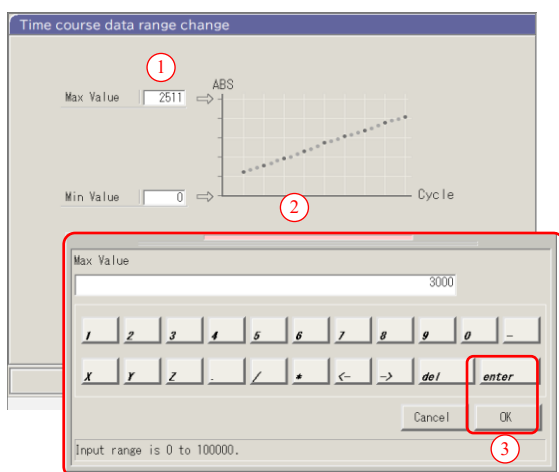
3 Set ABS.
(Available range: 0 - –0000)

① Touch the entry field of [Max Value] or [Min Value]. The numeric keypad opens.
② Enter a number.
③ Touch {OK} or {enter}.
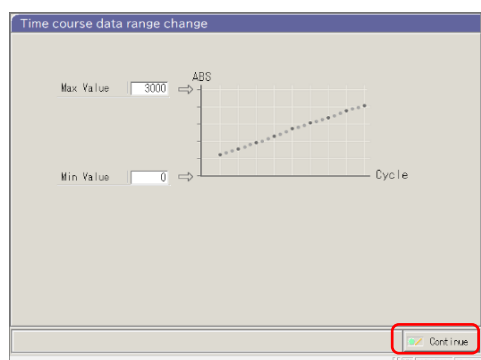
4 Touch {Continue}.
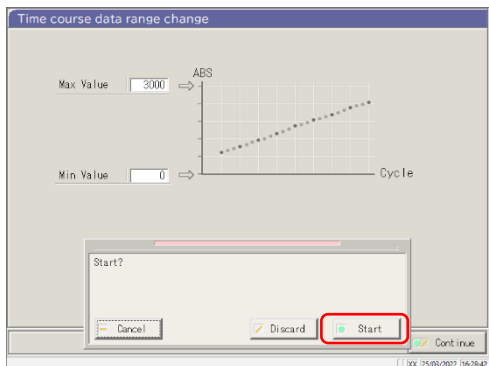
5 Touch {Start}.

　　　　* The range changes.

{Cancel}: Closes the dialog box.

{Discard}: Aborts the range change and returns to the [Time course data] screen.

{Start}: Changes the range.
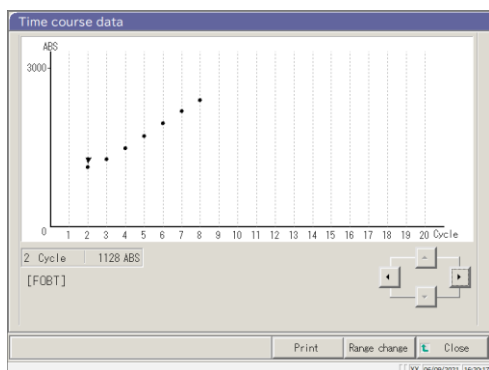
6 The time course after the range change has been displayed.

{Print}　　: Prints the time course. If {Close} is touched during printing, the printing is aborted.

{Close}: Returns to the [Replicate] screen.
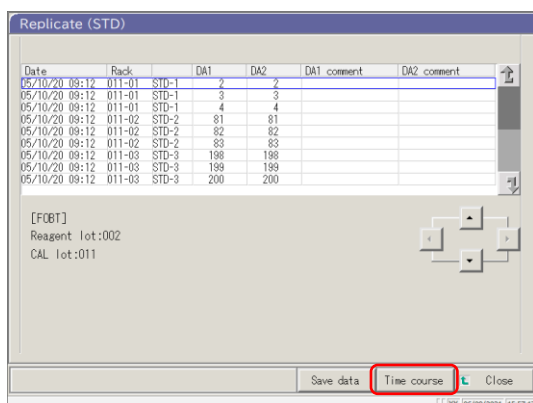
3.3.12 Changing the Time Course Range (STD)

On the [Time course data range change] screen, the range is changed by entering the "Max Value" and the "Min Value."

The explanation starts from the condition at which the [Replicate (STD)] screen is displayed.

☞ Page 118 "3.3.2 Displaying [Replicate (STD)] Screen"
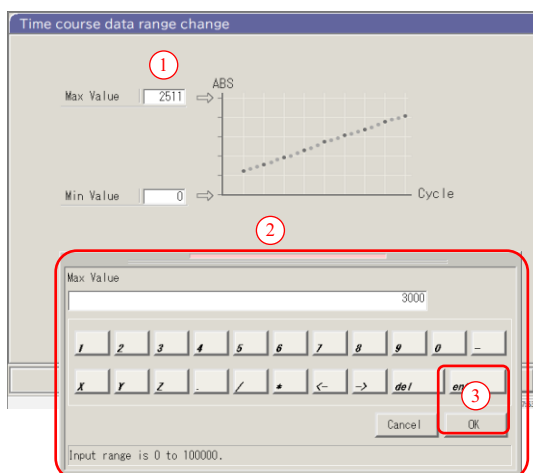
(Note) The time course data for which the range was changed will not be saved to the hard disk.

1 Display the time course.
① Touch a Date.
* The specified data is enclosed by a blue frame.

② Touch {Time course}.
* The time course of the specified data is displayed.

2 Touch {Range change}.

3 Set ABS.
(Available range: 0 - –0000)

① Touch the entry field for [Max Value] or [Min Value]. The numeric keypad opens.
② Enter a number.
③ Touch {OK} or {enter}.

3
Applied
Operations
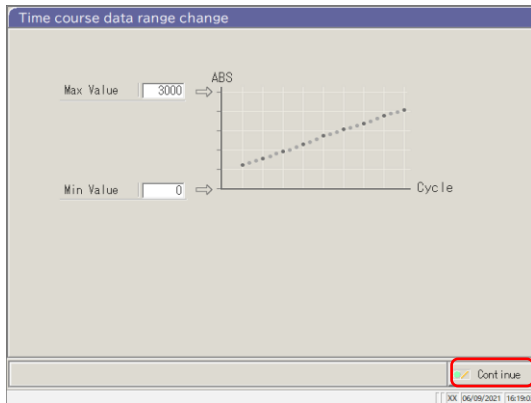
4   Touch {Continue}.
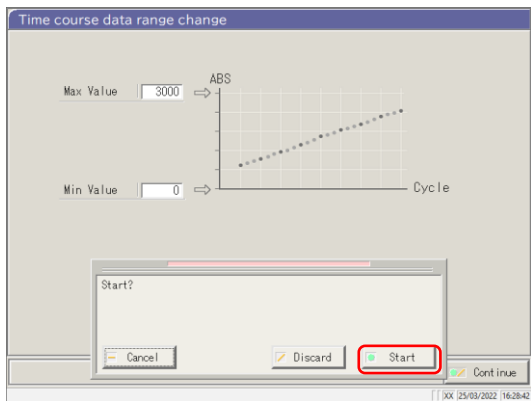
5   Touch {Start}.

{Cancel}： Closes the dialog box.

{Discard}： Aborts the range change and
　　　　　 returns to the [Time course data] screen.

{Start}： Changes the range.
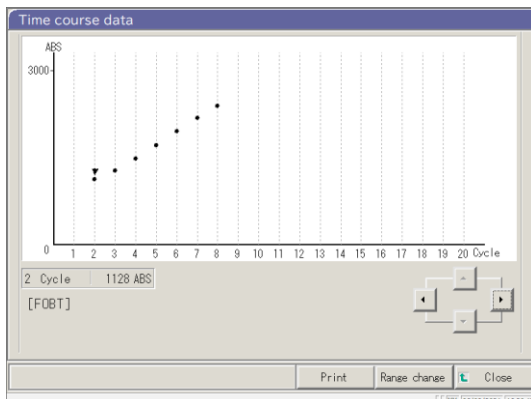
6   The time course after the range change
　　　 has been displayed.

{Print}： Prints the time course. While printing,
　　　　 touching {Close} aborts printing.

{Close}： Returns to the [Replicate (STD)] screen.

3.4 Accuracy Control

On the accuracy control screen, QC lot select, Intra-day/Inter-day, and $\overline{X}$-R control are displayed.

In addition, the Intra-day/Inter-day and $\overline{X}$-R control range can be edited.

3.4.1 Displaying the QC Lot List ([QC lot select] screen)

Touching {Process data} - –Process QC} on the [MENU] screen or touching {Process QC} tab on the [Analyzing] screen will display the QC lot select ([QC lot select] screen).

(Required to select a test item and to operate the {Start} button)

On this screen, the {Intra-day/Inter-day} tab and the {$\overline{X}$-R control} tab are provided in addition to the {QC lot select} tab.

(Note) When there is no test data, switching from the {QC lot select} tab to another tab is not available.
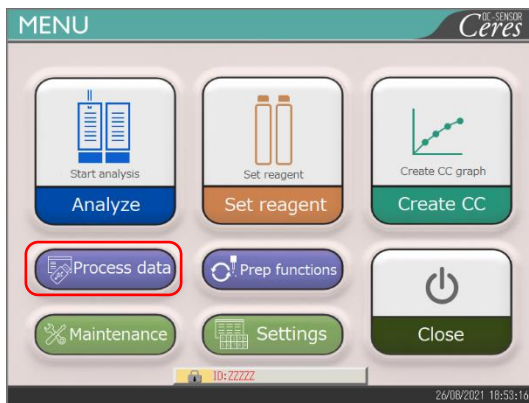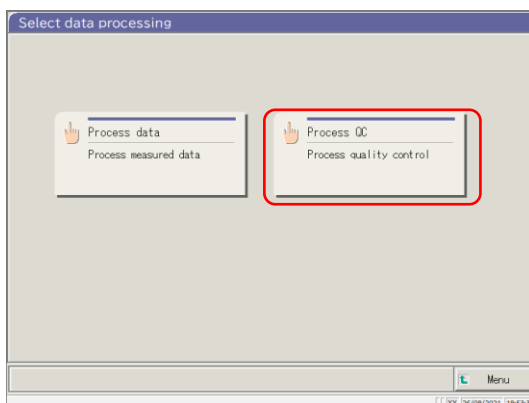
1 Touch {Process data}.

2 Touch {Process QC}.
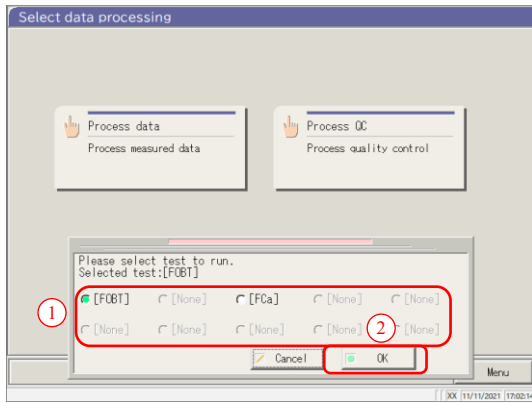
3 Select a test item.

① Select a radio button (•).

② Touch {OK}.

{Cancel}: Closes the dialog box.
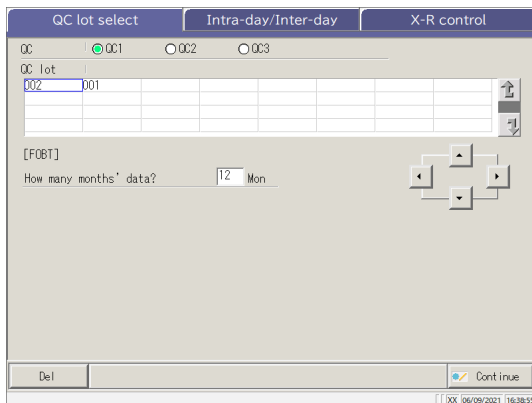
4 The [QC lot select] screen opens.

· {QC lot select} tab

· {Intra-day/Inter-day} tab

· {X̄-R control} tab

* The currently used QC lots are displayed sequentially.

(The display order is from left to right and from top to bottom.)
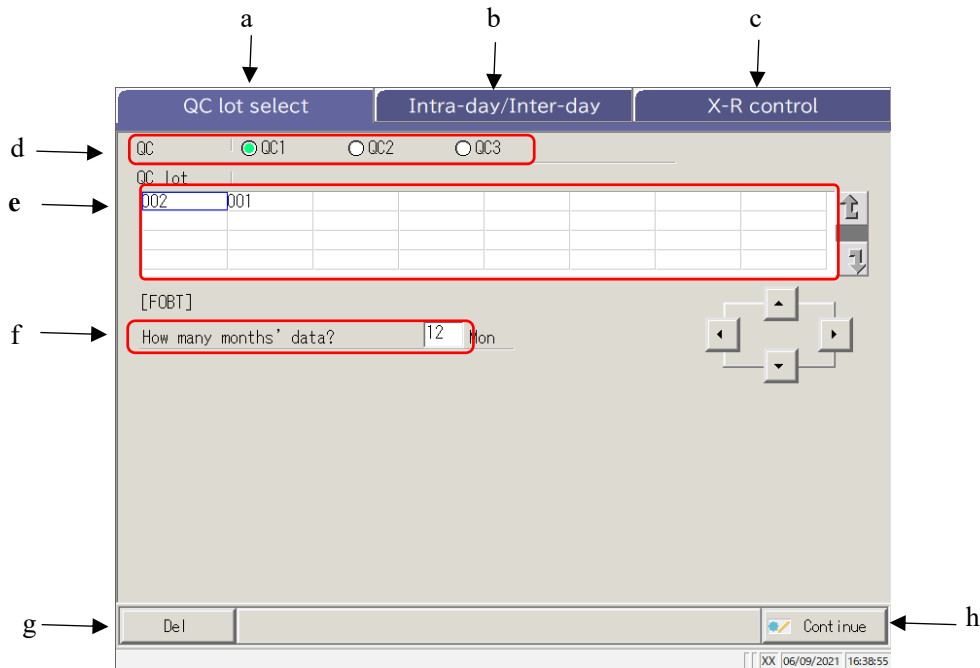
[Screen]: QC lot select screen

a	QC lot select	Displays the QC lots saved in QC1 - –C3.
b	Intra-day/Inter-day	Displays the specified QC# and the intra-day/inter-day data of the lot.
c	$\overline{\text{X}}$-R control	Displays the $\overline{\text{X}}$-R control of the intra-day/inter-day data.
d	QC	Selects a QC# for the displayed QC lot.
e	QC lot	Displays the QC lot of the selected QC#. Selects the QC lot to be used.
f	Mon	Specifies the QC lot to be used in units of months. Enter the number of months to process the data.
g	Del	Deletes the selected QC lot.
h	Continue	Registers the changed data.

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3.4.2   Selecting a QC Lot

When the [QC lot select] screen is opened, a list of QC lots is displayed. The QC No. and QC lot selected

in this list are the target data to be processed on the {Intra-day/Inter-day} tab and the {X̄-R control} tab.

☞   Page 142 "3.4.4 Opening the [Intra-day/Inter-day] Screen"

☞   Page 151 "3.4.8 Displaying X̄-R Control"

The explanation starts from the condition at which the [QC lot select] screen is displayed.

☞   Page 137 "3.4.1 Displaying the QC Lot List ([QC lot select] screen))"

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Applied Operations
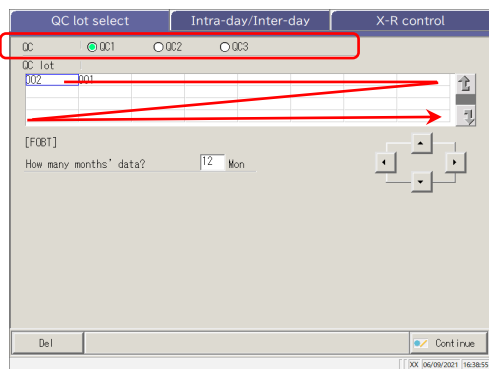
1   Touch QC No. (QC1 - –C3)

* The currently used QC lots are displayed sequentially.
(The display order is from left to right and from top to bottom.)
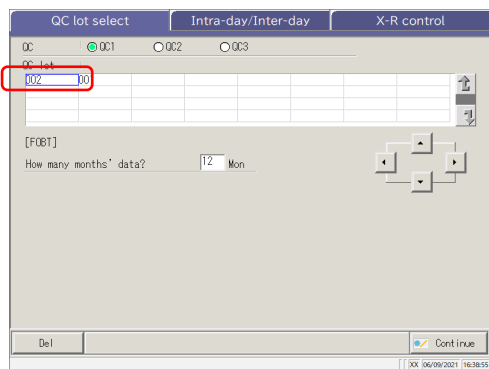
2   Touch a QC lot (selecting is also available using the cursor keys).
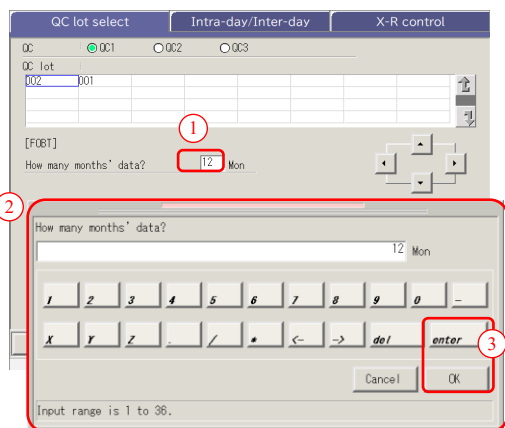
3   Enter the number of months of data to process. (For an example entry, see ⓝ Note .)

①   Touch the entry field.

②   Enter a number using the numeric keypad.

③   Touch {OK} or {enter}.

Note   In the QC lot list, the data of the latest month to the specified number of months are displayed (1 to 36 months in units of months).
(Example 1) When "one month" is entered on the current date of June 15, the data from June 1 to June 15 are displayed.
(Example 2) When "three months" is entered on the current date of June 15, the data from April 1 to June 15 are displayed.

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3.4.3 Deleting a QC Lot

The QC No. - –C lot selected in "3.4.2 Selecting a QC Lot" can be deleted.

After the QC lot to be deleted is selected, touch {Continue} and touch {Start} in the dialog box.

When the data for the selected QC No. - –C lot is deleted, the hard disk is updated.

* If {Start} is not touched, the hard disk is not updated.

The explanation starts from the condition at which operation **2** in "3.4.2 Selecting the QC Lot" is completed.

☞ Page 140 "3.4.2 Selecting a QC Lot"
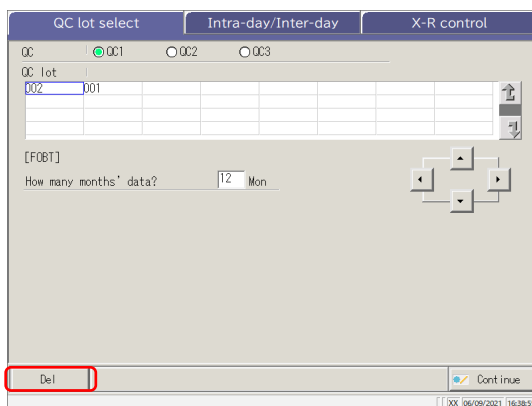
1 Touch {Del}.
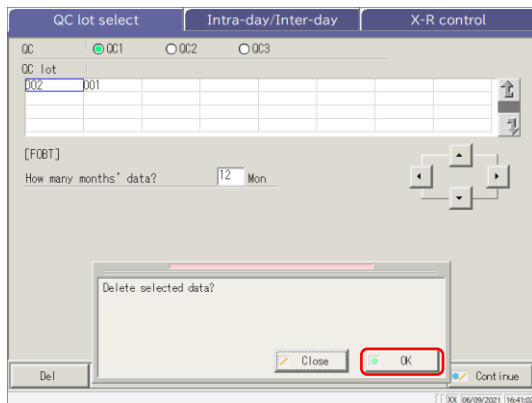
2 Touch {OK}.

> * The data in memory is updated.

[Close]: Aborts deletion of the QC lot.
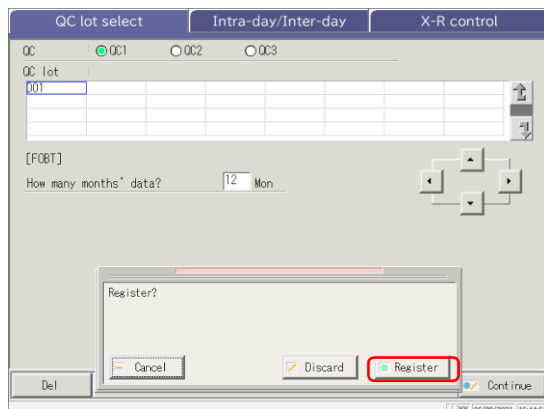
3 Save the updated data.
  ① Touch {Continue}.
  ② Touch {Register}.

> * The updated data is saved on the hard disk.

{Cancel}: Closes the dialog box.

{Discard}: Returns to the [Select data processing] screen.

3.4.4 Opening the [Intra-day/Inter-day] Screen

When the {Intra-day/Inter-day} tab is touched on the [QC lot select] screen, the [Intra-day/Inter-day] screen opens. On this screen, the intra-day/inter-day data of the QC No. - –C lot specified on the [QC lot select] screen is displayed.

(Note) If there is no test data, changing from the [QC lot select] tab to another tab is not available.
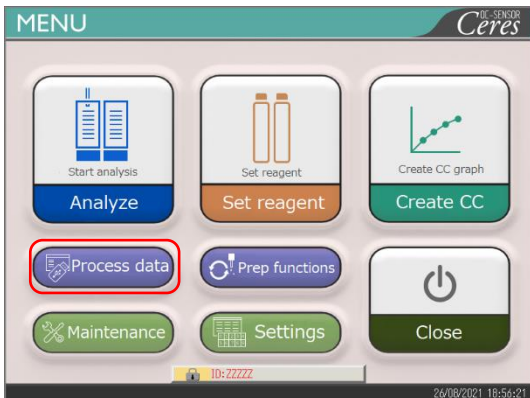
1 Touch {Process data}.
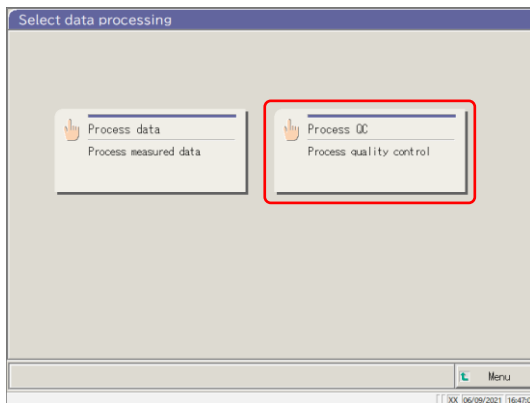
2 Touch {Process QC}.
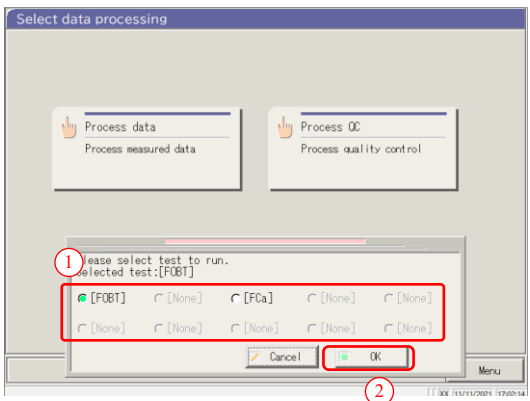
3 Select the test item.

① Select the radio button for the corresponding item (●).

② Touch {OK}.

{Close}: Returns to the previous screen.
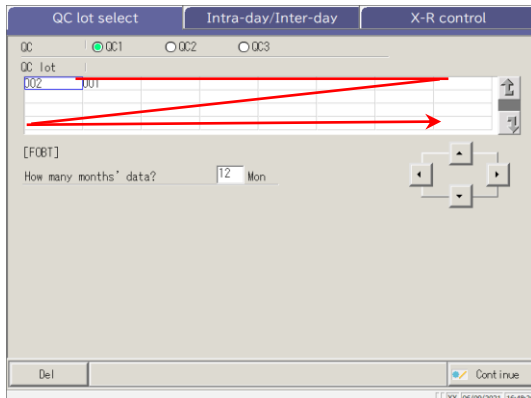
4 The [QC lot select] screen opens.
   * The currently used QC lots are displayed sequentially.
     (The display order is from left to right and from top to bottom.)
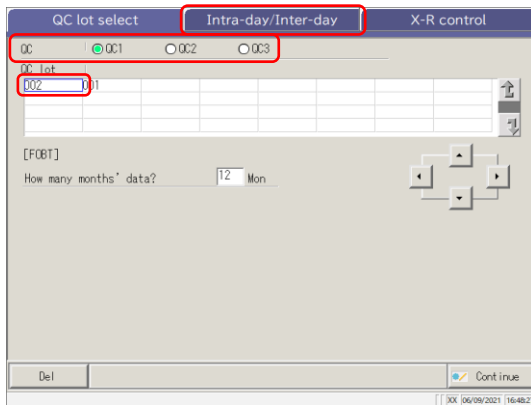
5 The QC and QC lot have been selected.

☞ Page 140 "3.4.2 Selecting a QC Lot"
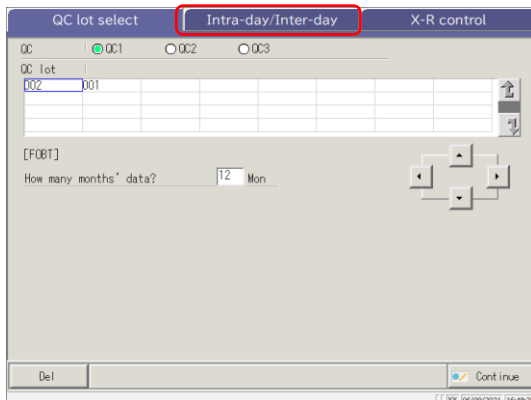
6 Touch the {Intra-day/Inter-day} tab.
   * The [Intra-day/Inter-day] screen opens. (See the next page.)
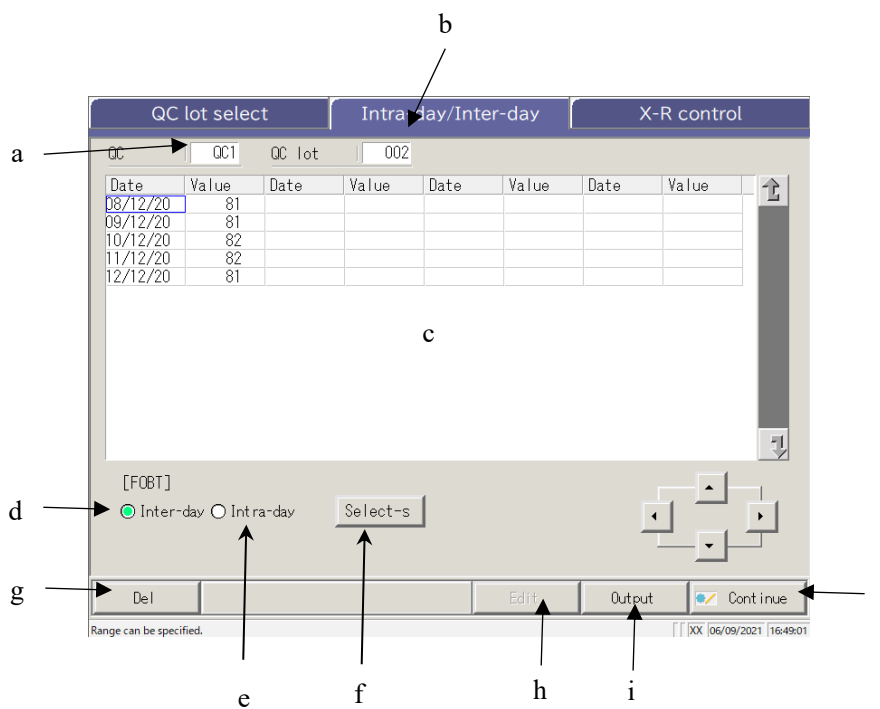
[Screen]: Intra-day/Inter-day data

a	QC	Displays the QC (QC1 - –C3) specified on the [QC lot select] screen.
b	QC lot	Displays the QC lot specified on the [QC lot select] screen.
c	QC data (Date, Value)	When the intra-day data is selected Displays the test date and average value of the specified QC and QC lot. When the inter-day data is selected Displays the test time and average value of the specified QC and QC lot.
d	Inter-day	Displays the inter-day data (Test date, Value).
e	Intra-day	Displays the intra-day data (Test date, Value).
f	{Select-s}	Specifies the range of intra-day data or inter-day data. The data range can also be specified using the cursor buttons.
g	{Del}	Deletes the specified intra-day or inter-day data.
h	{Edit}	Edits the intra-day or inter-day data.
i	{Output}	Outputs the intra-day or inter-day data (printer, external media)
j	{Continue}	Registers the edited intra-day or inter-day data on the hard disk. Displays the data [registration check] screen. Touch {Register}.

3.4.5 Editing (Recalculating) Intra-Day and Inter-Day Data

When the {Intra-day/Inter-day} tab is touched on the [QC lot select] screen, the [Intra-day/Inter-day] screen opens. On this screen, the intra-day or inter-day data of the specified QC No.-QC lot is displayed. The radio buttons are used to switch between the intra-day and inter-day data.

> Intra-day data: Edit the intra-day data.
> Inter-day data: Edit the replication data.

The explanation starts from the condition at which the [QC lot select] screen is switched to the [Intra-day/Inter-day] screen.

> * The QC lot has already been selected on the [QC lot select] screen.
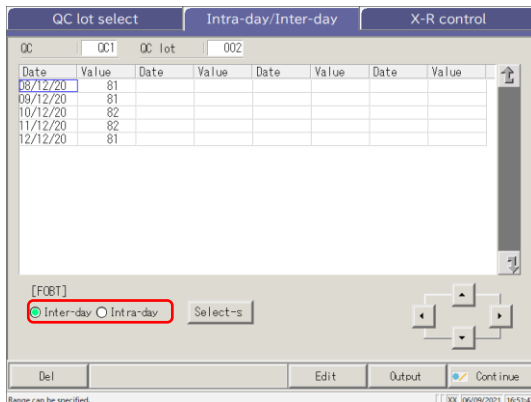
☞ Page 142 "3.4.4 Opening the [Intra-day/Inter-day] Screen"

(Note) When there is no test data, switching from the {QC lot select} }ab to another tab is not available.

(Note) The maximum number of tests available for a day with one QC# and QC lot is ten.

(Note) The results of the 11th and later tests are not saved even if they are conducted.

When the user is logged with an administrator ID, or when "No" is selected for "Operator mode," editing is possible.

1 Select the data to be edited.
 ○ Intra-day data
 ○ Inter-day data

2 Touch {Edit}.

3 Edit the intra-day data (or inter-day data).
① Touch an entry field.
② Enter a number using the numeric keypad.
③ Touch the [OK] or [enter] button.
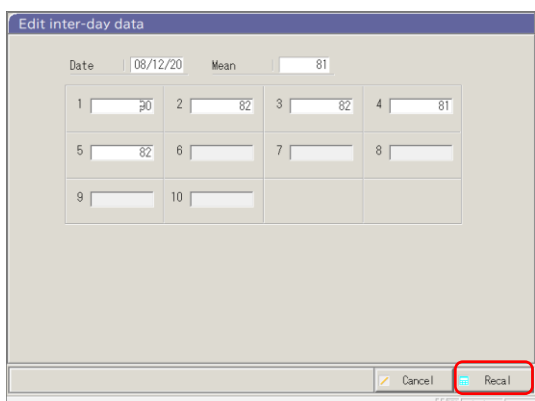
4 Touch {Recal}.

{Cancel}: Aborts the editing of the intra-day or inter-day data. Returns to the [Intra-day/Inter-day] screen.
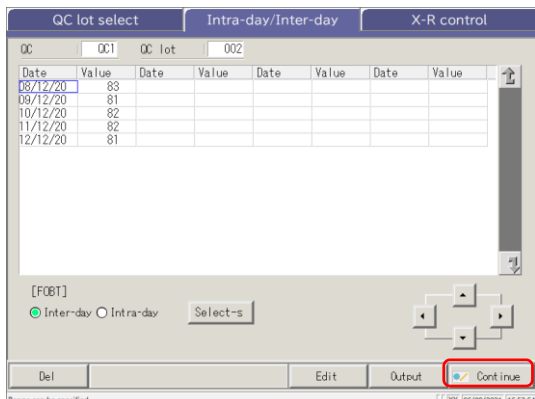
5 Touch {Continue}.
* The new average value is displayed.
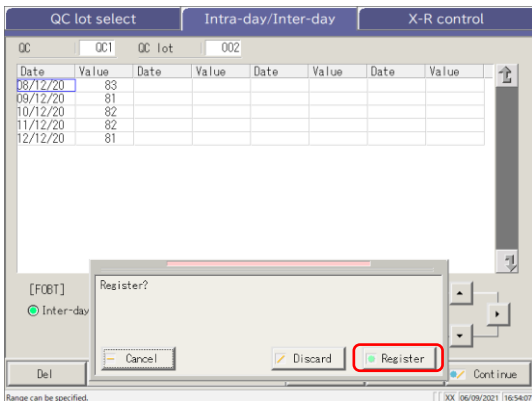
6 Touch {Register}.
* The recalculated result is registered.

{Cancel}: Closes the dialog box.

{Discard}: Returns to the [Select data processing] screen.

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3.4.6   Deleting Intra-Day and Inter-Day Data

The intra-day or inter-day data can be deleted by specifying a data range on the [Intra-day/Inter-day] screen. After deletion, the specified data will no longer be displayed on the screen. However, the hard disk data is not updated until {Register} is touched.

The explanation starts from the condition at which the [QC lot select] screen is switched to the [Intra-day/Inter-day] screen.

* The QC lot has been selected as the [QC lot select] screen.

☞   Page 142 "3.4.4 Opening the [Intra-day/Inter-day] Screen"

(Note)   When there is no test data, switching from the [QC lot select] tab to another tab is not available.
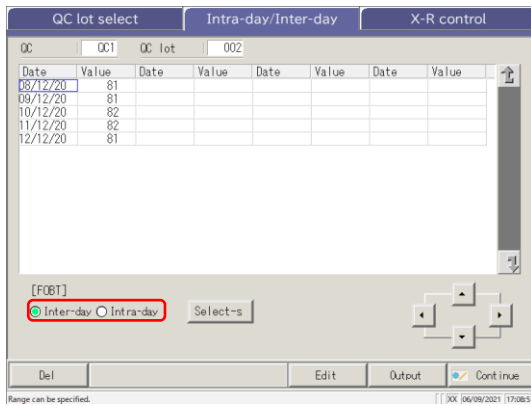
1 Select the data to be edited.
  ○   Intra-day data
  ○   Inter-day data
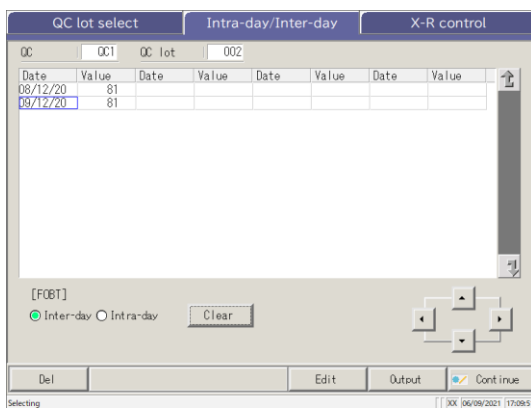
2 The range of data to be deleted is specified.

* Only the selected data is displayed.

☞   Page 149 "3.4.7 Selecting Intra-Day and Inter-Day Data with {Select-s}"
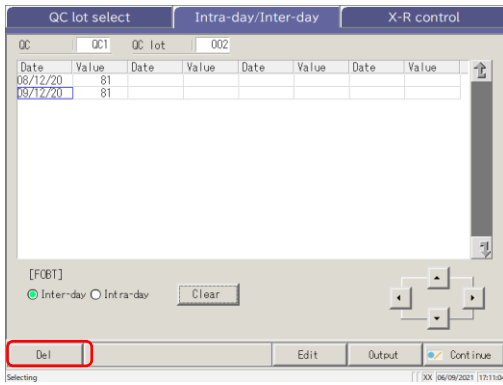
3   Touch {Del}.

(Note)   When the {Del} button is touched, the data in the memory is deleted. However, the data on the hard disk is not deleted until {Register} is touched.
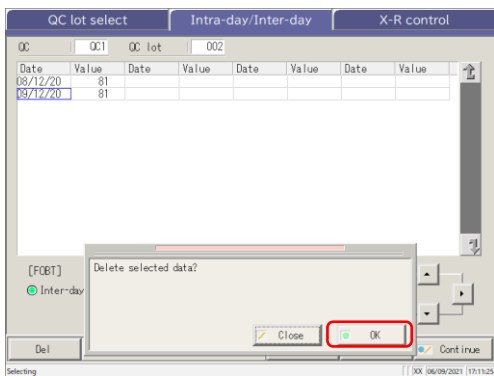
4   Touch {OK}.

* The data in memory is updated.
* The data specified on the screen is deleted.

{Close}: Aborts deleting the intra-day and inter-day data.
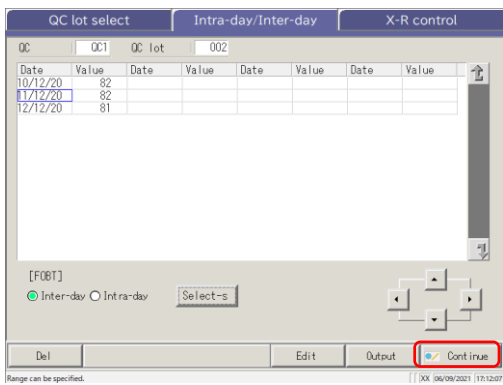
5   Touch {Continue}.
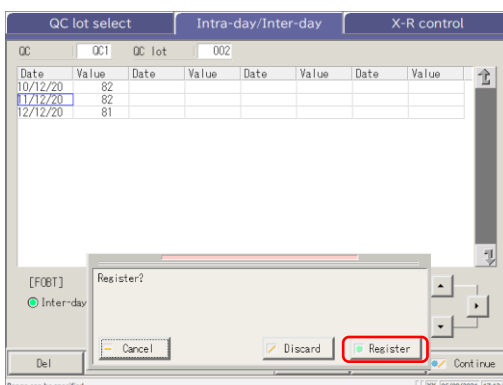
6   Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Returns to the [Select data processing] screen.

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3.4.7　Selecting Intra-Day and Inter-Day Data with {Select-s}

On the [Intra-day/Inter-day] screen, the data can be specified within a test date range (from starting point to ending point).
It is used when deleting a batch of intra-day or inter-day data or when displaying the $\overline{X}$-R control.

The explanation starts from the condition at which the [QC lot select] screen is switched to the [Intra-day/Inter-day] screen.

* The QC lot has been selected already on the [QC lot select] screen.

☞　　Page 142 "3.4.4 Opening the [Intra-day/Inter-day] Screen"
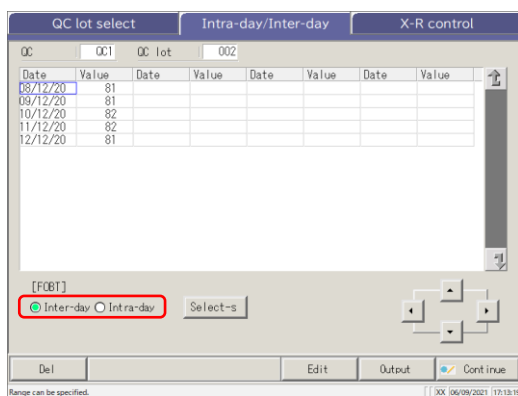
1 Select the data to be specified.
- ○　Inter-day data
- ○　Intra-day data
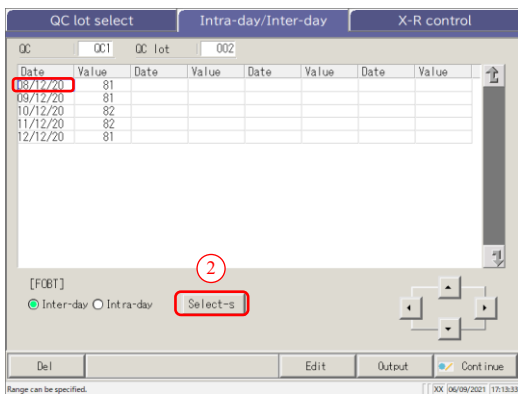
2 Specify the test date of the starting point.
- ①　Touch the test date to be the starting point.
- ②　Touch {Select-s}.
  * The starting point is set.
  * When the starting point is set, {Select-s} changes to {Select}.
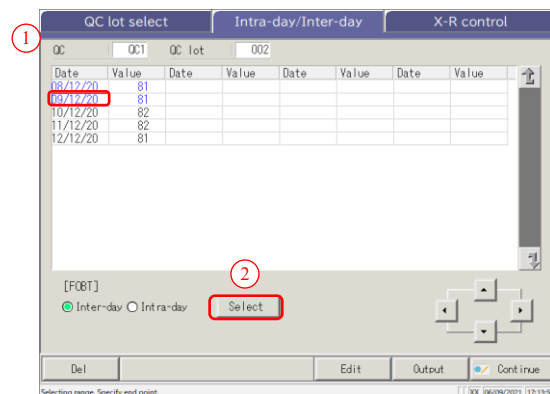
3 Specify the test date of the ending point.
- ①　Touch the test date to be the ending point.
- ②　Touch {Select}.
  * The ending point is set.
  * When the ending point is set, {Select} changes to {Clear}.

{Select-s}: Sets the starting point of the range.
{Select}: Sets the ending point of the range.
{Clear}: Aborts the range specification.

(Note) When the dates specified as the starting point and ending point are the same, only one test data set is specified. To redo the range specification, touch {Clear}.

(Note) All test data are displayed, and no range is specified.

(Note) If the [$\overline{X}$-R control] screen is opened instead of the [Intra-day/Inter-day] screen from the [QC lot select] screen, all the data are specified.

3.4.8 Displaying X̄-R Control

The X̄-R control of the intra-day and inter-day data can be displayed.
On the [QC lot select] screen, when the intra-day data is selected, <u>X̄-R control of the intra-day data</u> opens.
When the inter-day data is selected, <u>X̄-R control of the intra-day data</u> is displayed.

(Note) When there is no test data, switching from the [QC lot select] tab to another tab is not available.
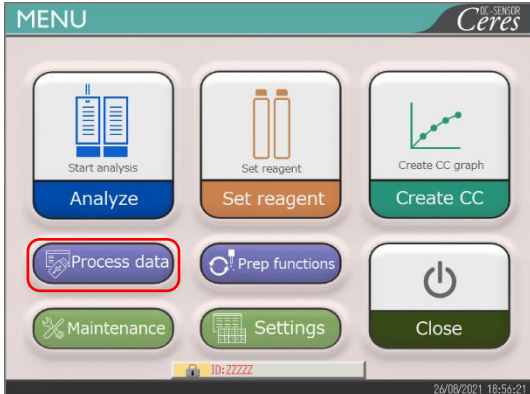
	1 Touch {Process data}.
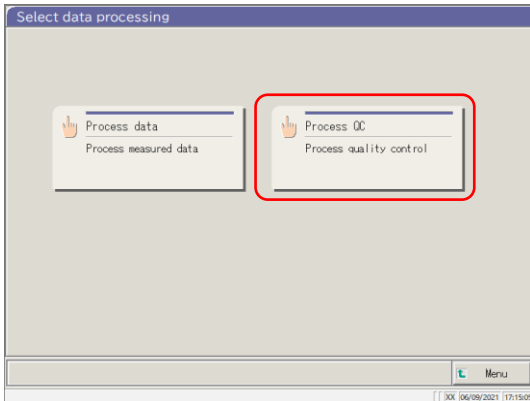
2 Touch {Process QC}.
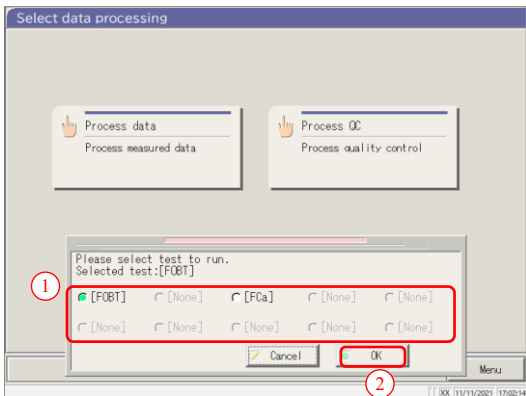
3 Select the test item.

① Select an item with a radio button (●).
② Touch {OK}.

{Close}: Returns to the previous screen.
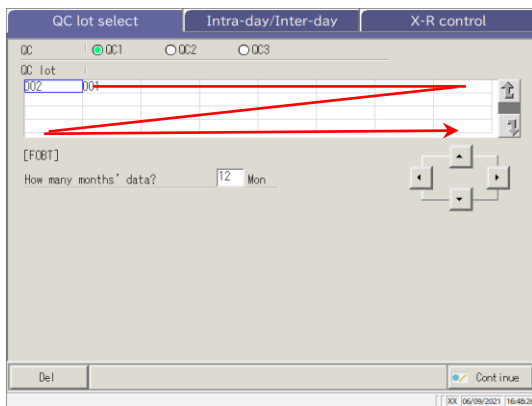
4 The [QC lot select] screen opens.
* The QC lots used in recent days are
displayed sequentially.
(The display order is from left to right and
from top to bottom.)
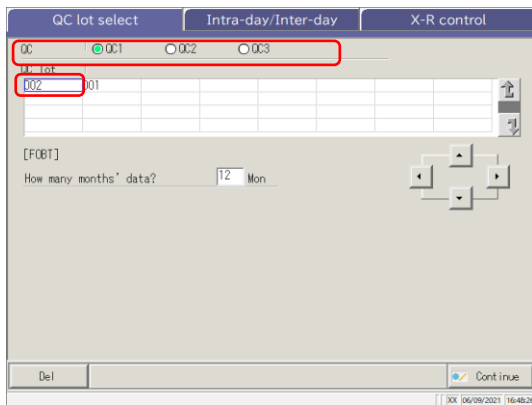
5 Select a QC and QC lot.

☞ Page 140 "3.4.2 Selecting a QC Lot"
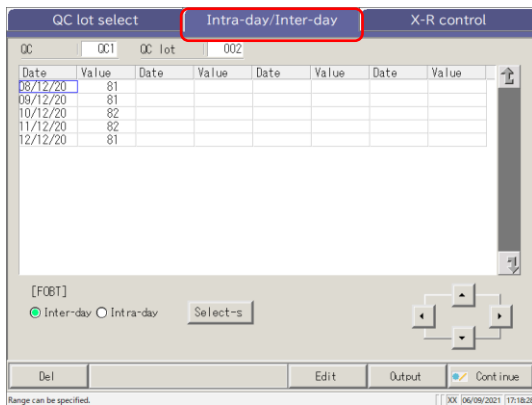
6 Touch the {Intra-day/Inter-day} tab.
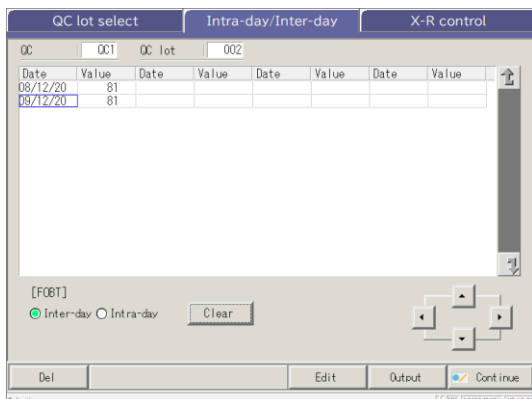
7 Select the X̄-R control data.

☞ Page 149 "3.4.7 Selecting Intra-Day
and Inter-Day Data with {Select-s}"
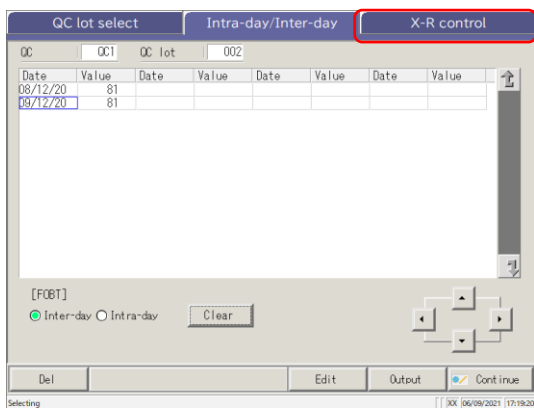
8 Touch the {X̄-R control} tab.

3

Applied
Operations
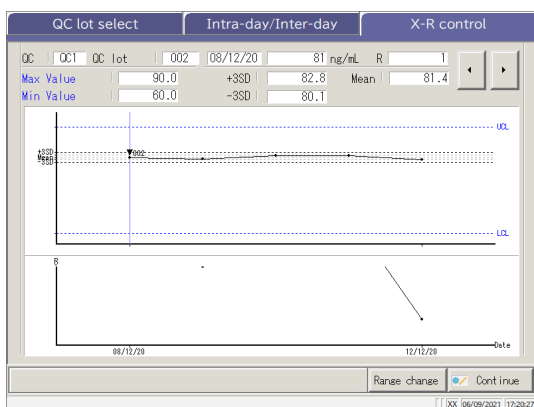
9 X̄-R control is displayed.

(Note)   The max value is determined by replicate number and measured value.

3.4 Accuracy Control

[Screen] : $\overline{X}$-R control

a	$\overline{X}$ graph (upper graph)	·	Displays the data for the test date or test date and time.
		·	Displays the mean of all values and ± #SD.
		·	The max. value and the min. value set on the [Assay] - –QC process] - –Set} tab are displayed in blue.
		·	Data <u>less than min. value +1</u> and <u>more than max. value +1</u> are displayed in red.
b	R graph (lower graph)	·	Displays the <u>data range</u> for each test date or the test date and time.
		·	Displays the R upper control limit..
c	Max Value	·	Displays the Max. Value set on the [Assay] - –QC process] - –Set} tab.
	Min Value	·	Displays the min. value set on the [Assay] - –QC process] - –Set} tab.
	+ #SD	·	Displays the calculated + #SD value and the SD coefficient (# = 1 – 9) set on the [Assay] - –QC process] - –Set} tab.
	-#SD	·	Displays the calculated - #SD value and the SD coefficient (# = 1 – 9) set on [Assay] - –QC process] - –Set} tab.
	Mean	·	The calculated mean value
d	▼ (In the graph)	·	Indicates that the CC has changed.
		·	Displays the R1/R2 reagent lot next to the ▼ mark.
e	◄ ►	·	Moves the cursor (vertical line) displayed on the graph.
f	{Range change}	·	Changes the range in $\overline{X}$-R control (max. and min. concentrations and R max. value)

3.4.9 Changing the Range of $\bar{X}$-R Control

The $\bar{X}$-R control (graph) range can be changed.

The explanation starts from the [$\bar{X}$-R control] screen.

☞ Page 151 "3.4.8 Displaying $\bar{X}$-R Control"
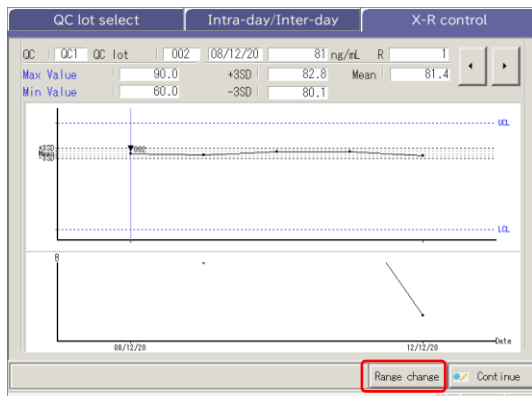
1 Touch {Range change}.
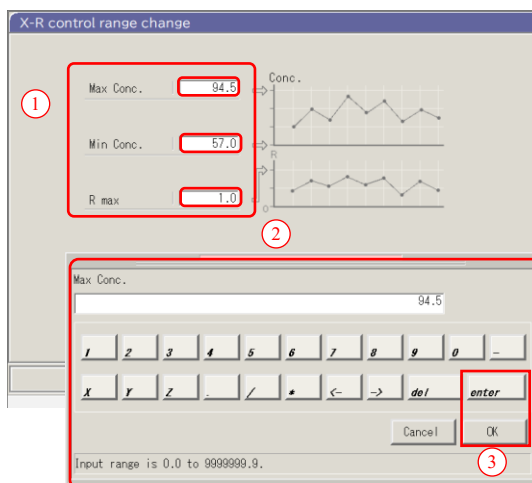
2 Change the range.

① Touch the entry field of a setting.

② Enter a number using the numeric keypad.

・Max. value of concentration

・Min. value of concentration

・R max limit.

③ Touch {OK} or {enter}.
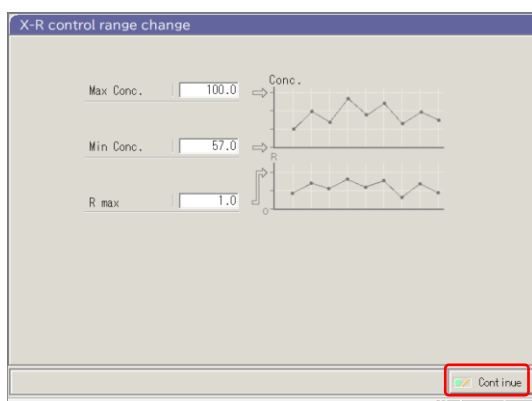
3 Touch {Continue}.
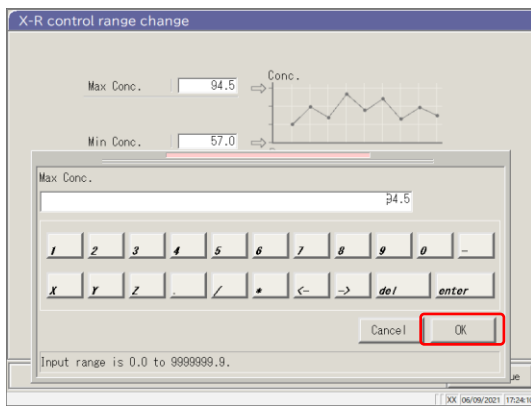
4 Touch {OK}.

* Displays the X̄-R control after the range change.

{Cancel}: Closes the dialog box.
{Close}: Aborts the range changing process and returns to the [X-R control] screen.
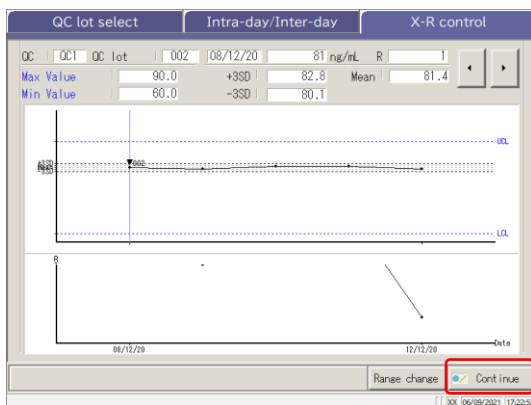
5 Touch {Continue}.
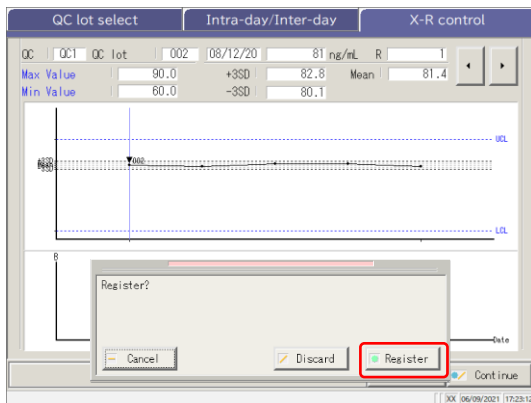
6 Touch {Register}.

* X̄-R control is registered.
* Returns to the [Select data processing] screen.

{Cancel}: Closes the dialog box.
{Discard}: Aborts the registration of X̄-R control and returns to the [Select data processing] screen.

3.5 LOG IN/LOG OUT

To use all the functions on the [MENU] screen, logging in is necessary. Enter the operator ID on the [LOGIN] screen and log in. The operator ID is then displayed.
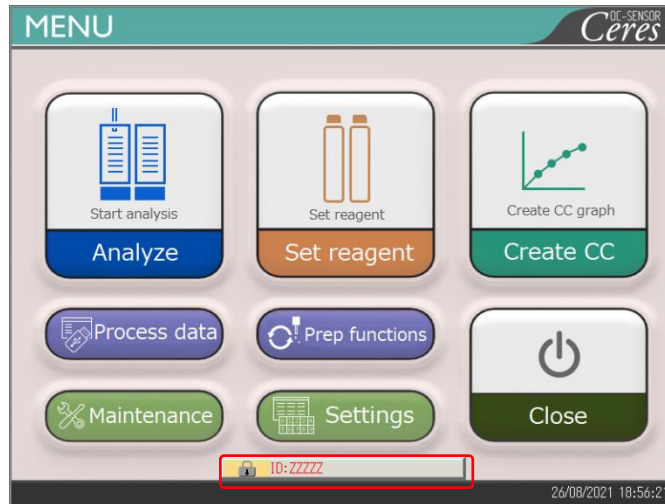
3.5.1 LOGIN

When the system starts up, the [LOGIN] screen opens.

☞ For the login procedure, see the page 28 "2.3 Logging In."

3.5.2   LOGGING OUT
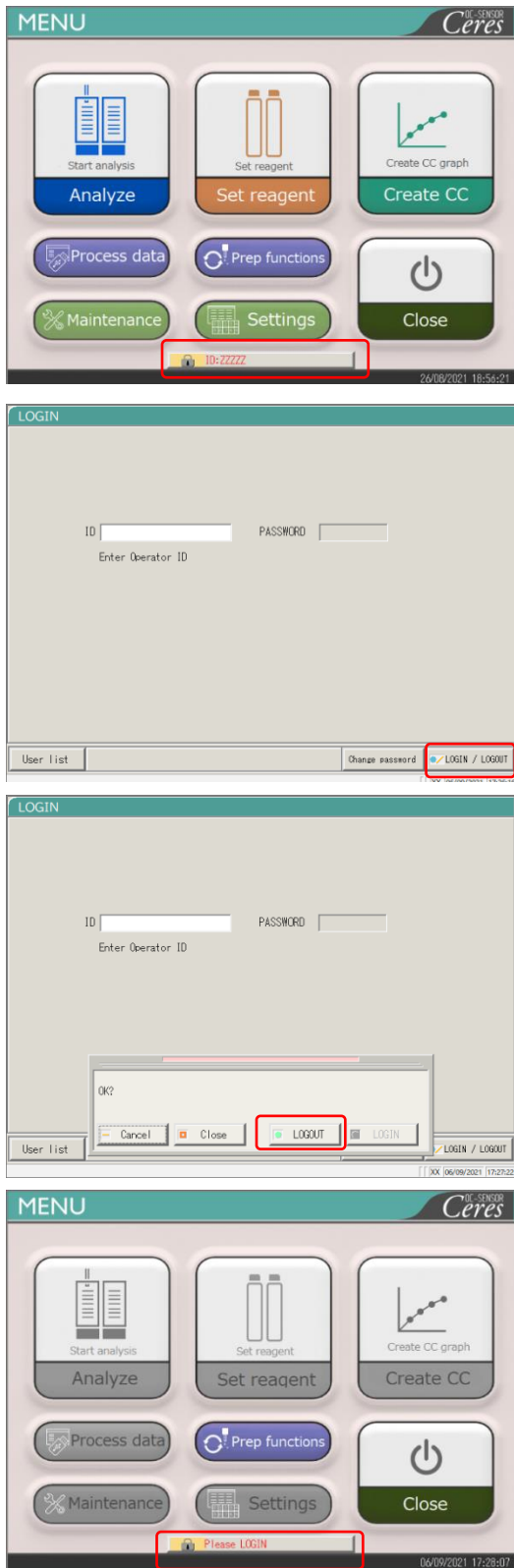
1   Touch the {Lock} mark at the lower section of the [MENU] screen (displaying the currently logged in operator ID).

2   Touch {LOGIN / LOGOUT}.

3   Touch {LOGOUT}.

{Cancel}: Closes the dialog box.

{Close}: Returns to the [MENU] screen while keeping the current LOGIN/LOGOUT condition.

4   Returns to the [MENU] screen. The ID display changes to the "Login" message (indicating the logged-out condition).

3.5.3   Changing a Password

The password of the currently logged in operator can be changed.

The explanation starts from the logged in condition.

☞   For the logging in procedure, see page 28 "2.3 Logging In."
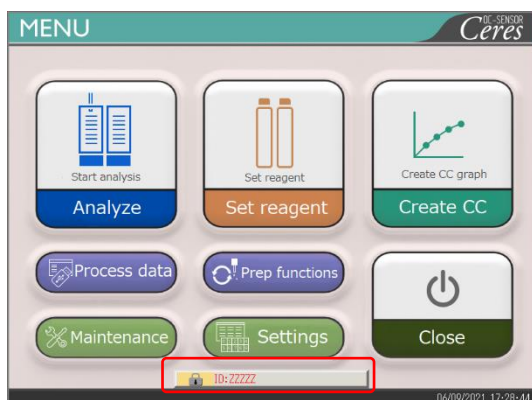
1   Touch the {Lock} mark at the lower section of the [MENU] screen (the operator ID of the currently logged in operator is displayed).
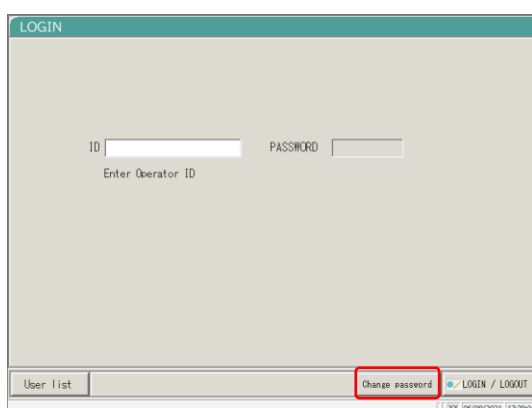
2   Touch {Change password}.
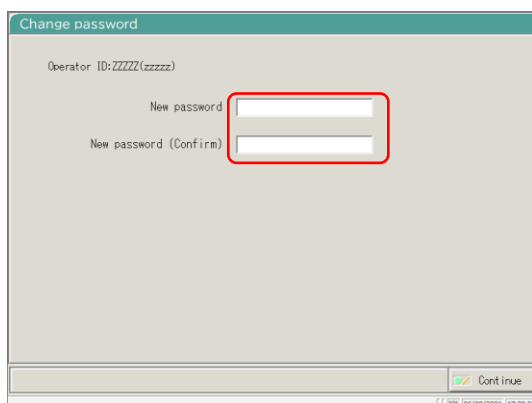
3   Set a new password.

① Enter the "new password".

② Enter the same password again in the "New password (Confirm)" field.

zzzzz: Operator ID

(zzzzz) : Operator name
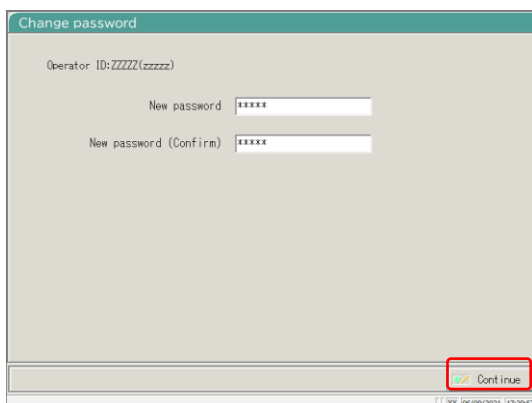
4 Touch {Continue}.
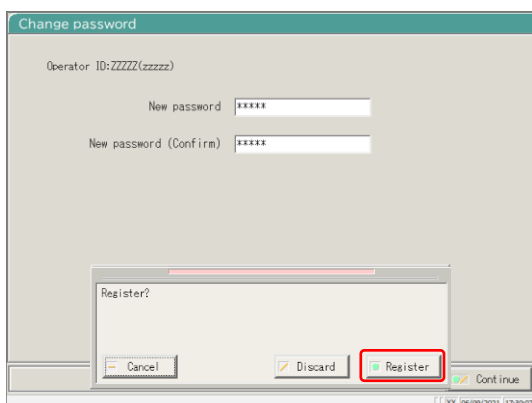
5 Touch {Register}.
The password is changed.

* The display returns to the [LOGIN] screen.

{Cancel} : Closes the dialog.

{Discard} : Returns to the [LOGIN] screen.
The password is not changed.

Chapter 4   Prep Functions

QC-SENSOR
Ceres

Chapter 4 Prep Functions

4.1 Initialization

This function initializes (moves to the standby position) each mechanism in the system. The following mechanisms will be initialized.

・ Sample nozzle	・ Reagent nozzle	・ Mixer
・ Reaction table	・ Puncturing system	・ Squeezing system
・ Rack setting position	・ Reagent refrigerator	・ Rack transfer system

Touching {Prep functions} on the [MENU] screen opens the [Initialize] screen.
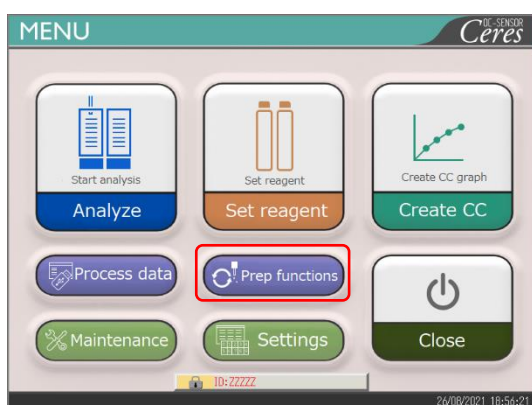
1 Touch {Prep functions}.
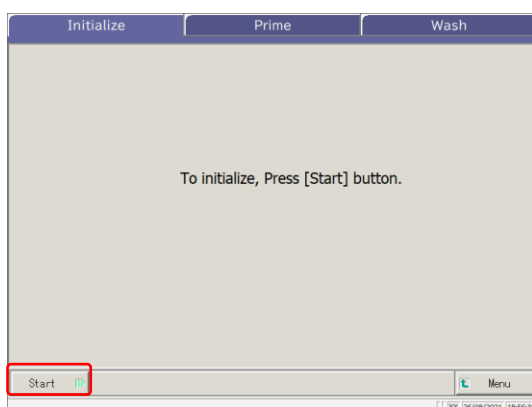
2 Touch {Start}.

{Menu}: Returns to the [MENU] screen.
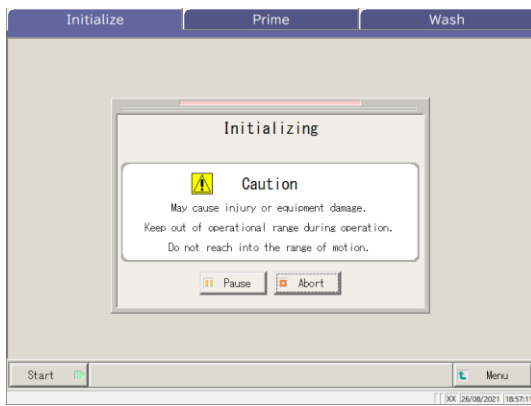
3 Initialization is executed.

{Pause}: Pauses initialization.
{Start}: Starts initialization.
When {Pause} is touched, the button changes to
    {Start}.
{Abort}: Aborts initialization.
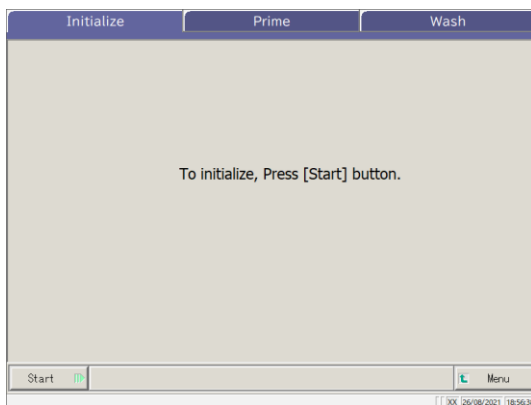
4 Initialization has ended.

4
Prep
Functions

4.2　Priming

This function introduces washing solution and purified water into the pipes.
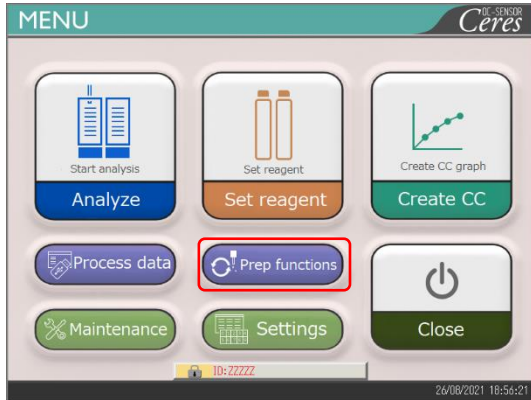
1　Touch {Prep functions}.

2　Touch the {Prime} tab.
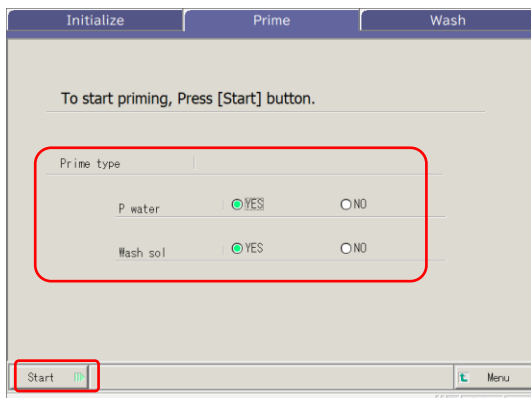
3　Select the items to prime.
- ○　YES: Executes priming
- ○　NO: Does not execute priming

4　Touch {Start}.
*　Priming starts.
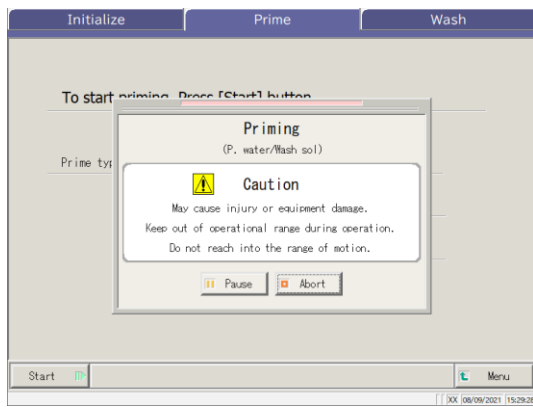
5   Priming is executing.

* When priming completes, the dialog box closes.

{Pause}：Pauses the process.

{Start}：The process restarts. Touching {Pause} changes the button to {Start}.

{Abort}：Aborts the process in mid-course.

4

Prep
Functions

4.3　Washing

When the {Wash} tab is touched on the [MENU] – [Prep functions] screen, the [Wash] screen opens. Select the parts to be washed and the storage process (soak wash), and touch {Start}.
Washing of each part starts.
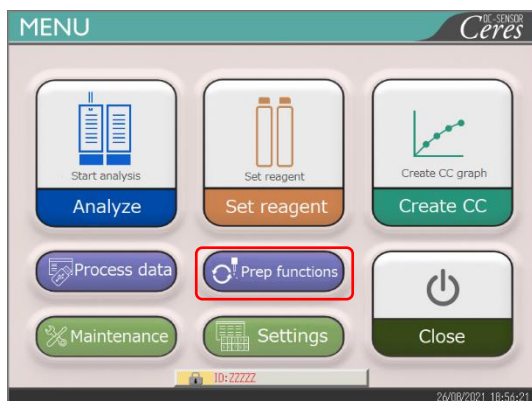
1 Touch {Prep functions}.
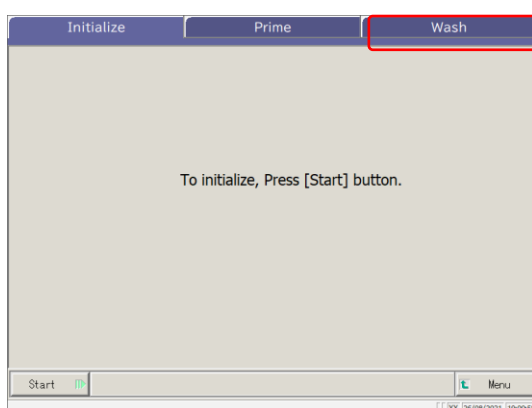
2 Touch the {Wash} tab.
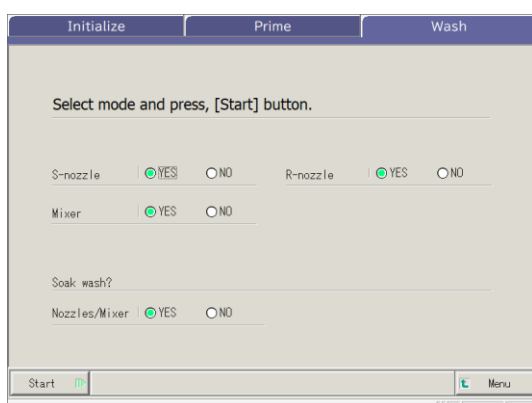
3 Select "YES" or "NO" for each part to be washed. (See the table on the next page.)

Part to be washed	Range/selection	Content
● Washing		
Sample dispensing nozzle	Yes : No :	Washes the sample dispensing nozzle. Does not wash the sample dispensing nozzle.
Reagent dispensing nozzle	Yes : No :	Washes the reagent dispensing nozzle. Does not wash the reagent dispensing nozzle.
Mixer	Yes : No :	Washes the mixer. Does not wash the mixer.
● Storage		
Nozzle and mixer	Yes : No :	Soak the nozzle and mixer for storage. Does not soak the nozzle and mixer for storage.
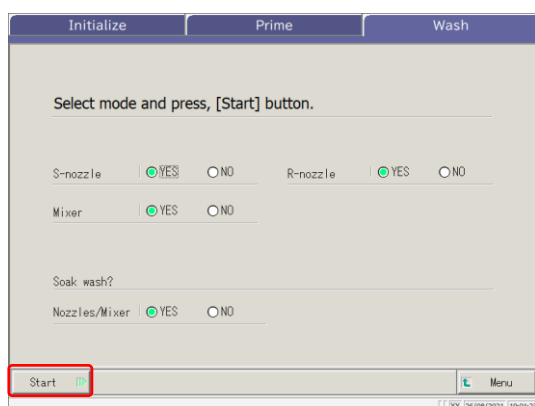
4 Touch {Start}.

{Menu}：Returns to the [MENU] screen.

5 Washing is executed.

{Pause}：Pauses washing.

{Start}：Starts washing.

Touching {Pause} changes the button to {Start}.

{Abort}：Aborts washing.
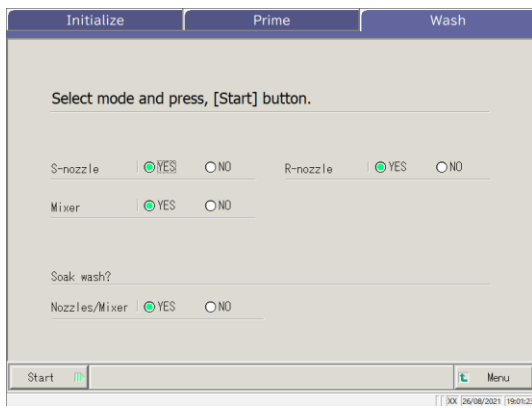
6   Washing has ended.

Chapter 5   Maintenance

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Chapter 5   Maintenance

5.1   Inspection and Maintenance

On the [Maintenance] screen, inspection and maintenance items to be conducted periodically (daily, weekly, and monthly) are displayed.

In addition, touching {Procedure} enables inspections and maintenance orders.

5.1.1 Opening the [Maintenance] Screen

On the [MENU] screen, touching {Maintenance} opens the [Maintenance] screen.
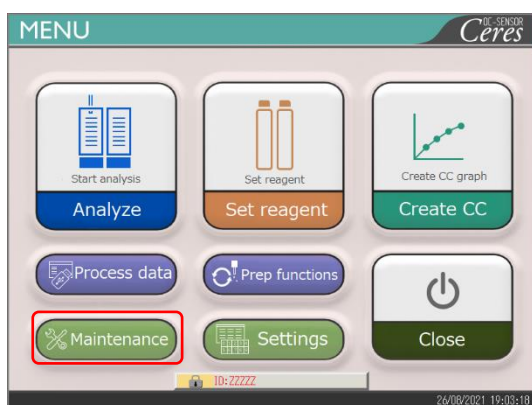
1   Touch {Maintenance}.
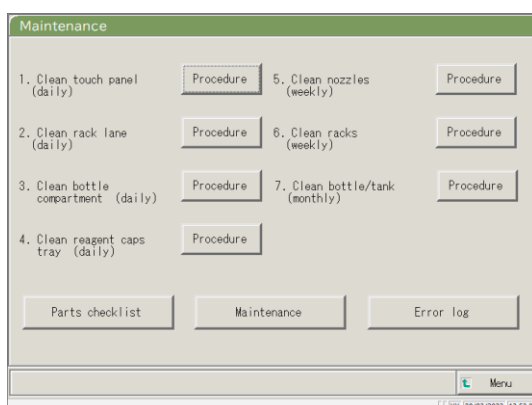
2   The [Maintenance] screen opens.

5.1.2 Cleaning Control Panel (Daily)

On the [Maintenance] screen, touching {Procedure} on the right side of [1. Clean touch panel] displays the cleaning procedure.
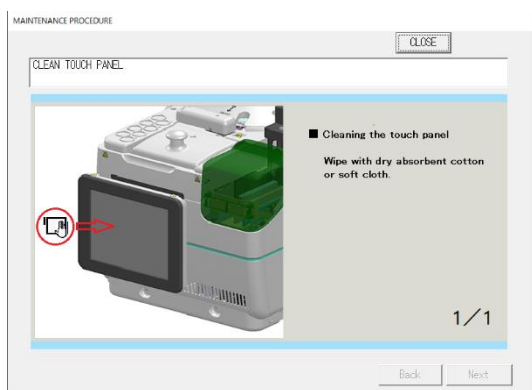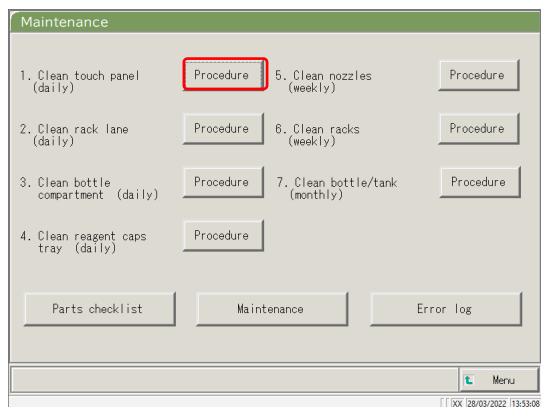
■ Procedure

Wipe the touch panel with cotton or a soft towel.

{Close}: Returns to the [Maintenance] screen.

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5.1.3   Cleaning the Rack Lane (Daily)

On the [Maintenance] screen, touching {Procedure} on the right side of [2. Clean rack lane] displays the cleaning procedure.

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Maintenance
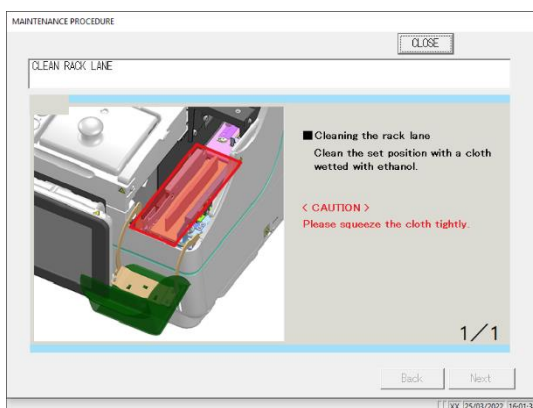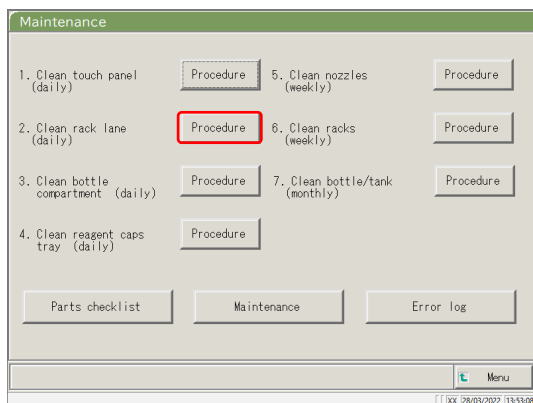
■   Procedure

①   Wet a soft cloth with ethanol.

⚠ Caution: Wring the cloth tightly.

②   Wipe the rack lane with the cloth described in ①.

{Close}: Return to the [Maintenance] screen.
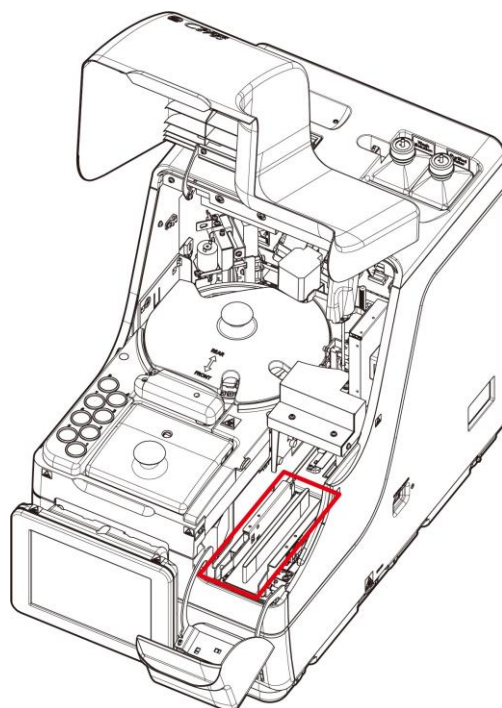
5.1.4 Cleaning Washing Solution and Purified Water Compartments (Daily)

On the [Maintenance] screen, touching {Procedure} on the right side of [3. Cleaning Washing Solution and Purified Water Compartments] displays the cleaning procedure.
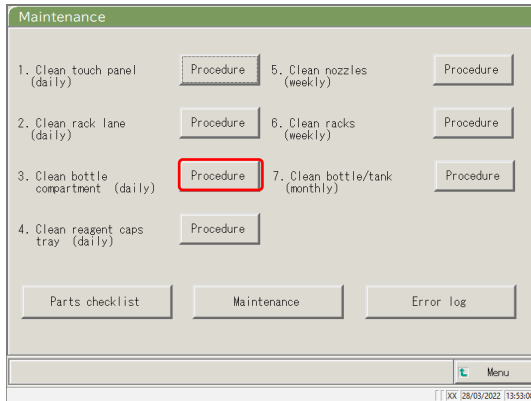
■ Procedure

① Wet a soft cloth with ethanol.

⚠ Caution: Squeeze the cloth tightly.

② Wipe the compartment with the cloth described in ①.

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{Close}: Returns to the [Maintenance] screen.

5.1.5   Cleaning the Reagent Cap Tray (Daily)

On the [Maintenance] screen, touching {Procedure} on the right side of [4.Clean reagent caps tray] displays the cleaning procedure.
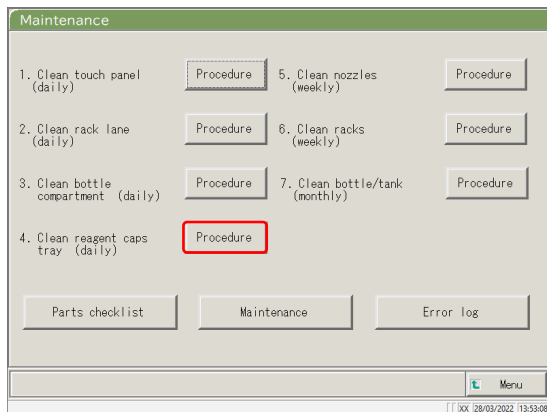
■   Procedure

① Clean the reagent cap tray using a cloth wetted with purified water.

② Clean the reagent cap tray using a cloth wetted with ethanol.

⚠ Caution: Please squeeze the cloth tightly.

{Close}：Returns to the [Maintenance] screen.

5.1.6 Cleaning the Nozzles (Weekly)

On the [Maintenance] screen, touching {Procedure} on the right side of [5. Cleaning nozzles] displays the cleaning procedure.
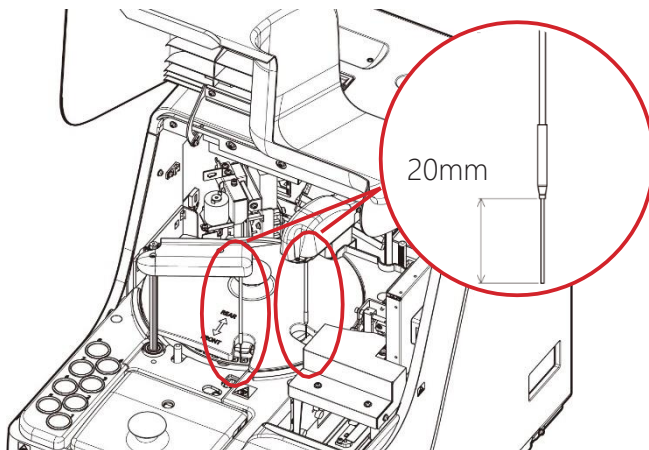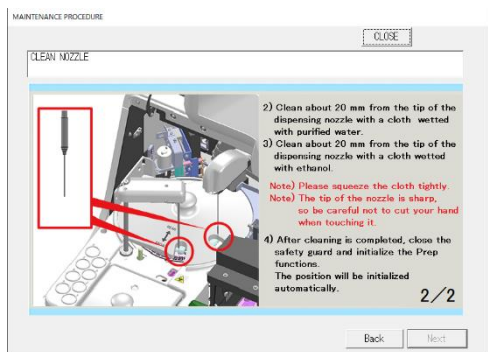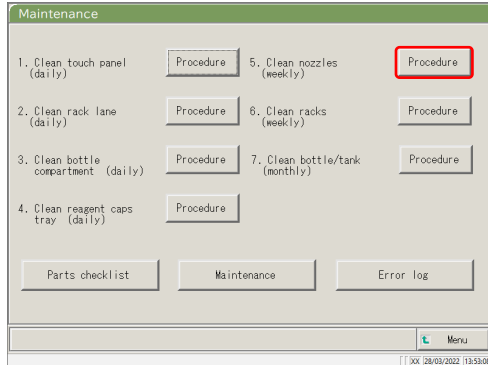
■ Procedure

① Hold the red circles on the covers of the sample nozzle and reagent nozzle, slowly lift them up, and rotate to a position where it is easy to clean.

⚠ Caution: Do not hold the nozzle itself to lift it. The nozzle may bend.

⚠ Caution: The tip of the nozzle may break so be careful not to touch other mechanical parts when moving it.

② Clean about 20 mm from the tip of the dispensing nozzle with a cloth wetted with purified water.

③ Clean about 20 mm from the tip of the dispensing nozzle with a cloth wetted with ethanol.

⚠ Caution: Please squeeze the cloth tightly.

⚠ Caution: The tip of the nozzle is sharp, so be careful not to pierce your hand when cleaning it.

④ After cleaning is completed, close the safety guard and initialize the Prep functions. The position will be initialized automatically.

{Close}: Returns to the [Maintenance] screen.

{Next}　: Changes the screen to the next page.

{Back}: Changes the screen to the previous page.

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5.1.7   Cleaning the Racks (Weekly)

On the [Maintenance] screen, touching {Procedure} on the right side of [6. Clean racks] displays the cleaning procedure.
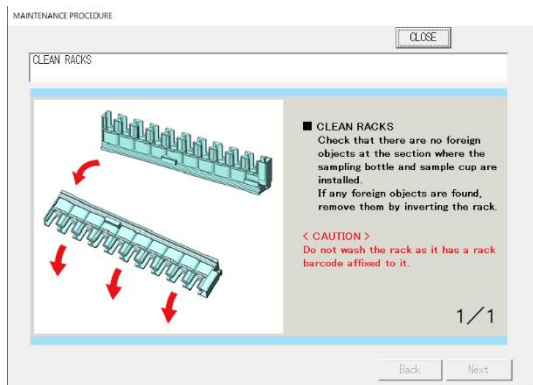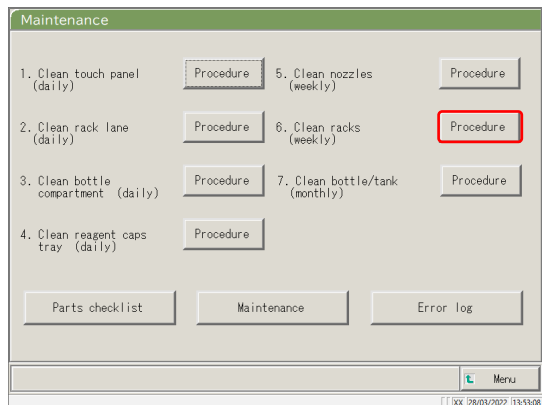
■   Procedure

Check that there are no foreign objects at the section where the sampling bottle and sample cup are installed. If any foreign objects are found, remove them by inverting and shaking the rack.

⚠   Caution: Do not wash the rack as it has a rack barcode affixed to it.

{Close}: Returns to the [Maintenance] screen.

5.1.8   Cleaning Bottles/Tanks (Monthly)

On the [Maintenance] screen, touching {Procedure} on the right side of [7. Clean bottle/tank] displays the cleaning procedure. Clean the tank once a month.
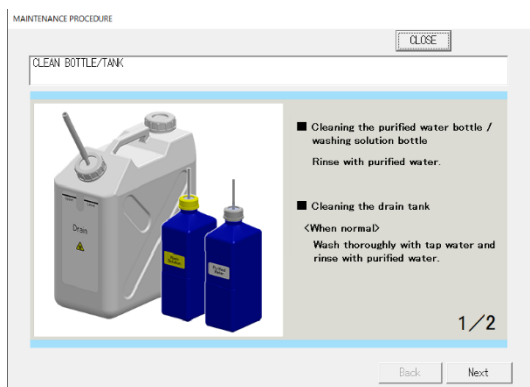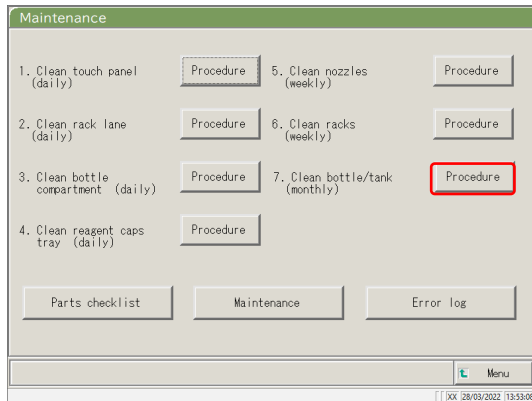
■   Procedure

Purified water bottle/washing solution bottle
   Rinse with purified water.
Drain tank
   <When normal>
   Wash thoroughly with tap water and rinse with purified water.
   <In case of severe contamination>
   ① Wash thoroughly with tap water.
   ② Pour 2L of tap water and 20 mL of washing solution into the tank.
   Tap water: 2L, Washing solution: 20 mL
   ③ Close the tank cap securely and shake the tank. (In case of severe contamination, leave for about one hour.)
   ④ Wash inside the tank thoroughly with tap water and rinse with purified water.

{Close}：Returns the screen to the [Maintenance] screen.

⚠ Caution : Insufficient rinsing with purified water may affect the test data.

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5.2 List of Parts to Check and Replace

On the [Parts checklist] screen, the part names, last replacement date, number of months used, and number of use counts are displayed.

5.2.1 Opening the [Parts checklist] Screen

On the [Maintenance] screen, touching [Parts checklist] opens the [Parts checklist] screen. The parts that have expired (the number of months or use count has been exceeded) will be indicated in yellow.
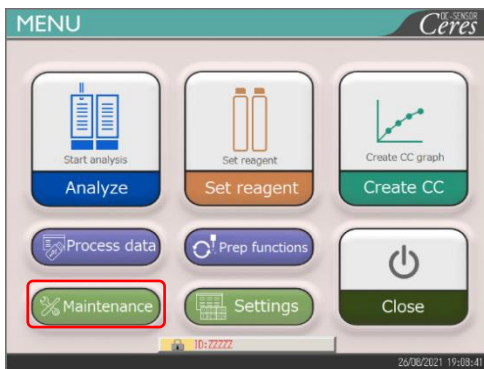
1 Touch {Maintenance}.
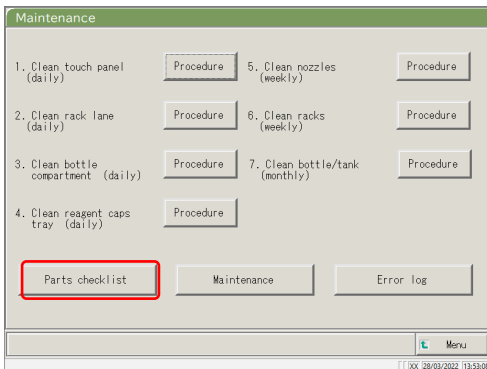
2 Touch {Parts checklist}.
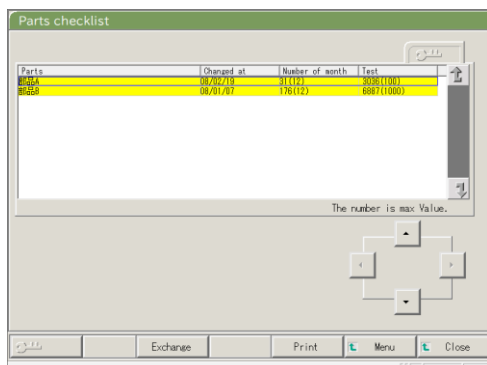
3 The [Parts checklist] screen opens.

(Note) The lines of the expired parts are yellow.

5.2.2 Replacing Parts

The expired parts can be replaced.

This explanation starts from the condition at which the [Parts checklist] screen is displayed.
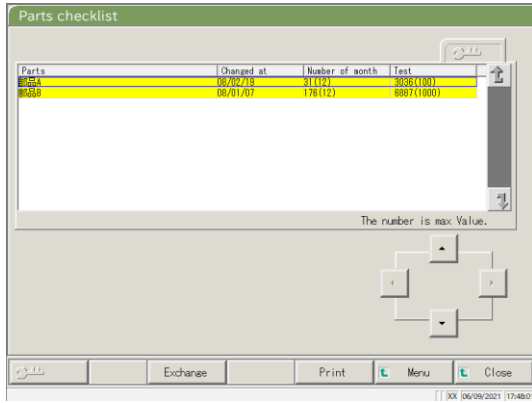
1 Replace the parts marked in yellow.
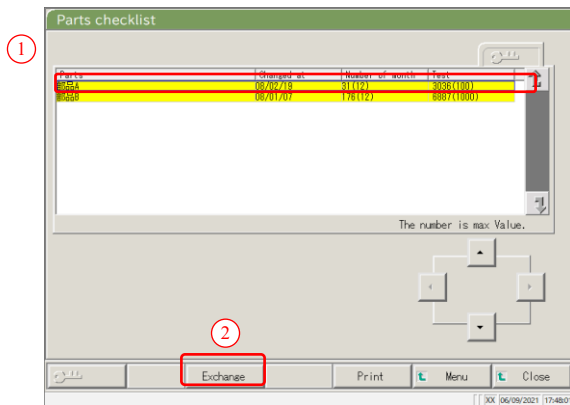
2 Reset the number of month and use count for the parts replacement.

① Touch the line of the replaced part.

② Touch {Exchange}.
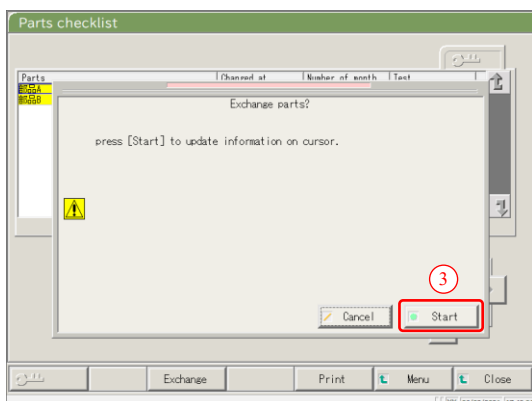
③ Touch {Start}.

 * The number of months and use count become "0."

 * The dialog box closes.

{Close}: Aborts the resetting of the months and use count.

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Chapter 6 Settings

6.1 System Settings

When using the system for the first time, the system settings must be set. After the system settings are completed, no change is necessary for daily testing, unless other settings are needed.
For an outline of the setting items in "System Settings," see page 31 "2.4.1 System Settings."

6.1.1 Sample Barcode Settings (Common)

This section describes the common settings which are used to read the sample barcodes.

(Note) When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," changing the settings becomes possible.
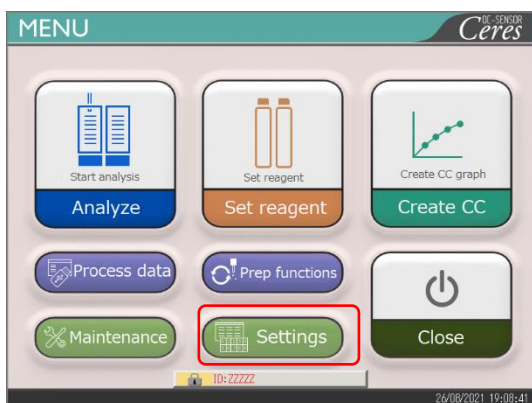
1 Touch {Settings}.
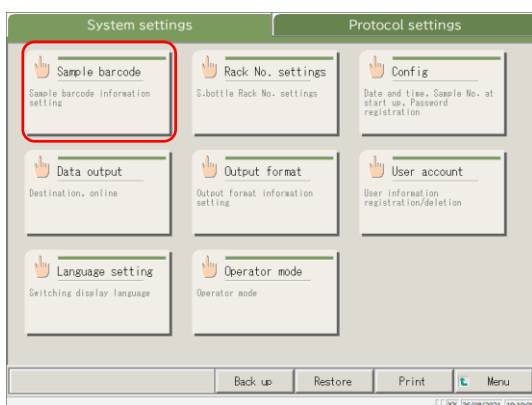
2 Touch {Sample barcode}.

3   Set the items on the {Common} tab.
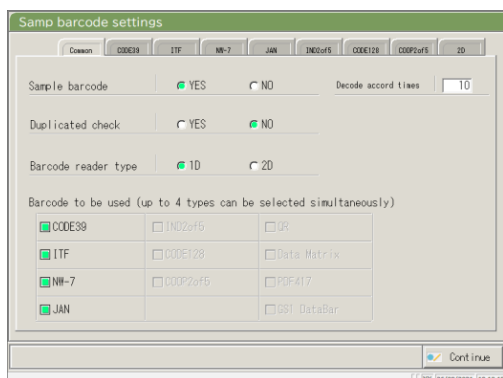
Setting item	Selection/setting	Content
Sample barcode	YES:	Barcodes are affixed to the samples.
	NO:	Barcodes are not affixed to the samples.
Duplicated check		From system startup to power off:
	YES:	<u>Checks</u> for duplicate sample barcodes.
	NO:	<u>Does not check</u> for duplicate sample barcodes
		However, even if this is set to "YES," if the test mode is retest or dilution and retest, the duplicate check is not conducted.
Barcode reader type	1D:	Uses only 1D codes.
	2D:	Uses both 1D and 2D codes.
Decode accord times	Number input	Sets 10 times as a rough target.
Barcode to be used		Select the barcodes to be used (■).
		Up to four types of barcodes can be selected.

(Note)   Decode accord times

The barcode reader scans a maximum of 500 times when reading a sample barcode. In this process, the number which the barcode has been properly read is called the <u>decode times</u>.

"Decode accord times" is the number of reading which is sufficient for proper reading.

When the larger number is set to [Decode accord times], erroneous reading of the barcode can be prevented.

However, at the same time, occurrence rate of "barcode reading error" increases.
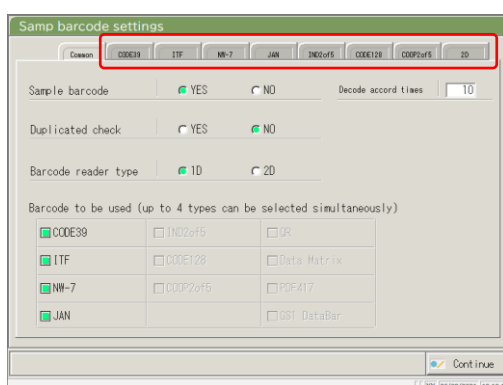
4   Detailed settings for each barcode type are set next.

☞   Page 184 "6.1.2 Sample Barcode Settings (Detailed Settings for Each Barcode Type)"

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<div style="border:1px solid black; padding:10px;">

6.1.2   Sample Barcode Settings (Detailed Settings for Each Barcode Type)

</div>

In [Samp barcode settings], there are items to set according to barcode types in addition to the common settings. Available barcodes are CODE39, ITF, JAN, NW-7, IND2of5, CODE128, and COOP2of5. The barcode settings can be seen by selecting the corresponding barcode name tabs.

(Note)   When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," the settings can be changed.

The explanation starts from the condition at which the [Samp barcode settings] screen is displayed.

☞   Page 182 "6.1.1 Sample Barcode Settings (Common)"
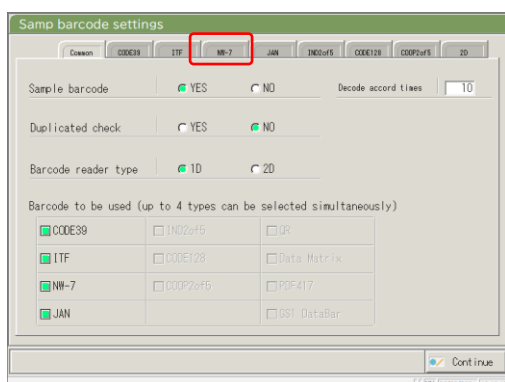
1   Touch the barcode tab to be set.

(Example)
Touch the {NW-7} tab.

2   Set each item.
(See Tables 6.1.1 - –.1.4.)
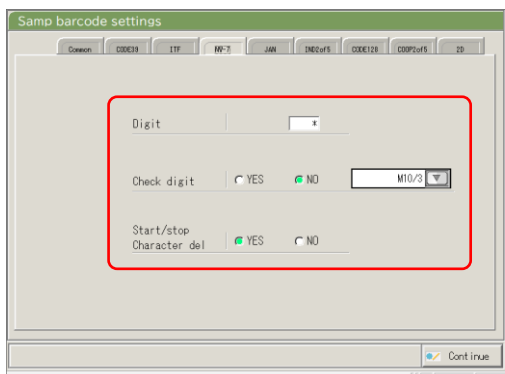
(Note)   For the CODE39, JAN, and ITF barcodes, the check digit calculation method cannot be changed.

3   Touch {Continue}.
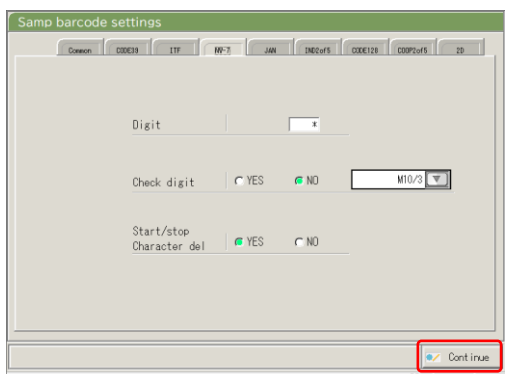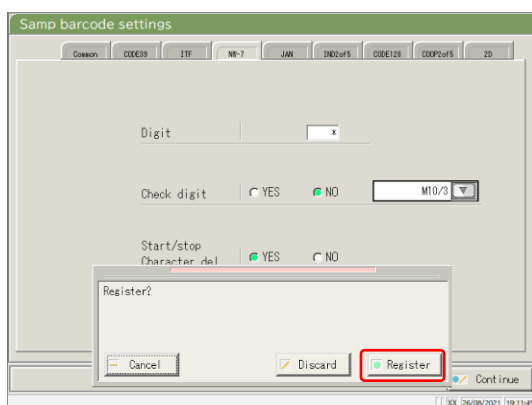
4 Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Aborts registration of the Samp barcode
settings and returns to the [System Settings]
screen.
{Register}: Registers the set contents.

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(Note) When "YES" is selected for the check digit test, the last character of the barcode (one character before the start/stop character) is tested as a check digit.

Table 6.1.1 Samp barcode settings

Set item	Selection/setting	Content
Barcode digits Digit		Sets the number of digits of sample barcode. When "*" is input, the number of barcode digits is not checked. (Used when several number of digits exist for the sample barcode.) The range of input changes according to the "YES" or "NO" setting for "Start/stop character del." See Table 6.1.2 for details.
Start/stop character del		Sets whether the start/stop character is deleted. (Valid when NW-7 is selected.)
	YES :	Deletes the start/stop character.
	NO :	Does not delete the start/stop character.
Check digit test		Sets whether the check digit test is conducted or not.
	YES :	Conducts the check digit test.
	NO :	Does not conduct the check digit test.
Check digit calculation method	See Table 6.1.3	Sets the check digit calculation method. (Valid when NW-7 is selected.)

(Note) For the input range and the calculation method of the check digit, see Table 6.1.3.

Table 6.1.2 Range of input for barcode digits

Barcode type	Start/stop character deletion	Input range	
		Max.	Min.
NW-7	Yes	17	5
	No	15	
ITF	Invalid	15	6
IND2of5			
COOP2of5			
CODE39	Invalid	15	5
JAN			
CODE128			
QR	Invalid	50	6
Data MatriX			
PDF417			
GS1 DataBar Omni-directional			

Table 6.1.3 Input No. and Calculation Method

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	Weighting modulus
8	Loons

Table 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
	Weighting modulus
	Loons
IND2of5	No check digit
CODE128	No check digit
COOP2of5	No check digit
QR	No check digit
Data Matrix	No check digit
PDF417	No check digit
GS1 DataBar Omni-directional	No check digit

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6.1.3 Rack Setting

The range of sample rack numbers.used for S sample bottle are set here.

During testing, racks with numbers in this range are processed as "sample racks."

(Note) When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," settings can be changed.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞ ☞ Page 182 "6.1.1 Sample Barcode Settings (Common)"

☞
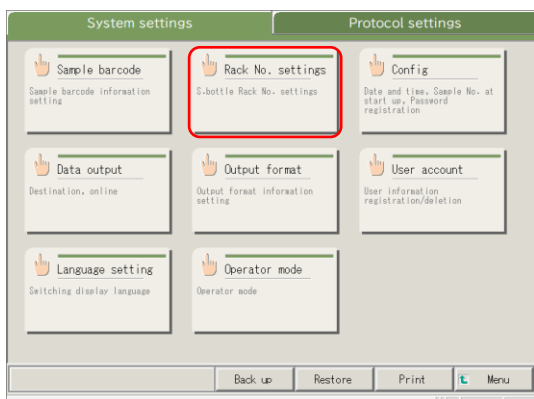
1 Touch {Rack No. settings}.
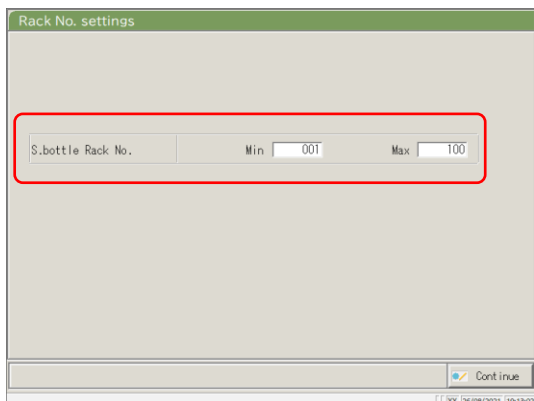
2 Set the range of sample rack numbers.
(See page 189)
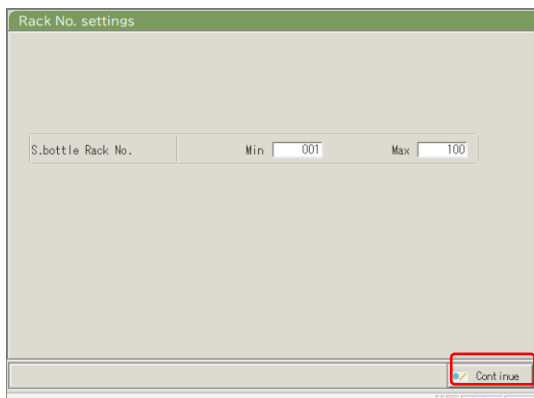
3 Touch {Continue}.

* The dialog for the change/registration check appears.

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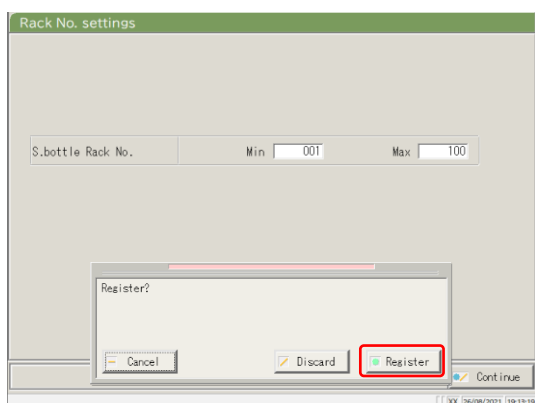
4   Touch {Register}.

{Cancel}：Closes the dialog box.
{Discard}：Aborts the rack range setting and returns to
the [System Settings] screen.
{Register}：Registers the set contents.

Table 6.1.5 Rack setting

Setting	Value	Meaning
S. bottle Rack No. Min.: Max.:	1 - 99–	Sets the Rack No. range for S sample bottle. When "*" is entered, the range specification is disabled.

(Note)   To disable the rack No. range setting, enter "*."

After "*" is entered for the Min. or Max. value, touch the other value (Max. or Min. value). "*" is automatically

set, and Rack No. range setting is disabled.

(If only one of Min. and Max. is "*," registration is not possible.)

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<div style="border: 2px solid black; padding: 10px;">

6.1.4   Config.

</div>

In Config., the following items are set.

·   Date and time
·   Password

(Note)   When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," settings can be changed.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞   Page 182 "6.1.1 Sample Barcode Settings (Common)"

1   Touch {Config.}
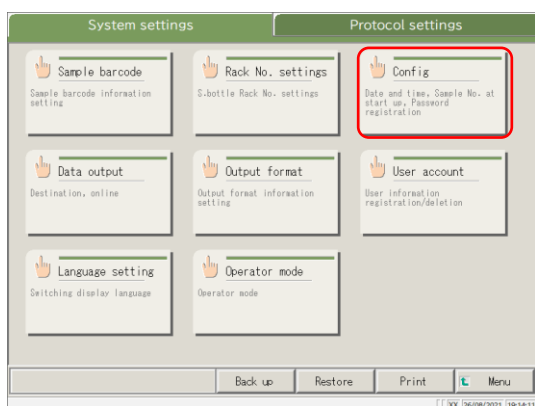
When a password is not registered
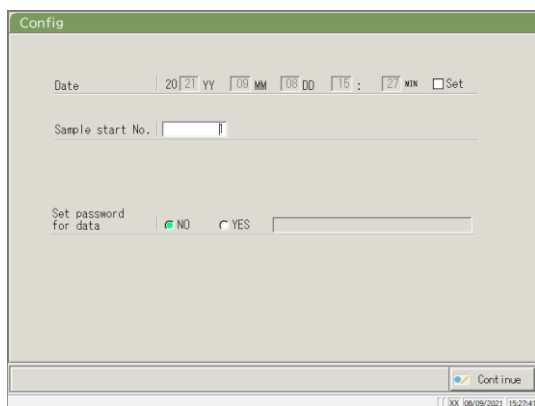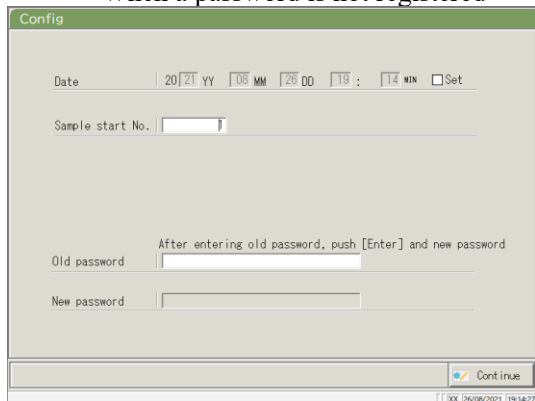
2   Set the Config.
      (See the next page.)

(Note)   The screen differs depending on whether or not a password is registered.

When a password is registered

3 Touch {Continue}.

4 Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Aborts Config. and Returns to the [System Settings] screen.
{Register}: Registers the set contents.

Setting	Value	Meaning
Date 20(XX)YY – (XX)MM – (XX)DD ( ):( )MIN	□ Setting Year:0- 99 Month:1- 12 Day:1- 31 Hour:0- 23 Minute:0- 59	To set the date and time, select the checkbox (■).
Sample start No.	1 - 99–99	Sets an initial value for the sample sequence No.
Password registration Password:	Yes: No: 5 – 30 ch. (0 - 9,–, X, Y, Z, . , /)	Selects whether or not a password is registered. Registers a password. Does not register a password. Enter the password here.
Old password New password	5- 30 ch. (0 - 9,–, X, Y, Z,. , /)	(When a password is set) Changes the password.

(Note) To delete a password, touch {Continue} to register without entering anything in the "New password" field.

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<div style="border:1px solid black; padding:10px;">

6.1.5   Data Output - [S–lecting Data Output Destination]

</div>

The following destinations can be set for data output:

- ・   Output of test data to a printer (printing)
- ・   Output of test data to external media
- ・   Output of time course to external media
- ・   Output of test data to a computer

(Note)   When the user is logged with an administrator ID, or when "No" is selected for "Operator mode," settings can be changed.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞   Page 182 "6.1.1 Sample Barcode Settings (Common)"
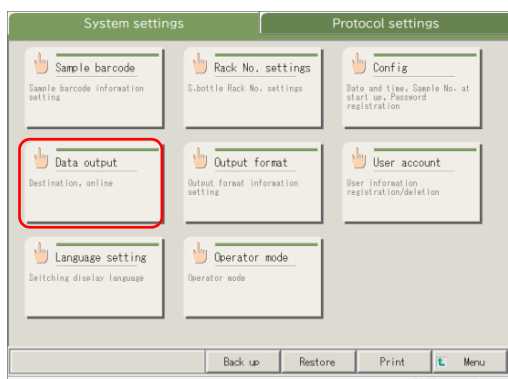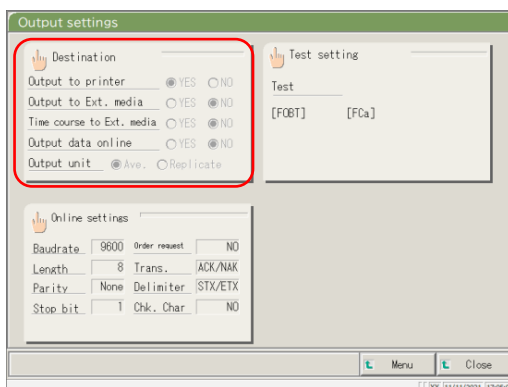
1   Touch {Data output}.

2   Touch {Destination}.

{Menu}: Returns to the [MENU] screen.

{Close}: Returns to the [System Settings] screen.
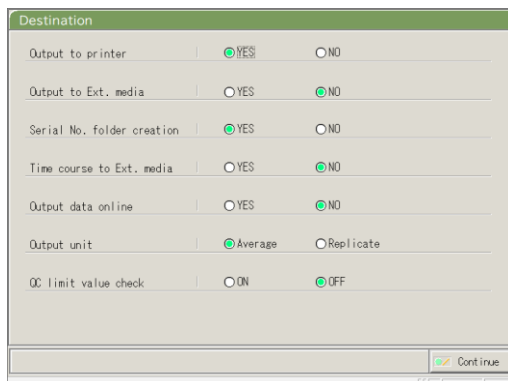
3   Select the destinations for data output (see the next page).

Setting	Value	Meaning
Output to printer		Selects whether or not test data is printed.
	YES	During a test, the test data is printed in real time. If "Print Saving mode" in which only the STD and QC process results and errors are printed is desired, please contact your seller.
	NO	Does not print test data.
Output to Ext. media		Selects whether or not test data is automatically sent to the external media upon completion of the test.
	YES	Output to the external media.
	NO	Not output to the external media.
Serial No. folder creation		Selects whether or not a serial No. folder is created on the external media when outputting test data.
	YSE	Creates a serial No. folder. (Ex. 00226)
	NO	Does not create a serial No. folder.
Time course to Ext. media		Selects whether or not a time course is output to the external media.
	YES	Output to the external media.
	NO	Not output to the external media.
Output data online		Selects whether or not the test data is output to a computer. Detailed settings for computer output are found on the [Online settings] screen.
	YES	Outputs online.
	NO	Does not output online.
Output units		Selects the output format for sample or QC test data output online.
	Average	Outputs an average value of the output test results.
	Replicate	Outputs all measured data.
QC limit value check		Selects the QC control limit value check.
	ON	If the data is normal as a result of the check, the test result is output as is. Otherwise the QC control limit value error is output.
	OFF	Outputs the measured results as-is.

6
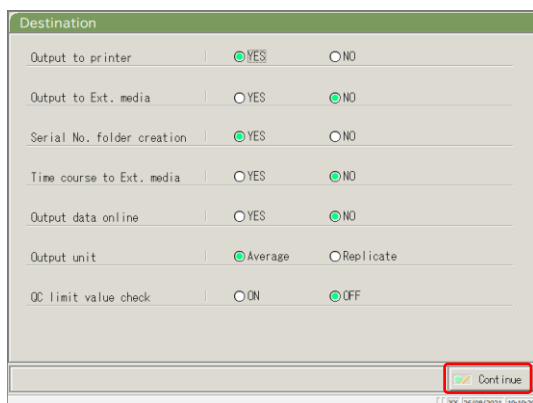
Settings

4   Touch {Continue}.
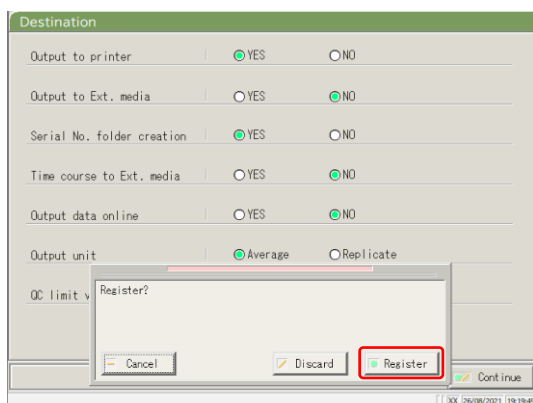
5   Touch {Register}.

{Cancel}: Closes the dialog box.

{Discard}: Aborts selection of data output and returns the screen to the [Data output] screen.

{Register}: Register the set contents.

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<div style="border:1px solid">

6.1.6   Data output - [O–line Settings]

</div>

The control conditions for network communication are set.

For details, refer to "OC-SENSOR Ceres Interface Specifications."

(Note)   When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," settings can be

changed.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞   Page 182 "6.1.1 Sample Barcode Settings (Common)"
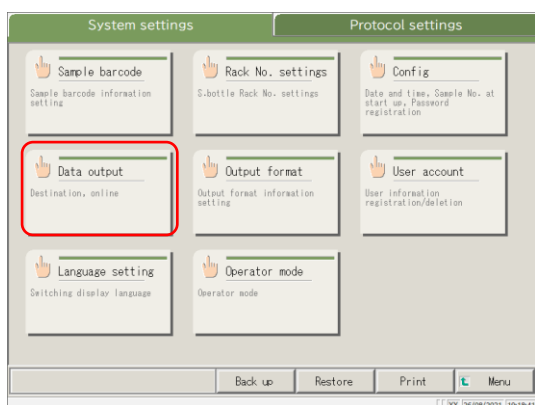
1   Touch {Data output}.
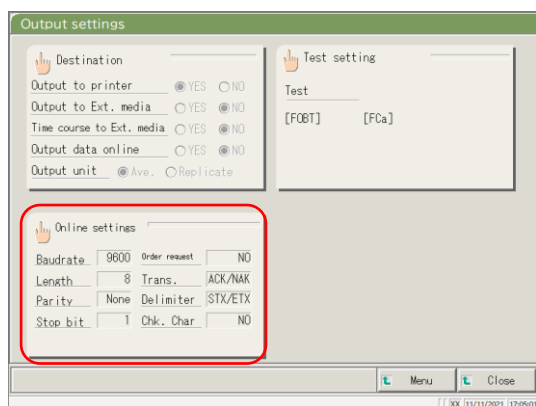
2   Touch {Online settings}.

{Menu}: Returns to the [MENU] screen.
{Close}: Returns to the [System Settings] screen.
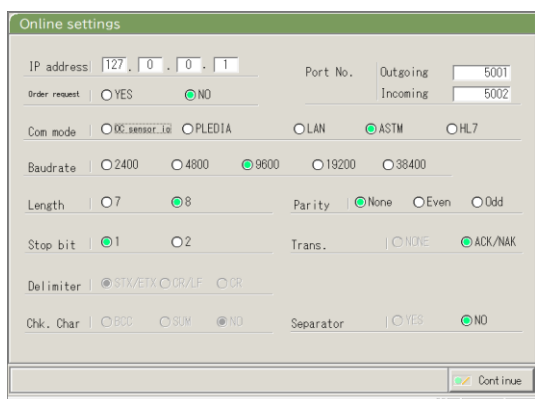
3   Select the conditions for network
communication (see the next page).

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6.1 System Settings

Setting	Value	Meaning
IP address □.□.□.□	0 - 25–	Sets the IP and port number for the network connection. * Valid only when the communication mode is LAN or HL7.
Port No. Outgoing/Incoming	1 - 65–35	
Order request		Selects whether or not order requests are sent to the upper level system.
	YES	Sends an order request.
	NO	Does not send an order request.
Com mode		Selects a communication mode.
	OC sensor IO	OC sensor IO compatible mode
	PLEDIA	OC sensor PLEDIA-compatible mode
	LAN	LAN communication mode
	ASTM	ASTM communication mode
	HL7	HL7 communication mode
Baudrate		Selects the communication speed.
	2400	2400 bps
	4800	4800 bps
	9600	9600 bps
	19200	19200 bps
	38400	38400 bps
Length		Selects the word length
	7	7 bits
	8	8 bits
		Select 8-bit when sending 2-byte characters.
Parity		Selects the parity check.
	None	Do not use parity check.
	Even	Check with even-number parity.
	Odd	Check with odd-number parity.
Stop bit		Select as the stop bit.
	1	1 bit
	2	2 bits
Trans.		Selects the transmission control.
	NONE	Does not use transmission control
	ACK/NAK	Uses ACK/NAK control.
Delimiter		Selects the delimiter.
	STX/ETX	Start of Text (0x02) / End of Text (0x03)
	CR/LF	Carriage Return (0x0D) / Line Feed (0x0A)
	CR	Carriage Return (0x0D)
Chk. Char		Selects the error detecting method.
	BCC	Block Check Code
	SUM	Sum
	NO	Does not use a check character.
Separator		Selects whether or not commas (,) are used to separate data items.
	YES	Separated by commas.
	NO	Not separated by commas.

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(Note) In the case of LAN or HL7 communication, the settings for delimiter, check character, and item separation become "none."

(Note) For ASTM communication, the settings for delimiter, check character, and item separation are fixed. They cannot be changed on the setting screen.
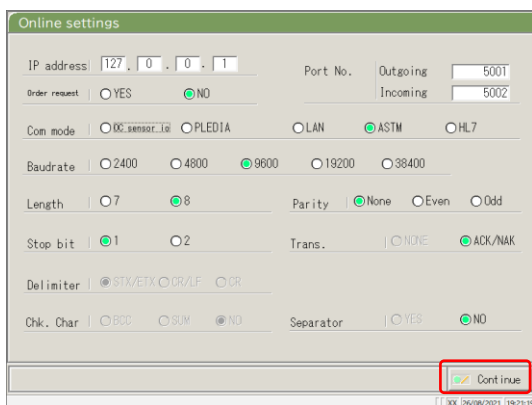
4 Touch {Continue}.
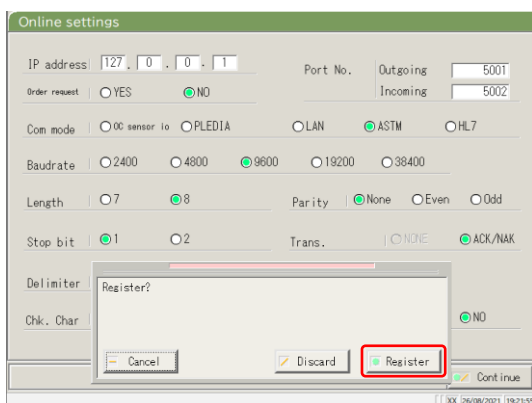
5 Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Aborts Online settings and returns to the [Data output] screen.
{Register}: Registers the set content.

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6.1.7   Data Output - [T–st Setting]

The test items to be handled by the system are set here.

(Note)   When the user is logged with an administrator ID, or when "No" is selected for "Operator mode," settings can be changed.

(Note)   Settings are also available from the [Assay] screen, [Retest] screen, [QC process] screen, and the [Set reagent] screen.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞   Page 182 "6.1.1 Sample Barcode Settings (Common)"
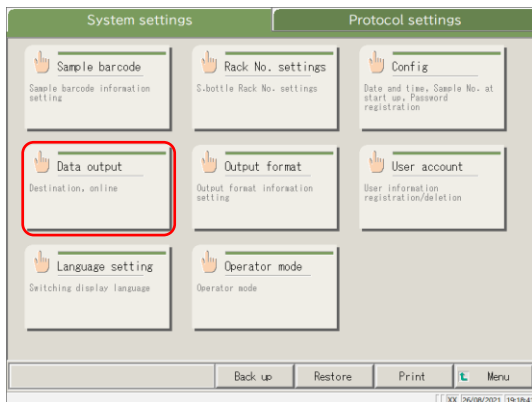
1   Touch {Data output}.
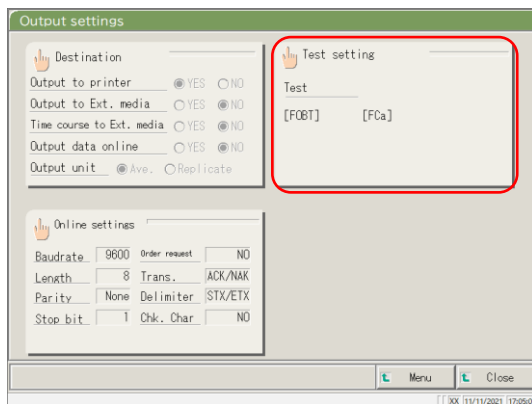
2   Touch {Test setting}.

{Menu}: Returns to the [MENU] screen.
{Close}: Returns to the [System Settings] screen.
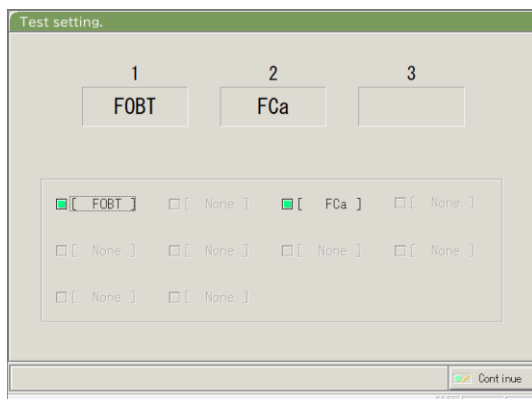
3   Selects the test items (see the next page).

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Setting	Value	Meaning
Test item		selects the test item.
	[FOBT]	Fecal hemoglobin
	[FCa]	Calprotectin
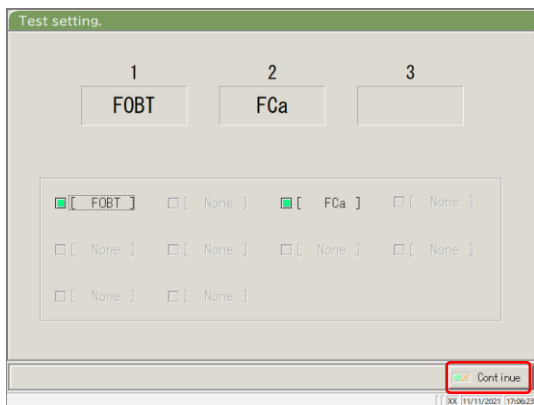
4   Touch {Continue}.
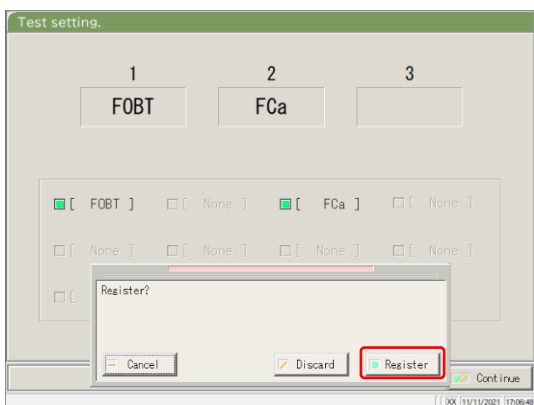
5   Touch {Register}.

{Cancel} : Closes the dialog box.

{Discard} : Aborts the test setting and returns to the previous screen.

{Register} : Registers the set content.

<div style="border:1px solid black; padding:8px">

6.1.8   Output Format Settings (Basic Format)

</div>

The output format of data such as the rack, sample No., sample ID, etc. can be set for each output destination (printer, external media, and network).

For data output to a printer, the settings for the rack, sample No., and sample ID cannot be changed.

(Note)   When the user is logged with an administrator ID, or when "No" is selected for "Operator mode," the settings can be changed.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞   Page 182 "6.1.1 Sample Barcode Settings (Common)"
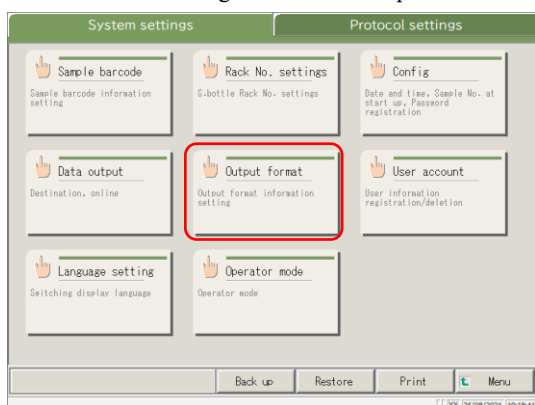
1   Touch {Output format}.
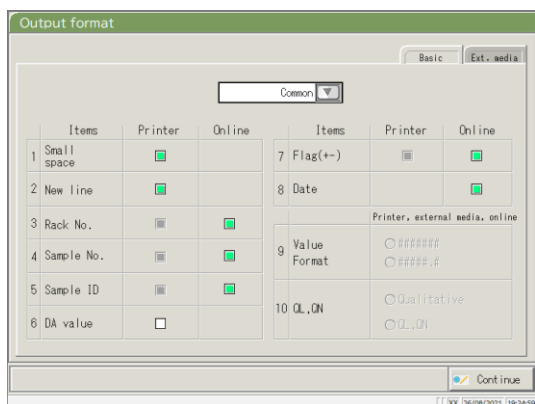
2   Select an output item (see page 202).

3   Touch {Continue}.

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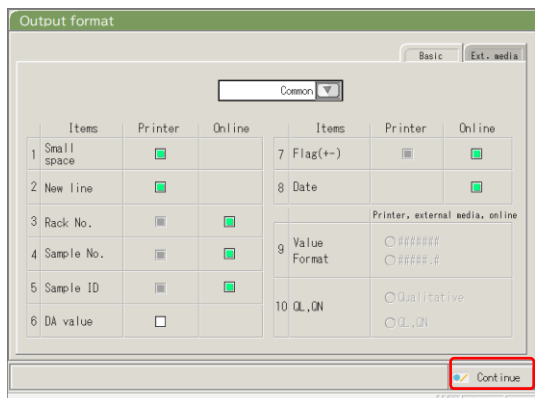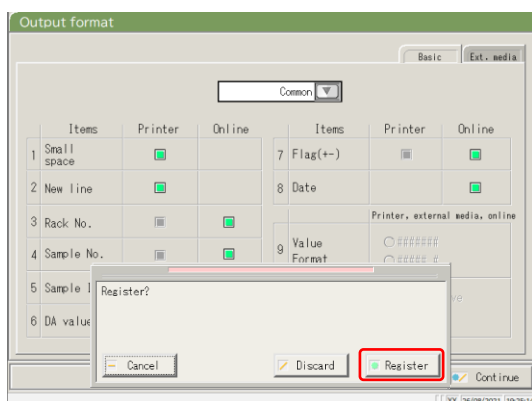
4 Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Aborts the output format and returns to the [System Settings] screen.
{Register}: Registers the set content.

Note   An item with a check mark is output.

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Output item		Meaning
Test item		Selects test items for output.
	Common	common settings (items 1 - 8)–
	90 : [FOBT]	FOBT setting (items 9 - 10–)
	53 : [FCa]	FCa setting (items 9 - 10–)
1.Small space		
	Printer	Line spacing becomes narrower when printing.
2. New line		
	Printer	A line feed is output at the following positions during printing.
		· Between test data sets
		· Between items when testing multiple items
		(Applied for both real time and processed data printing.)
3. Rack No.		
	Printer	Rack No. and Rack Position No. are output.
	Online	Rack No. and Rack Position No. are output.
4. Sample No.		
	Printer	Outputs sample Nos.
	Online	Outputs sample Nos.
5. Sample ID		
	Printer	Outputs sample IDs.
	Online	Outputs sample IDs.
6. DA value		
	Printer	Prints DA values.
		Outputs DA values.
7. Flag (+-)		
	Printer	Outputs judged results.
	Online	Outputs judged results.
8. Date		
	Online	Outputs test dates.
9. Value Format		Selects the output format for the measured data.
	####### (integer)	Outputs integers.
	#####.# (1st digit of decimal number)	Outputs numbers with one decimal digit (all measured data values are rounded up.)
10. QL, QN		
	Qualitative	Outputs the qualitative value of the measured results.
	QL, QN	Outputs the qualitative and quantitative values of the measured results.

Note   When the communication mode is set to ASTM on the [Online settings] screen, only the [Value Format] and [QL, QN]

settings are applied, and other settings are not applied.

6.1.9   Output Format Setting (External Media)

The data output to external media can be selected, and the output order can be changed.

(Note)   When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," the settings

can be changed.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞   Page 182 "6.1.1 Sample Barcode Settings (Common)"
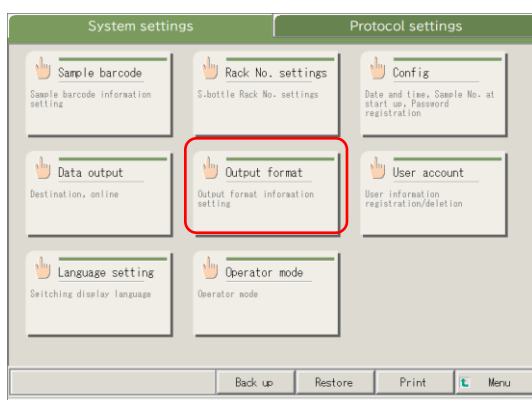
1 Touch {Output format}.
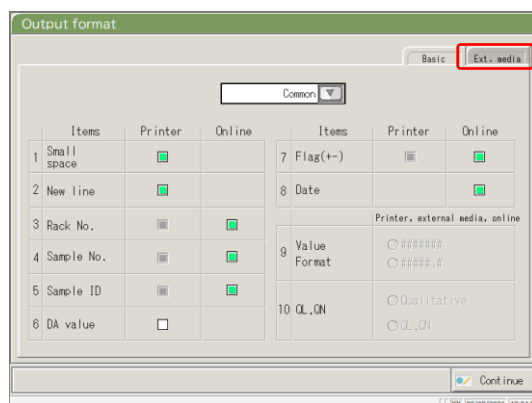
2 Touch the {Ext. Media} tab.
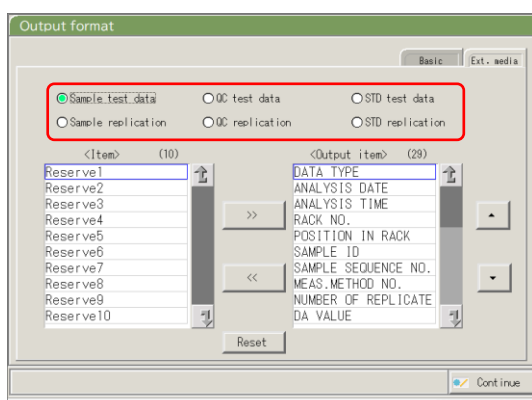
3 Select the test information to be changed using the radio buttons.

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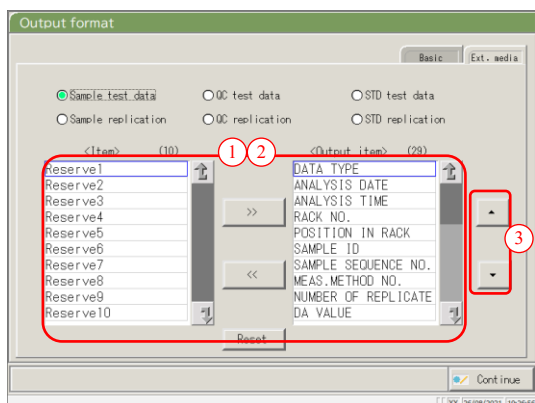
4 Change the order of output and select the output data.

Output items: List of items to be output

Output order to: The data is output in the order shown.

① When an item on the left-side <Item> list is selected and the {>>} button is clicked, the corresponding item is added to the right-side <Output items> list.

② To delete an item from <Output items>, select the item in the list and touch the {<<} button.

③ Use the {▲} and {▼} buttons to change the order of a selected item.

{Reset}: Returns to the initial condition.

{ ⬆ }: Scrolls the list upward.

{ ⬇ }: Scrolls the list downward.

(Note) Some items are necessary for output. Such items cannot be deleted from the <Output items> list. For the items required for output, see ☞ 271 "4 Saving to External Media."

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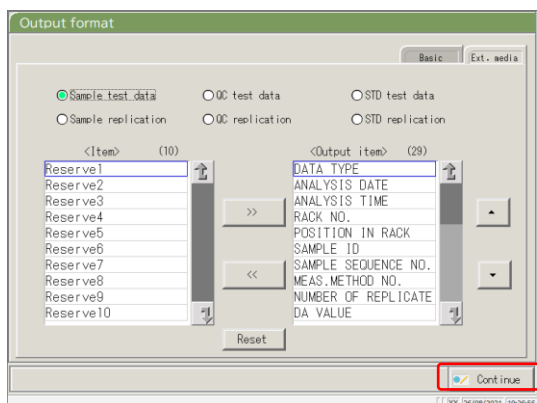
5 Touch {Continue}.
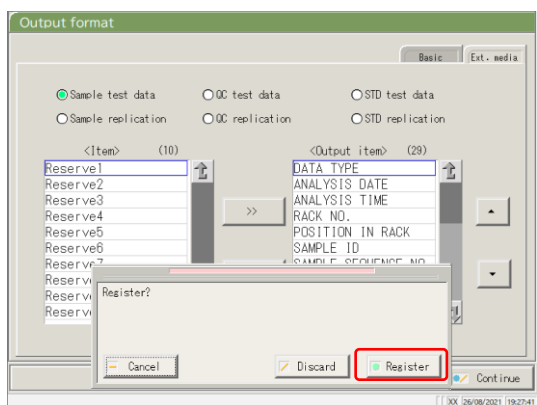
6 Touch {Register}.

{Cancel}：Closes the dialog box.

{Discard}：Aborts output format and returns to the [System Settings] screen.

{Register}：Registers the set content.

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```
┌──────────────────────────────────────────────────────────────────────────────┐
│                                                                                │
│        6.1.10  User Account Settings                                           │
│                                                                                │
└──────────────────────────────────────────────────────────────────────────────┘
```

Operator IDs can be registered, deleted, and changed.

(Note) If the current operator ID is "User," registration and changing the operator ID of the administrator is not

possible. Setting an administrator ID is available only when the user is logged in with an administrator ID or

when Operator mode is set to "NO."

The explanation starts from the condition at which the [System Settings] screen is displayed.
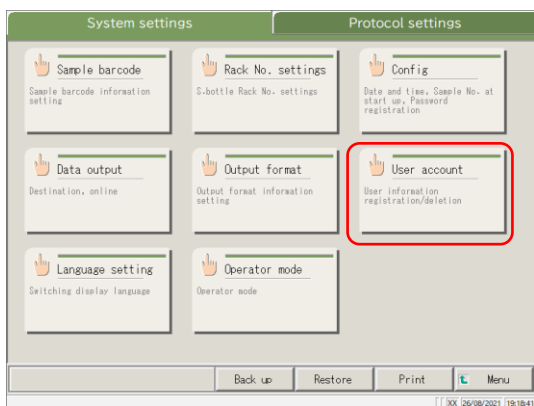
1 Touch {User account}.
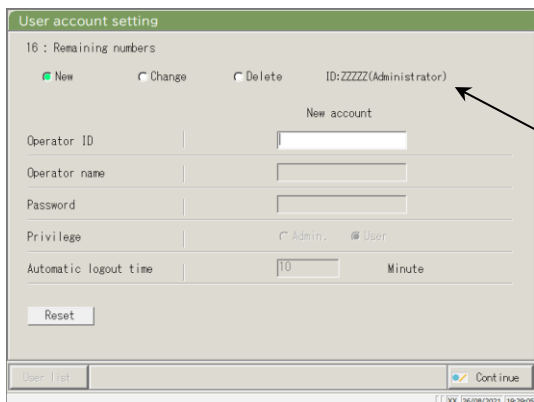
2 Select "New," "Change," or "Delete."

* At "ID:", the ID of the currently logged in
operator is displayed.

3 Enter each setting.

<In case of a new registration>
Register a new operator ID by entering the
items in the following order.
① Operator ID
② Operator name
③ Password
④ Privilege
⑤ Automatic logout time

{Reset}: Clears the entered value.
The privilege returns to "User."

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Up to 20 operator IDs can be registered.

The operator ID registered first automatically becomes an administrator
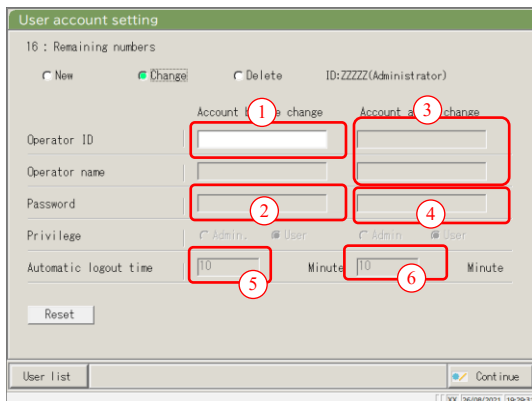
<To change an ID>
Enter the items in the following order for the operator ID to be changed.

① Enter the current operator ID.
   * Selecting from the {User list} is also available.
   * The current operator name, new operator ID and operator name are automatically filled in.

② Enter the current password.

③ Enter the new operator ID and name.
   The current operator ID and name can be left as they are.

④ Enter a new password.
   To use a new password, enter a password different from the current password.

   {Reset}: Clears the entered value.
            The privilege returns to "User."

⑤ Set the new privilege.
⑥ Set the automatic logout time.

<To delete an ID>

Enter the items in the following order for the operator ID to be deleted.

① Operator ID
   * Selecting from the {User list} is also available.
   * The Operator name will be automatically filled in.

② Password

   {Reset}: Clears the entered value.

6
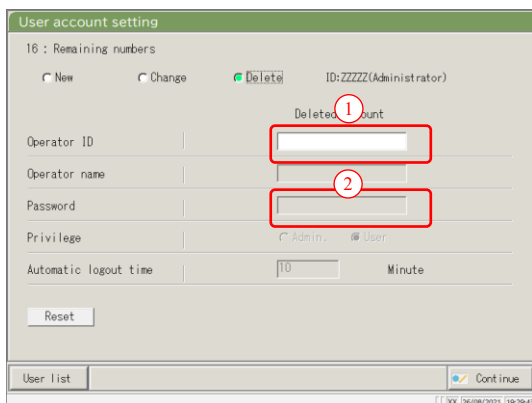
Settings

Setting		Meaning
Operator ID	1 - 20–digits alphanumeric characters	Enter an operator ID. <when changing/deleting> Selecting from the {User list} is available.
Operator name	1 - 20–digits alphanumeric characters	Displays the name or the entered operator ID. <when changing> Enter the new operator's name.
Password	5 - 10–digits alphanumeric characters	Enter a password.
Privilege	Admin. User	Displays the privilege. <when changing> The privilege can be changed.
Automatic logout time	0 – 99 min.	While the [MENU] screen is displayed, if no operation is conducted for this length of time, automatic logout occurs.

4 Touch {Continue}.

5 Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Aborts the user account setting and returns to the [System Settings] screen.
{Register}: Registers the set content.

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6.1.11 Language Settings

Application language can be selected.

(Note) When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," the settings can be changed.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞ Page 182 "6.1.1 Sample Barcode Settings (Common)"
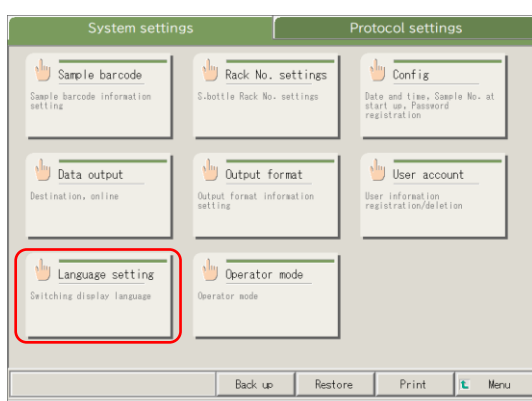
1 Touch {Language setting}.
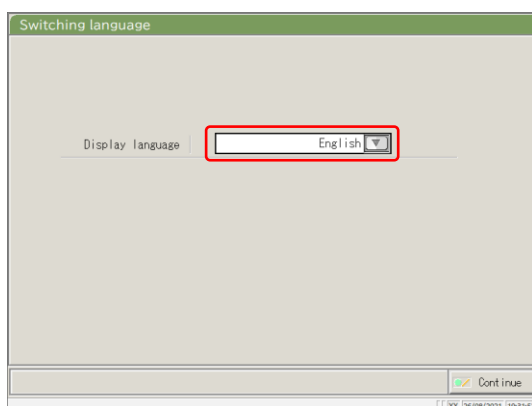
2 Touch {▼} to select a language.

3 Touch {Continue}.

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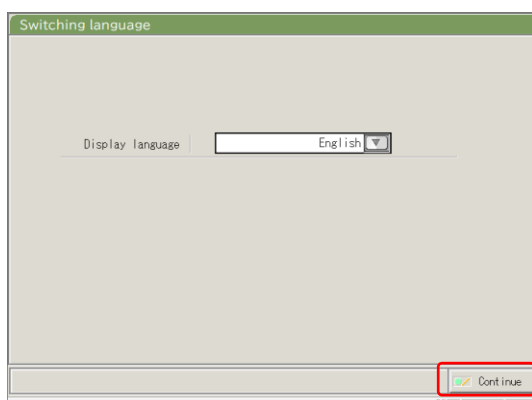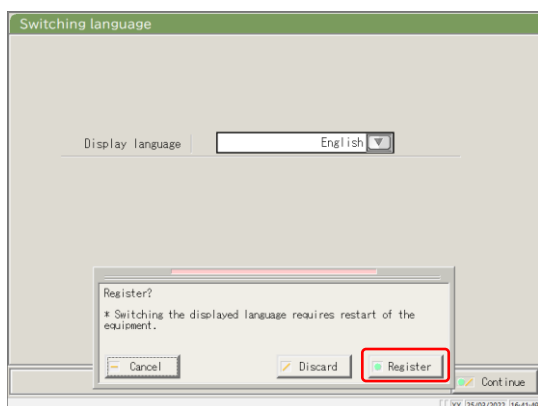
6.1 System Settings

4 Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Aborts changing the language and returns to the [System Settings] screen.
{Register}: Enables the selected language.

5 After changing the language, restart the system.

① Shut down the system.

☞ Page 89 "2.7 Shutting Down the System"

② Press the System switch to start up the system.

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6.1.12 Operator Mode

The operator mode can be changed.

The explanation starts from the condition at which the [System Settings] screen is displayed.

☞   Page 182 "6.1.1 Sample Barcode Settings (Common)"
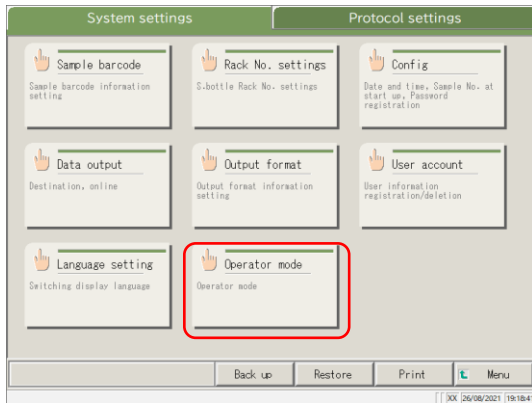
1   Touch {Operator mode}.
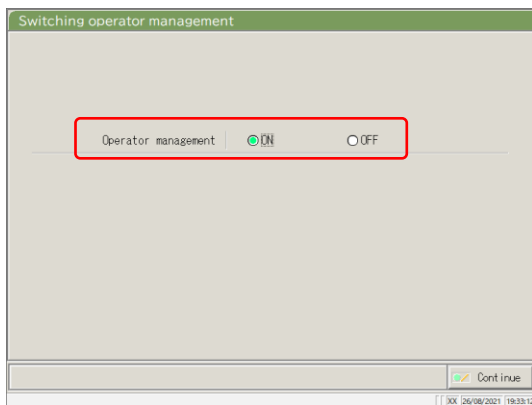
2   Switch the Operator mode.

(Note)   Switching from "ON" to "OFF" is available only when logged in with an administrator ID.
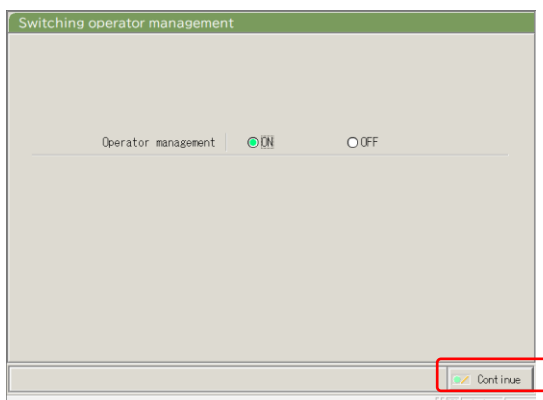
3   Touch {Continue}.
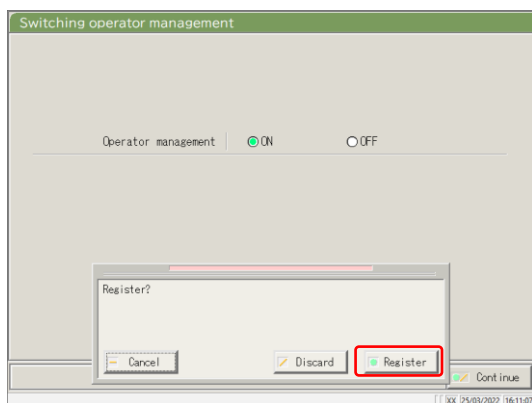
4 Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Aborts switching the Operator mode and
returns to the [System Settings] screen.
{Register}: Registers the set content.

\<When changed from "ON" to "OFF"\>
Returns to the [MENU] screen.
Continue using the system as is.
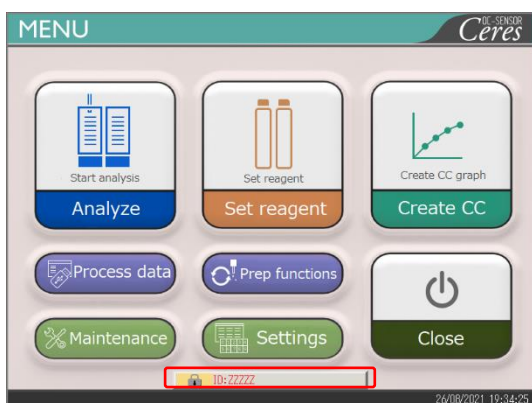
\<When changing from "OFF" to "ON"\>
Returns to the [MENU] screen and logs-out.
Touch the LOGIN button to log in.

☞ Page 28 "2.3 Logging In"

6
Settings

6.1.13   Printing the System Settings

The information registered in System Settings can be printed.
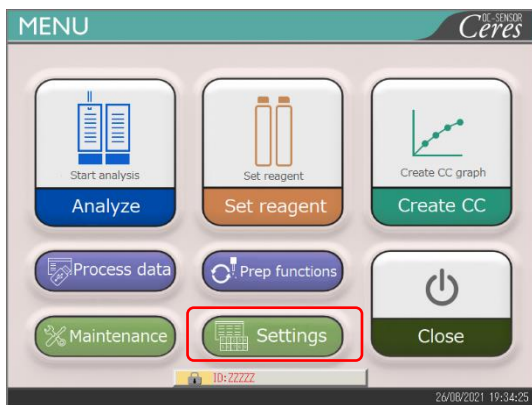
1   Touch {Settings}.
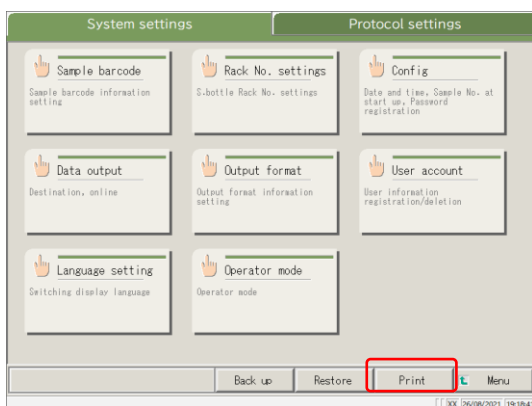
2   Touch {Print}.

  * All the settings registered in [System Settings] are printed.

6.1.14 Backing Up System Settings and Protocol Settings

The system settings and protocol settings can be backed up.

(Note)   When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," backup is possible.
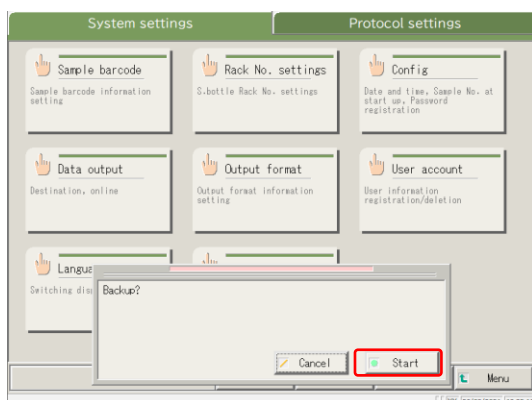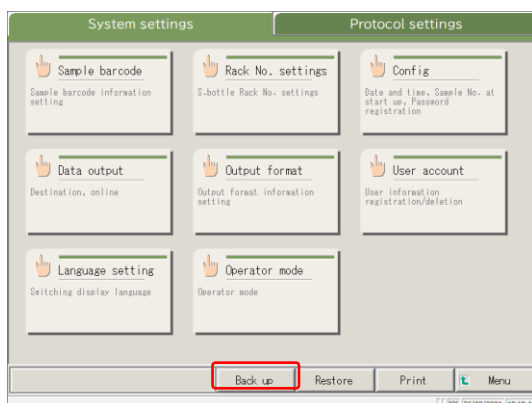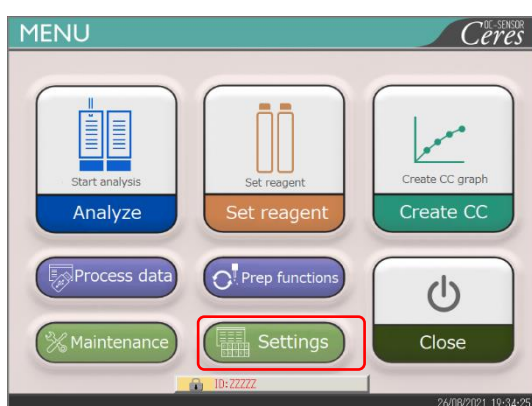
1 Connect the management USB stick to the system.
☞ For the management USB stick, see Page 283 "Appendix 5 Management USB Stick Setting"

2 Touch {Settings}.

3 Touch {Back up}.

4 Touch {Start}.

* [System settings] and [Protocol settings] are backed up to the external media.

{Close}: Aborts backup.
{Start}: Executes backup.

6
Settings

<div style="border:1px solid;">

6.1.15 Restoring System Settings and Protocol Settings

</div>

System settings and protocol settings can be restored from external media.

(Note)   When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," restoration

becomes possible.
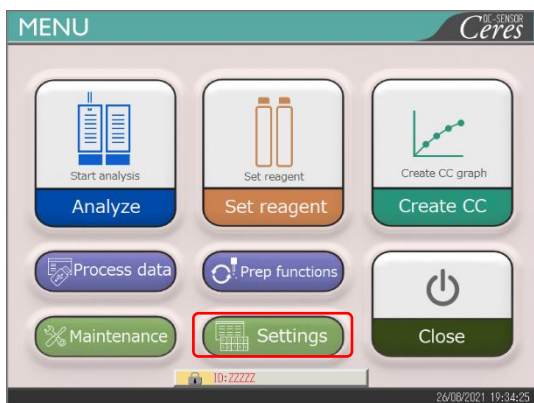
1   Connect the management USB stick to the system.

☞   For the management USB stick, see page 283 "Appendix 5 Management USB Stick Setting"
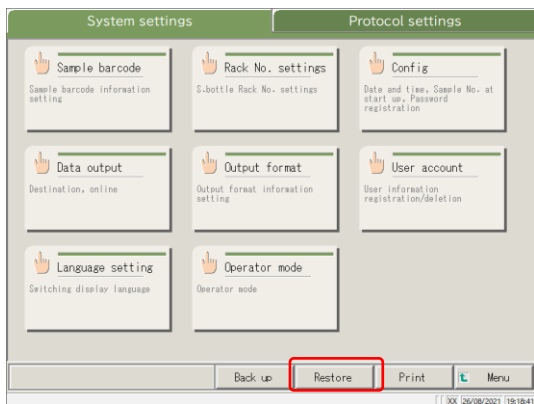
2   Touch {Settings}.

3   Touch {Restore}.
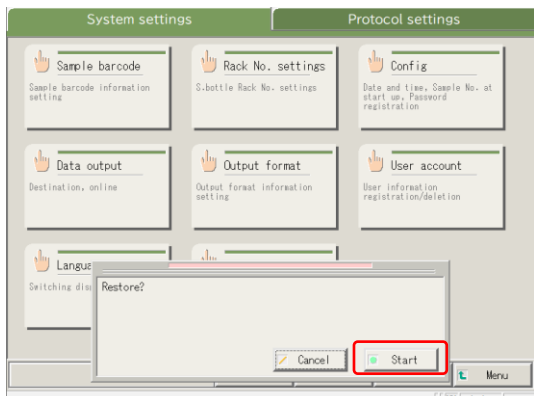
4   Touch {Start}.

* [System Settings] and [Protocol settings] are restored from the external media.

{Close}: Aborts restoring.

{Start}: Executes restoring.

6.2　Protocol Settings

The protocol settings can be roughly divided into the following three types:

- ・　Conditions for samples and QC samples (Sample/QC protocol settings)
- ・　CC protocol settings
- ・　Common conditions for testing samples, STD samples, and QC samples (maker settings)

Protocol settings do not need to be changed for normal test flows unless the contents of the flow are changed. In addition, the maker settings are set before shipping from the factory and are not available for users.

6.2.1　Sample/QC Protocol Settings

Conditions to test the samples (including interrupted samples) and QC samples can be set. The setting screen consists of two pages, and the tabs are used to switch the pages.

(Note)　When the user is logged in with an administrator ID, or when "No" is selected for "Operator mode," the settings can be changed.
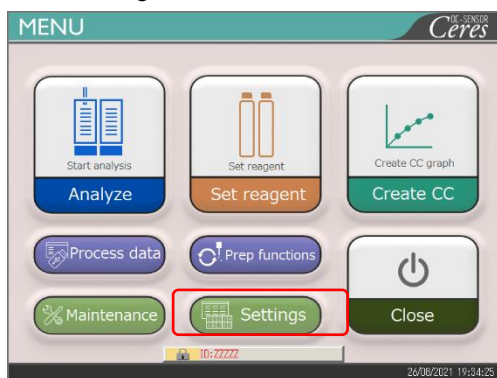
1　Touch {Settings}.
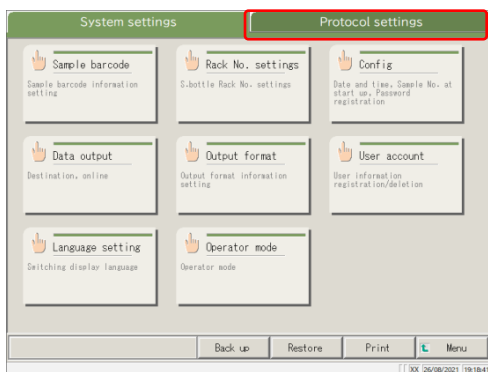
2　Touch the {Protocol settings} tab.
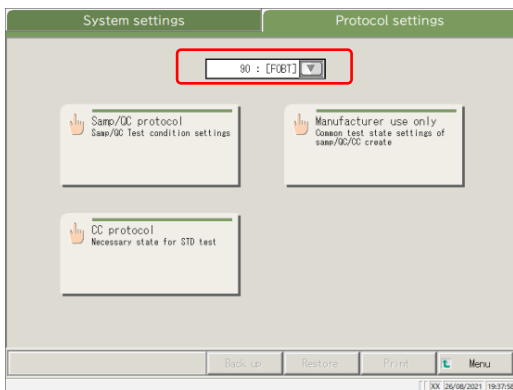
3 Select a test item from the pull-down menu.
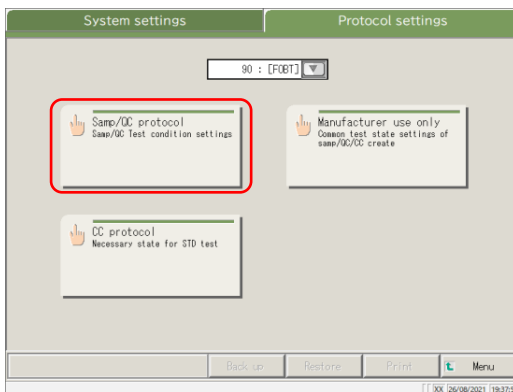
4 Touch {Samp/QC protocol}.
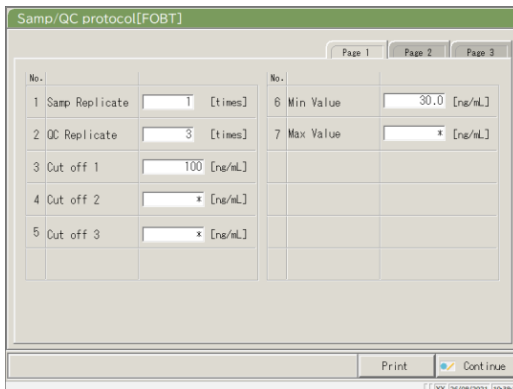
5 Set each item (see page 220).

{Print}: Prints the [Sample and QC Protocol] settings.
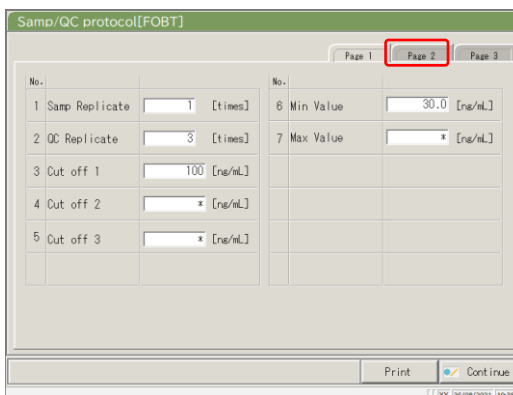
6 Touch the {Page 2} tab.

{Print}: Prints the contents of [Samp/QC protocol].

6
Settings
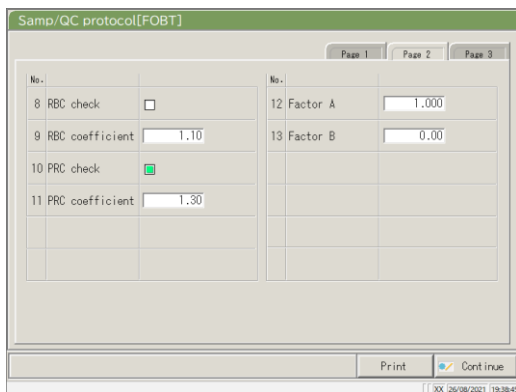
7 Set each item (see page 221).

{Print}：Prints the contents of [Samp/QC protocol].
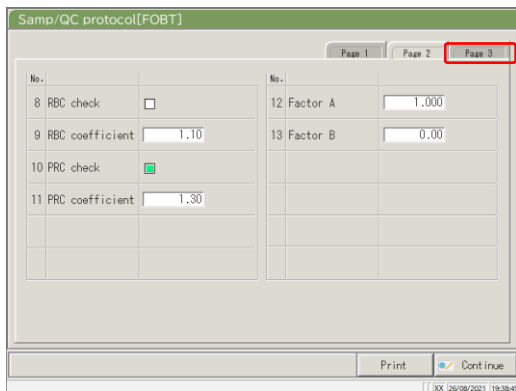
8 Touch the {Page 3] ta}.

{Print}：Prints the contents of [Samp/QC protocol].
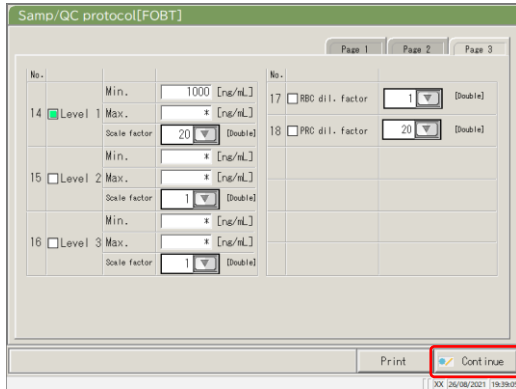
9 Set each item (see page 222).

{Print}：Prints the contents of [Samp/QC protocol].

10 Touch {Continue}.

6
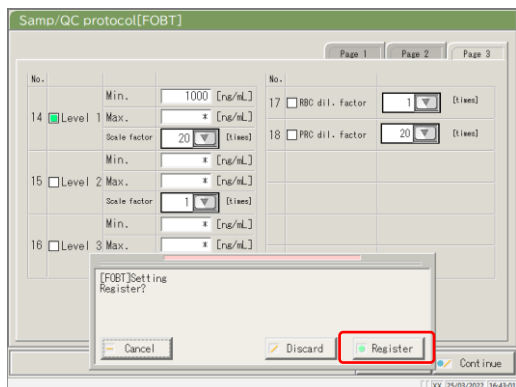
Settings

11 Touch {Register}.

{Cancel}：Closes the dialog box.

{Discard}：Aborts and returns to the [Protocol settings]
　　　　　　 screen.

{Register}：Registers the set content.

{Page 1} tab

	Setting	Value	Meaning	
1	Samp Replicate	1 – 10 times	Sets the number of sample tests.	
2	QC Replicate	1 – 10 times	Sets the number of QC sample tests.	
3	Cut off 1	0 - 99–9999 (integer)	Sets the criteria for Cut off 1.	
			1+	Measured data is higher than "Cut off 1" or equal to or lower than "Cut off 2"
			-	Measured data $\leqq$ Cut off 1
4	Cut off 2	*, 0 - 99–9999 (integer)	Sets the criteria for Cut off 2.	
			2+	Cut off 2 < Measured data $\leqq$ Cut off 3 When "*" is set, judging Cut off 2 is emitted. Cut off 1 < Cut off 2
5	Cut off 3	*, 0 - 99–999 (integer)	Sets the criteria for Cut off 3.	
			3+	Measured data exceeds the set value. When "*" is set, judging Cut off 3 is emitted. Cut off 2 < Cut off 3
6	Min Value	0.0 - 99–9999.9	UR	Displayed when the measured data is "Min. value or lower" in diluent retesting.
7	Max Value	0.0 - 99–9999.9	OR	Displayed when the measured data is "Max value" or higher.

6
Settings

{Page 2} tab

	Setting	Value	Meaning
8	RBC check		Sets whether or not the RBC check is conducted. If conducting the check, set by clicking the box. ☞ Page 238 "■ RBC method"
9	RBC coefficient	1.00 - 2.–0	At the detection point of the RBC method, when the sample ABS becomes larger than STD-6 ABS x "RBC coefficient," that sample is judged "prozone sample." ☞ Page 238 "■ RBC method"
10	PRC check		Sets whether or not the PRC check is conducted. If conducting the check, set by clicking the box. ☞ Page 239 "■ PRC method"
11	PRC coefficient	0.01 - 2.–0	At No. 2 detection point (T2), when the sample DA2 value becomes larger than STD-6 DA2 value x "PRC coefficient," that sample is judged to be a "prozone sample." ☞ Page 239 "■ PRC method"
12	Factor A	0.001 - 99–9.999	Measured data = A x Concentration value + B
13	Factor B	-999.999 - 99–.999	

6

Settings

{Page 3} tab

	Setting		Value	Meaning
14	Level 1	Check		Sets whether or not the automatic retest is conducted for samples within the Level 1 range.
		Min.	*, 0 - 9999999	Sets the minimum value.
		Max.	*, 0 - 9999999	Sets the maximum value. Min. value < Max. value
		Scale factor	1 10 20 100 200 400	Sets the dilution factor for automatic retest.
15	Level 2	Check		Sets whether or not the automatic retest is conducted for samples within the Level 2 range.
		Min.	*, 0 - 9999999	Sets the minimum value.
		Max.	*, 0 - 9999999	Sets the maximum value. Min. value < Max. value
		Scale factor	1 10 20 100 200 400	Sets the dilution factor for automatic retest.
16	Level 3	Check		Sets whether or not the automatic retest is conducted for samples within the Level 3 range.
		Min.	*, 0 - 9999999	Sets the minimum value.
		Max.	*, 0 - 9999999	Sets the maximum value. Min. value < Max. value
		Scale factor	1 10 20 100 200 400	Sets the dilution factor for automatic retest.

{Page 3} tab (continued)

	Setting		Value	Meaning
17	RBC dil. factor	Check		Sets whether or not an automatic retest is conducted for the prozone samples in the RBC method. ☞ Page 238 "■ RBC method"
		Scale factor	1 10 20 100 200 400	Sets the dilution factor for automatic retesting. ☞ Page 238 "■ RBC method"
18	PRC dil. factor	Check		Sets whether or not an automatic retest is conducted for the prozone samples in the PRC method. ☞ Page 239 "■ PRC method"
		Scale factor	1 10 20 100 200 400	Sets the dilution factor for automatic retesting. ☞ Page 239 "■ PRC method"

Note   To perform automatic retest of OR, set the Level 1 Min. and Max values as follows.

Ex. In case of FOBT, because the test Max. value is 1000 ng/mL, set 1000.

Level 1 Min. value = 1000

Max value = *

6
Settings

6.2.2 CC Protocol Settings

The necessary conditions for STD sample measurements can be set.

The setting screen consists of two pages, and the tabs are used to switch pages.

Note When the user is logged with an administrator ID, or when "No" is selected for "Operator mode," the settings can be changed.

.

The explanation starts from the condition at which the [Protocol settings] screen is displayed.

☞ Page 217 "6.2.1 Sample/QC Protocol Settings"
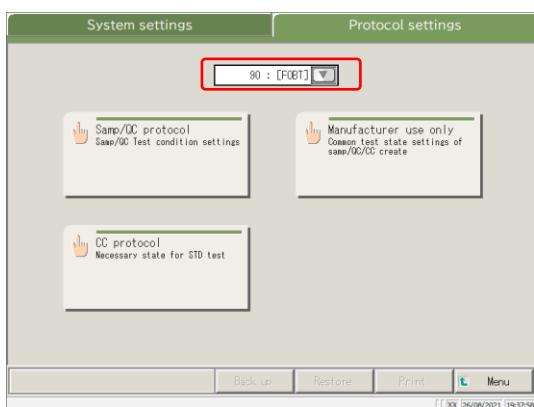
1 Select a test item.
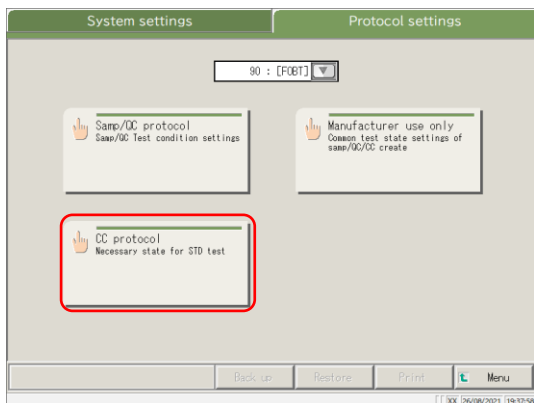
2 Touch {CC protocol}.
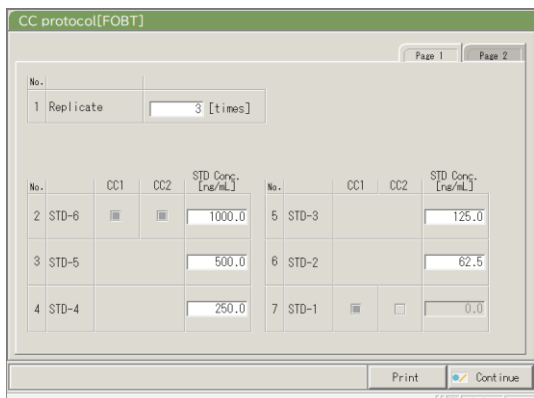
3 Set each item.

☞ Page 226 "{Page 1} tab"

{Print} : Prints the [CC protocol] settings.

---
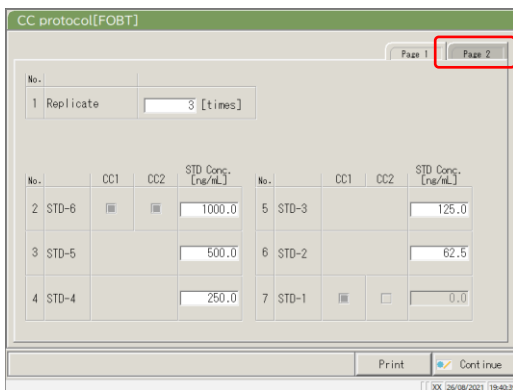
6 Settings

4 Touch the {Page 2} tab.
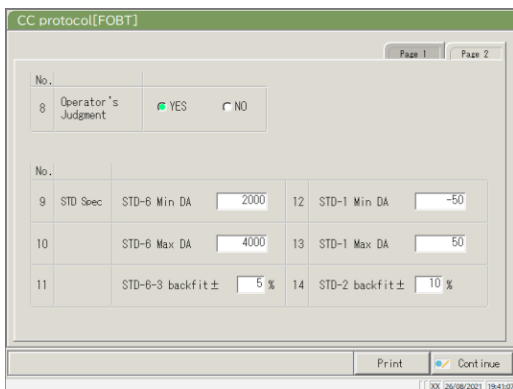
5 Set each item.

☞ Page 226 "{Page 2} tab"

{Print} : Prints the [CC protocol] settings.
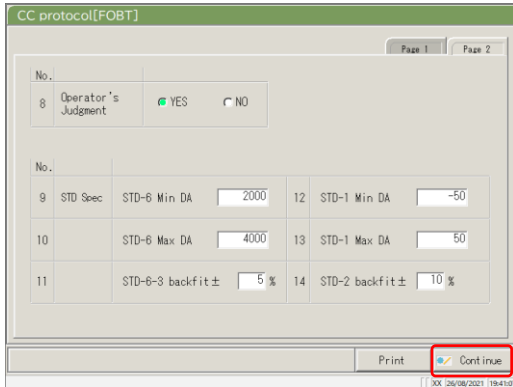
6 Touch {Continue}.
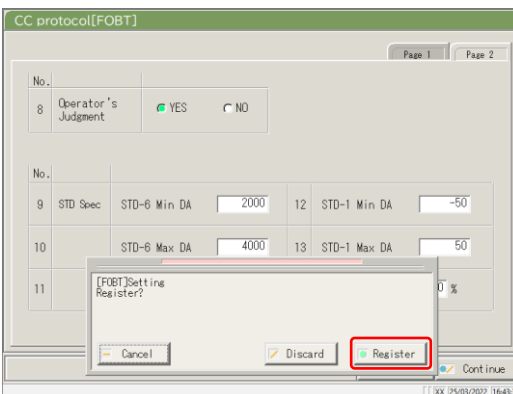
7 Touch {Register}.

{Cancel}: Closes the dialog box.
{Discard}: Aborts and returns to the [Protocol settings] screen.
{Register}: Registers the set content.

6.2 Protocol Settings

{Page 1} tab

	Setting	Value	Meaning
1	Replicates	1 – 10	Sets the number of STD sample tests.
2	STD-6	0 - 99–99.9	Sets the concentration value which is described in the calibrator operation manual.
3	STD-5		
4	STD-4		
5	STD-3		
6	STD-2		
7	STD-1	(No input)	

{Page 2} tab

	Setting	Value	Meaning
8	Operator's Judgment	YES	Sets whether or not the operator judges after creation of CC. The system enters standby after the creation of CC in order to wait for the operator's judgment.
		NO	The operator does not judge. When the measured data are normal, the measurement continues. When the measured data are abnormal, wait for the operator's judgment. The system enters standby.
STD Spec.			Sets the standard value for each STD point. The STD judgment is based on the specified values.
9	STD-6 DA Min DA	-9999 - 99–99	Checks against the DA1 value.
10	STD-6 DA Max DA	-9999 - 99–99	Sets as the Min. value < Max. value.
11	STD-6 - 3 –rigin value ± □ %	0 - 10–	Checks for deviation from the origin value.
12	STD-1 DA Min DA	-9999 - 99–99	Checks against the DA1 value.
13	STD-1 DA Max DA	-9999 - 99–99	Sets the Min. value < Max. value.
14	STD-2 DA Origin value ±□ %	0 - 10–	Checks for deviation from the origin value.

(Note) For the checking of the STD and QC measured data, see page 235 "1.1 STD/QC Sample Measured Data Check."

Chapter 7 Error Handling

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Chapter 7 Error Handling

When an error occurs, the [FUNCTION ERROR] screen opens. If several errors have occurred, they are displayed on multiple pages. Touch {Next err} to display them.

7.1 How to Read the [FUNCTION ERROR] Screen

FUNCTION ERROR

| Last err | Next err | | RETRY | ABORT | MUTE |

Sample nozzle No liquid error (1-032) Mode:0 Operation Seq:1 Solution:255 Remaining
pulse:0

The sample could not be detected.

<ERROR CANCELLATION>
1. If there is no error at the mechanical movement, press [Retry]. The process restarts.
2. If there is an error at the mechanical movement or if an error is issued again, press
[Abort]. Stop the process.

| Back | Next |
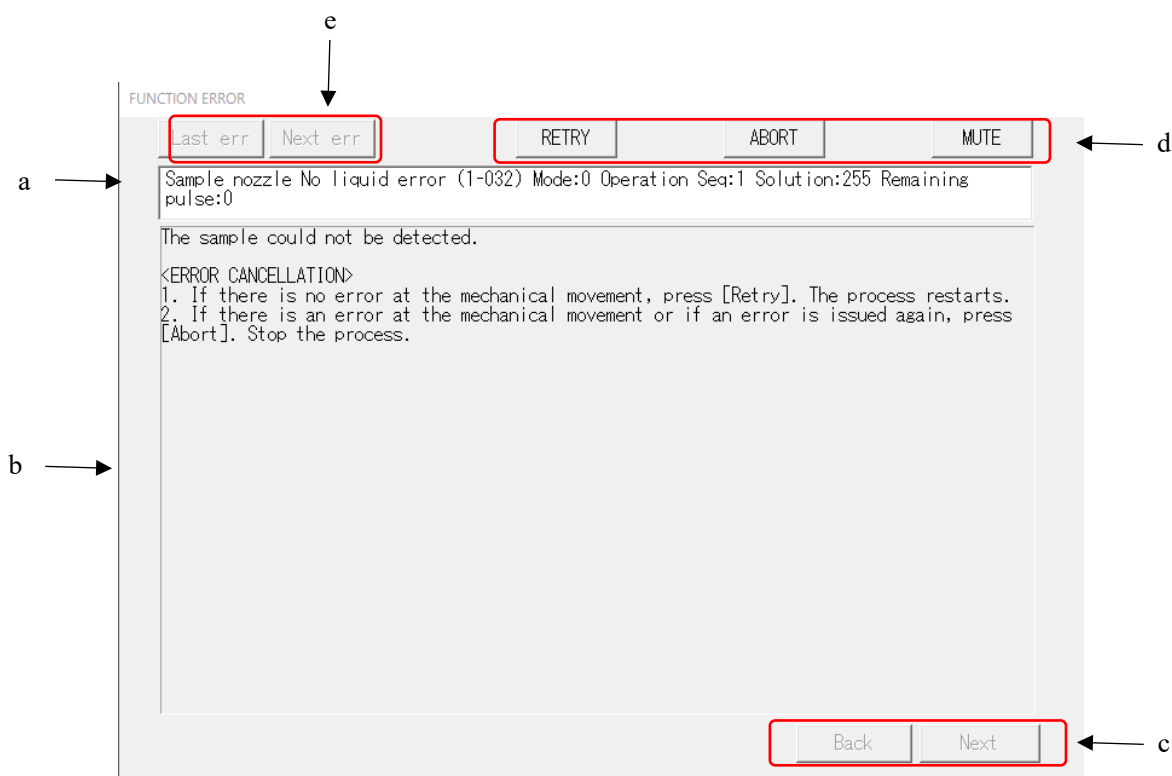
[FUNCTION ERROR] Screen

a	Error		Error No. and Error name.
b	Cause and method of cancellation		Explains errors and displays the cancellation method.
c	Page switching button		When the handling method for one error is explained over several pages, the pages can be switched.
		{Back}	Displays the previous page.
		{Next}	Displays the next page.
d	Handling buttons		Cancels an error.
			☞Page 229 "7.2 Error Handling Buttons"
e	Error select buttons		When several errors have occurred, error display is switched.
		{Last err}	Displays the previous error.
		{Next err}	Displays the next error.

7.2   Error Handling Buttons

At the top of the [ERROR FUNCTION] screen, there are buttons to handle the errors. Operations after touching the cancellation button are as follows.

Button name	Function
{RETRY}	Retries the sample process for which the error occurred.
{ABORT}	Ends the testing. When selected during testing, finishes the current sample process.
{Continue}	Resumes the operation of the mechanism stopped by the error.
{Close}	Closes the screen.
{MUTE}	Mutes the alarm sound.
{Shut down}	Shuts down the system. It may require a few minutes until the system shuts down.

(Note)   The cancellation button names change depending on the error.

7.3 Cancelling Errors

When an error occurs, cancel the error as follows:
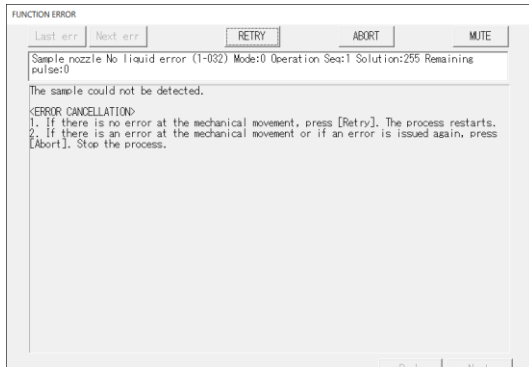
1 Check the error.
  ① Check the section with the error, and the error details.
  ② Touch one of the error handling buttons.
  ☞ Page 229 "7.2 Error Handling Buttons"
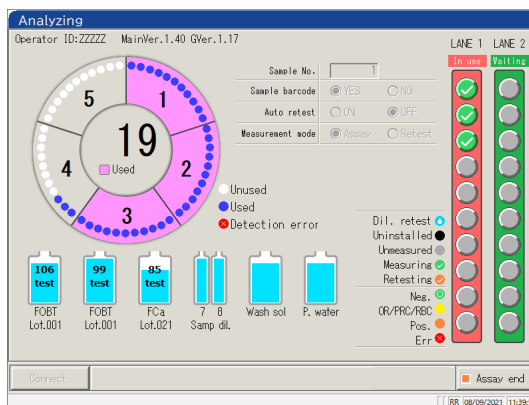
2 When a button other than {Abort} is selected, the error is cancelled, and the operation continues.
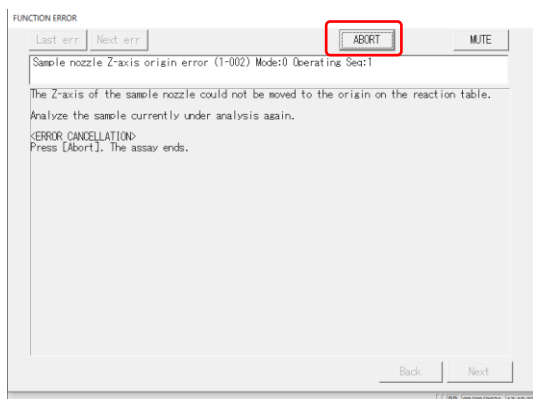
2 (Continued)

<When {ABORT} is selected>

① Touch { ABORT}.
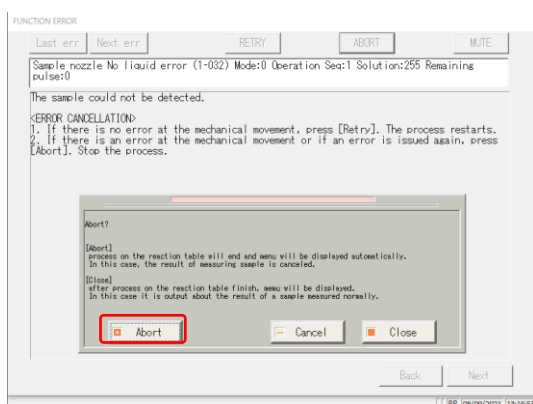
② Touch { Abort}.

    * Forcibly ends the processes on the reaction table and returns to the [Assay] screen. The results of samples testing are discarded.

{ Abort} : Forcibly ends the process and returns to the [Assay] screen.

{Cancel} : Aborts the forcible end and returns to the [Error] screen.

{Close} : Returns to the [Assay] screen upon completion of the process on the reaction table.

Note   For the following types of errors, touching {ABORT}

ends the process forcibly without opening the dialog box for forcible end execution.

    — Errors that occur during maintenance or prep functions (not during testing)

    — Errors that occur on the reaction table (Errors which cannot be closed)

7

Error Handling

7
Error
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Appendix

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1 Calculation Processing

The following calculation processes are performed during an analysis.

1.1 STD/QC Sample Measured Data Check

1.2 DA Value Calculation

1.3 Measured Data (Concentration) Calculation and Qualitative Assessment

1.4 Prozone Check

1.5 Reagent Blank Check (A1 Check)

1.6 Calculate Cell Blank

Appendix

1.1   STD/QC Sample Measured Data Check

Check whether the measurement data of STD samples or QC samples are proper values.

```
┌─────────────────────────────────────────────────┐
│  1.   STD sample measured data check            │
└─────────────────────────────────────────────────┘
```

① By looking at the large and small DA1 values at each point, check that the CC is showing an ascending curve.

② Check that the DA1 values of adjacent points are not the same. If the values are the same, the condition becomes "Abnormal."

③ Based on the STD standard set on the [CC Protocol] screen, check the deviation (%) between the theoretical value and the back fit value.

- STD-1   "Abn"rmal" if"DA is out of min/max range.

- STD-2   If the deviation is deviated from the set value, the

- STD-5   condition becomes "Abnormal."

- STD-6   "Abn"rmal" if"DA is out of min/max range.

The data is checked based on the limit value set on the {Set} tab on the [QC process] screen.

The condition becomes abnormal under the following conditions:

- When the QC setting is lower than the min value

```
┌─────────────────────────────────────────────────┐
│  2.   QC sample measured data check             │
└─────────────────────────────────────────────────┘
```

- When the QC setting is the max value or above

1.2   DA Value Calculation

The DA value is the final measurement result. Measured data (concentration value: X) are calculated from DA values and calibration curves. When a reagent is dispensed to a cell that has a sample dispensed, latex agglutination occurs and the 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).
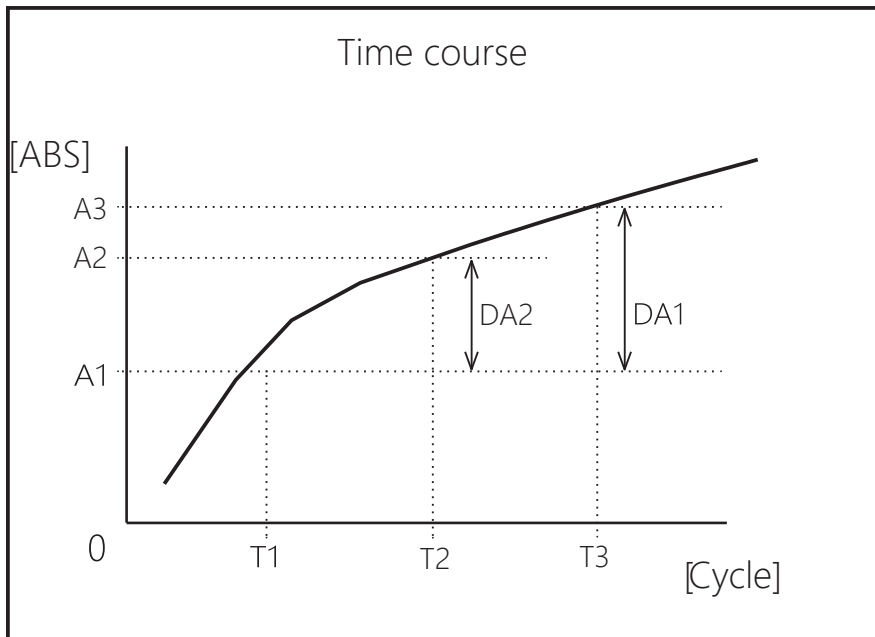
Figure 5

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 absorbances of the former and current cycles.

(Ex.) T1 = 3, T2 = 4, T3 = 12 [cycle]

A1 = (Absorbance of the 3rd cycle + Absorbance of the 2nd cycle)/2

A2 = (Absorbance of the 4th cycle + Absorbance of the 3rd cycle)/2

A3 = (Absorbance of the 12th cycle + Absorbance of the 11th cycle)/2

However, when T1 = 2, A1 = absorbance of the 2nd cycle.

DA values are the amount of change for A1, A2, and A3.

DA1 : A3 - A1–DA2 : A2 - A1–

1.3   Measured Data (Concentration) Calculation and Qualitative Assessment

Measured data (concentrations) are calculated using DA values and calibration curves. The qualitative assessment is performed by comparing the corrected measured data and the cut-off values.

```
┌─────────────────────────────────────────────┐
│ 1.  Calculate measured data (concentrations) │
│     using DA values and calibration curves.  │
└─────────────────────────────────────────────┘
```

☞Page 236 "1.2 DA Value Calculation"

```
┌─────────────────────────────────────────────┐
│ 2.  Range check by minimum/maximum           │
│     measurement value*                       │
└─────────────────────────────────────────────┘
```

OR   : Displayed when the measured data has exceeded the maximum measurement value.

Concentration   : Displayed when the measured data is at or below the maximum measurement value.

UR   : Displayed when the measured data is lower than the minimum measurement value.

☞Page 217 "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.

Appendix

1.4   Prozone Check

Prozone checking is conducted using two methods: RBC and PRC.

RBC method: Compares the absorbance of the RBC points in STD-6 (maximum concentration point) and the sample.

PRC method: Compares the DA2 values in STD-6 (maximum concentration point) and the sample.

■   RBC method

When comparing the RBC point sample absorbance (a) and STD-6 absorbance (b), if the following relationship is formed, the sample is designated as a "prozone sample."

$$\text{(b) x RBC method coefficient} < \text{(a)}$$

Time course

[ABS]

Prozone sample

a

b

STD-6

0

RBC point
[Measured max value]

[Cycle]
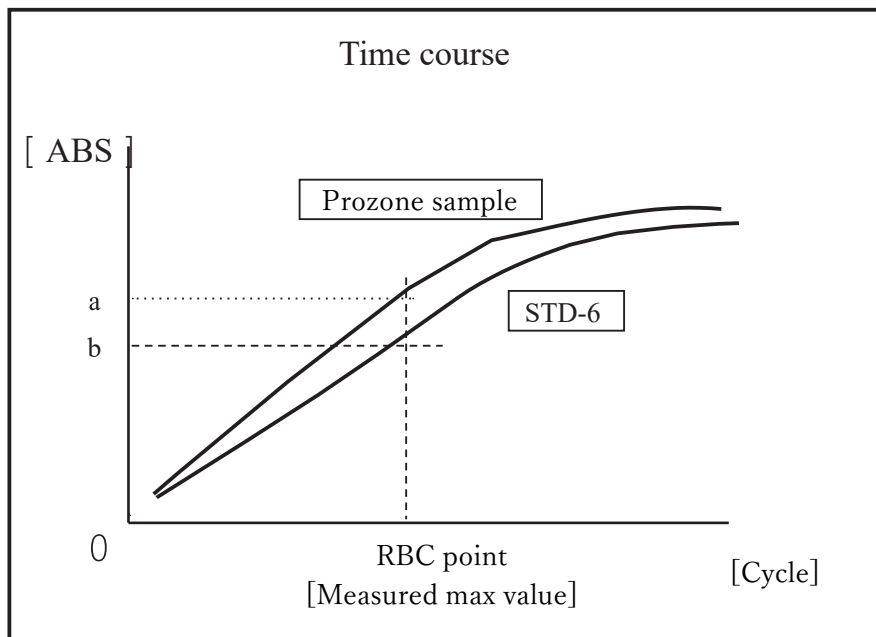
Figure 6

(Note)   RBC method coefficient is set by "9 RBC method coefficient" on {Page 2}a of [Protocol setting] - [S–mple/QC Protocol setting] screen.

(Note)   Sample absorbance (a) and STD-6 absorbance (b) are the mean values of the RBC point and the former point respectively.

   (Ex.) When the RBC point is 5

      (a) and (b) are

      (Absorbance of 5th cycle + absorbance of 4th cycle)/2.

■   PRC method

When comparing the DA2 values of the sample and STD-6, if the following relationship is formed, the samples are designated as "prozone samples."

$$DA2_{STD\text{-}6} \times PRC \text{ method coefficient} < DA2 \text{ sample}$$
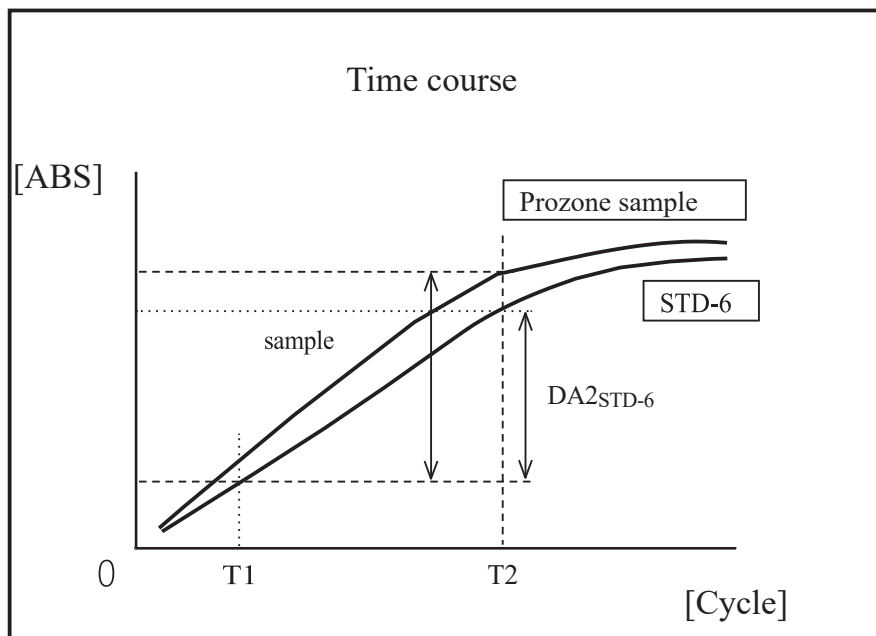
Figure 7

DA2 sample: DA2 value of prozone sample

DA2$_{STD\text{-}6}$: DA2 value of STD-6

NN1-1741 Rev.1

1.5   Reagent Blank Check (A1 Check)

Normal dispensing of the reagent is checked by using the T1 cycle absorbance.

The absorbance is obtained from the mean value of T1 cycle ADC value and T1-1 cycle ADC value. The value is compared with the max value and the min value of the A1 check.

The "reagent blank error" is output if the condition is as follows.

> Mean absorbance < A1 check min value
> or
> Mean absorbance > A1 check max value

(Note)   Absorbance = $\log_{10}$ (ADC space/ADC mean value) × 10000 – Cell blank value

(Note)   A1 check max and min values are set by the manufacturer. Users cannot change the settings.

1.6   Calculate Cell Blank

After the analysis starts, detection is performed for all cells (55 cells) for each cycle.

The cell blank value of each cell is calculated from the following formula using ADC value (ADC space, ADC blank cell) which was measured while the cell had no sample dispensed.

> Cell blank value = $\log_{10}$ (ADC $_{space}$/ADC $_{blank\ cell}$) x 10000

ADC $_{space}$: ADC value of the space between cells (no cell condition)

ADC $_{blank\ cell}$: ADC value when a blank cell is measured

2 Printing Examples

This section describes various printing examples.

2.1 Positive Sample printing

2.2 Final Result Printing at Retesting

2.3 Printing when STD Sample and QC Sample are Measured

2.4 Printing Error Messages

ID of an operator performing the test

Rack No.-
Rack position No.

Test item

Result of qualitative judgment

DA value

Sample sequence No.

Test complete date and time

System completion date and time

```
*********************************
POWER ON            20/02/03 09:00
*********************************
*********************************
START               20/02/03 10:00
ID:12345678901234567890
*********************************
FOBT   931    20/01/24 15:25
FCa    932    20/01/24 16:28
*********************************
005-01   00001   123456789012345
FOBT
 1+   200      ※      200 ng/mL

005-02   00002   234567890123451
FOBT
                 Reag.Pippet Err
*********************************
END                 20/02/03 10:30
*********************************
POWER OFF           20/02/03 15:40
*********************************
```

Date and time of system power on

Test start date and time

Test item name and reagent lot and CC measurement date and time

Sample ID

Measurement value

Error message (Reagent dispensing error) ☞Page 247

OR, UR, and PRC are printed at sections with ※.

2.1   Positive Sample Printing

<When the number of replications is 1>

"Sample information" and the <u>positive</u> "test result" are printed in bold letters.

```
005-01    00001        123456789012345
FOBT
   -      50               50 ng/mL


005-02    00002        234567890123451
FOBT
  1+     200              200 ng/mL
```

<When the number of replications>1 and the mean value is a positive sample>

Only the line containing the mean value is printed in bold.

(Example: Replications = 3)

```
005-01    00001        123456789012345
FOBT
   -      50               50  ng/mL
  1+     200              200  ng/mL
   -      50               50  ng/mL
___ __ __ ___ ___ ___ ___ ___ ___
  1+                      100  ng/mL
          86.60          86.6

005-01    00001        123456789012345
FCa
   -      50               50  ng/mL
  1+     200              200  ng/mL
   -      50               50  ng/mL
___ __ __ ___ ___ ___ ___ ___ ___
  1+                      100  ng/mL
          86.60          86.6
```

SD value of measured data

CV value of measured data

Note   The calculation of average depends on digit setting (integer or tenths place).

Printed value is rounded to the set digit.

☞   9. Value Format under "6.1.8 Output Format Settings (Basic Format)" on page 200.

Appendix

2.2   Final Result Printing at Retesting

The Dilution factor is printed after the item name. Other sections are the same as the first test.

<When the number of replications is 1>

```
094-03  00001   123456789012345
FOBT    (A100)
   1+    200            200 ng/mL
FCa     (A)
   -     50              50 ng/mL


040-04  00002   123456789012345
FOBT    (A200)
   -     40              40 ng/mL
FCa     (A100)
   -     34              34 ng/mL
```

Dilution factor

A: Retest without dilution

A10: Dilute by a factor of 10 and retest

A20: Dilute by a factor of 20 and retest

A100: Dilute by a factor of 100 and retest

A200: Dilute by a factor of 200 and retest

A400: Dilute by a factor of 400 and retest

2 Printing Examples

<When the number of replications is larger than 1>

```
005-04  0001      123456789012343
FOBT    (A100)
 -       50                50  ng/mL
 1+     200               200  ng/mL
 -       50                50  ng/mL
 ___ __ ___ __ ___ __ ___ __ ___ _
 1+                       100  ng/mL
           [ 86.60 ]   [ 86.6 ]

FCa     (A20)
 -       50                50  ng/mL
 1+      50                50  ng/mL
 -       50                50  ng/mL
 ___ __ ___ __ ___ __ ___ __ ___ .
 -                         50  ng/mL
           86.60          86.6


005-07  0002      123456789012343
FOBT    (A200)
 -       50                50  ng/mL
 1+     200               200  ng/mL
 -       50                50  ng/mL
 ___ __ ___ __ ___ __ ___ __ ___ .
 1+                       100  ng/mL
           86.60          86.6

FCa     (A100)
 -       50                50  ng/mL
 1+     200               200  ng/mL
 -       50                50  ng/mL
 ___ __ ___ __ ___ __ ___ __ ___ .
 1+                       100  ng/mL
           86.60          86.6
```

CV value of the measured value

SD value of the measured value

2.3   Printing when STD Sample and QC Sample are Measured

STD・QC sample measurement start

DA1 value

STD point No.

Average value of DA1

CV value of DA1

DA2 value

DA2 value used for CC

CV value of DA2

```
********************************
FOBT       STD START
********************************

049-03 STD6    2396    232
               2305    217
               2254    209
        - - - - - - - - - - - -
               2305    217
               0.0     0.0
```

```
049-08 STD1     23      9
                10      5
                15      7
        - - - - - - - - - - - -
                15      7
                0.0     0.0
********************************
FOBT       CAL. CURVE
********************************

STD1      0.0 ng/mL    15    7
DA1 (       0 ng/mL   +0.0)
STD2     56.3 ng/mL    77   15
DA1 (      57 ng/mL   +1.2)
```

Replicate No. 1

Replicate No. 2

Replicate No. 3

The replicate result and the mean value are printed for each STD point.

DX (%)

Theoretical value

Back fit

Regression coefficient

```
STD6    900.0 ng/mL   2305   217
DA1 (    900 ng/mL    +0.0)

CAL CURVE TYPE =   LNR-LNR
DIMENSION      =   3
CAL CURVE EQUATION
DA1 F(0)=   1.562235e+001
     F(1)=   7.215826e-001
     F(2)=   6.503654e-003
     F(3)=  -4.976670e-006

********************************
```

CC type

LNR-LNR : Primary - Tertiary
ALOKA   : Aloka curve
3-SPLINE : Spline
1-SPLINE : Polygonal line

CC dimension

Continue to the next page

2 Printing Examples

Continued from the previous page

QC sample measurement start

QC sample No.

Measured data

Mean value of measured values

SD value of measured data

CV value of measured value

The replicate result and the mean values are printed for each QC.

```
************************************
  FOBT          QC     C1/C2/C3
************************************
049-08 C-8000
          120      415 ng/mL
          122      415 ng/mL
          ----------------------
          121      415 ng/mL
           0.0       0.0
049-09 C-8001
          301      381 ng/mL
          304      380 ng/mL
          ----------------------
          302      381 ng/mL
           0.71      0.2
049-10 C-8002
          301      381 ng/mL
          304      380 ng/mL
          ----------------------
          302      381 ng/mL
           0.71      0.2

************************************
20/03/26 13:56    931
```

CC measurement date and time

Reagent lot.

CC graph

```
 DA
2325




                              -CONC.
           900.0
```

```
************************************
STD·QC END
CAL.CURVE·QC REGISTER
************************************
```

When CC is cancelled, CANCEL is printed.

Appendix

2.4   Printing Error Messages

Meanings of error messages are as follows.

```
************************************
 POWER ON        20/03/26 09:40
************************************

************************************
 START           20/03/26 10:56
ID:12345678901234567890
************************************
 FOBT    931     20/03/25 15:19
 FCa     932     20/03/25 16:25
************************************
 005-01 00001    123456789012343
FOBT
1+    200            200 ng/mL

 005-02 00002
FOBT
  7788        Reag. Pippet Err
************************************
 END             20/03/26 11:52
************************************
```
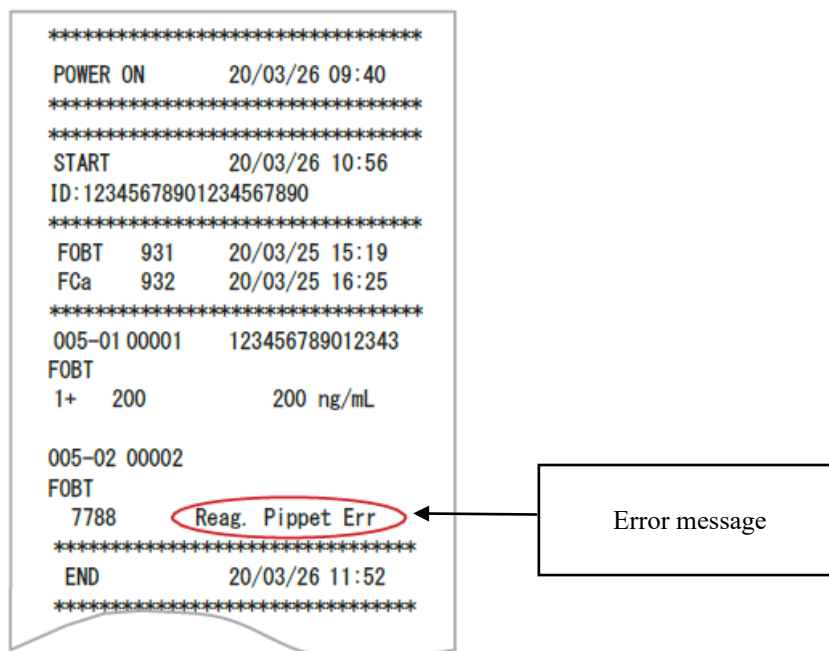
Error message

Printed Error Message	Meaning
Cell Blank Error	Cell blank error
No Sample	No sample
Sample Fusoku	Sample short
No Reagent1	No R1 reagent
No Reagent2	No R2 reagent
Mixing Error	Mixing error
Reag.Blank Error	Reagent blank error
Cal.Curve1 Error	STD error (DA1)
Cal.Curve2 Error	STD error (DA2)
Samp.Pippete Err	Sample not dispensed
R1. Pippete Err	R1 reagent no dispensing
R2. Pippete Err	R2 reagent no dispensing
Sample Blank Err	Sample amount error
Control Error	Control error

Appendix

<div style="border:1px solid black; padding:10px;">

3   Error List

</div>

This section describes error messages that are displayed on the screen, as well as error messages printed by the printer.

3.1   ERR# 0-1001 to 0-3005 (Main)

Error No. ERR#0-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
ERR# 0-1001 -		
1001	G communication error	(Not displayed on screen)
	G communication error	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [SHUT DOWN] Turn off the system.
1003	Unexpected command received	(Not displayed on screen)
	Unexpected command received	Operation continues automatically.
1004	TELEGRAM DATA ERROR	(Not displayed on screen)
	TELEGRAM DATA ERROR	Operation continues automatically.
1005	No reply from GLIFE command	(Not displayed on screen) Touch [SHUT DOWN] to turn off the power.
	No reply from GLIFE command	Finish the sample process currently being tested.
1006	No reply from G command	(Not displayed on screen) Touch [SHUT DOWN] to turn off the power.
	No reply from G command	Finish the sample process currently being tested.
1007	Abort failed	(Not displayed on screen)
	Abort failed	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [SHUT DOWN] Turn off the system. [CLOSE] Close error display
1008	Multiple absorbance data received in the same cycle.	INF1: Ready counter * No effect on the measurement data.
	Multiple absorbance data received in the same cycle.	However, if it occurs repeatedly, contact the seller. <ERROR CANCELLATION>
	Online ACK Timeout	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE] Close error display

Error No. ERR#0-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
ERR# 0-1100 -		
1101	Online ACK timeout error	(Not displayed on screen)
	Online ACK Timeout	An error occurred in communication with an external computer. Operation continues automatically.
1102	Online NAK count error	(Not displayed on screen)
	Online NAK count	An error occurred in communication with an external computer. Operation continues automatically.
1103	Online data reception error	(Not displayed on screen)
	Online data reception error	An error occurred in communication with an external computer. Operation continues automatically.
1111	Online connection error	(Not displayed on screen)
	Online connection error	An error occurred in communication with an external computer. Operation continues automatically.
1112	Online err [NG RECEIVE]	(Not displayed on screen)
	Online err [NG RECEIVE]	An error occurred in communication with an external computer. Operation continues automatically.
1113	Online err [ABNORMAL DATA]	(Not displayed on screen)
	Online err [ABNORMAL DATA]	An error occurred in communication with an external computer. Operation continues automatically.
1114	Online err [TIME OUT]	(Not displayed on screen)
	Online err [TIME OUT]	An error occurred in communication with an external computer. Operation continues automatically.
ERR# 0-1400 -		
1409	Insufficient test reagents	The reagent ran out.
	Insufficient test reagents	Set the reagent after the assay completes. <ERROR CANCELLATION> <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE]: Close error display.
1410	Insufficient buffer volume	Buffer ran out.
	Insufficient buffer volume	Set the buffer after the assay completes. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE]: Close error display.

Appendix

Error No. ERR#0-	Screen Message (Upper)	Error Description and Cancelling Procedure
	Printed Message (Lower)	
1416	Double sample barcode	(Not displayed on screen)
	Double sample barcode	A sample barcode is duplicated. This sample will not be tested. Operation continues automatically.
1417	Sample barcode reading error	(Not displayed on screen)
	Sample barcode reading error	A sample barcode couldn't be read. This sample will be tested. Operation continues automatically.
1418	Sample barcode digit error	(Not displayed on screen)
	Sample barcode digit error	While reading sample barcodes, for one sample, the number of barcode digits exceeded the limit was found. This sample will be tested. Operation continues automatically.
1430	Cell check error	(Not displayed on screen)
	Cell check error	A measurement cell has been set. Touch [ABORT] and set the cells.
1435	Reagent blank error	(Not displayed on screen)
	Reagent blank error	The reagent blank is abnormal. Operation continues automatically.
1436	Cell blank error	(Not displayed on screen)
	Cell blank error	Cell blank status is abnormal. Operation continues automatically. To replace the cells, touch [ABORT].
1437	Transportation Result Data Error	(Not displayed on screen)
	Transportation Result Data Error	An error occurred in rack transfer. Touch [ABORT].
1438	Container check results error	(Not displayed on screen)
	Container check results error	CONTAINER CHECK FAIL This sample will not be tested. Operation continues automatically.
1439	Maximum number of samples reached Warning	Rack loading stopped due to reaching maximum number of sample analysis after a system start up.
	Maximum number of samples reached Warning	Close error display. 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
1440	Program error	PROGRAM ERROR
	Program error	Close error display. Close the instrument under main analysis screen of [Completed] <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Close error display

Error No. ERR#0-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
1441	Detection start position error	Some cells output a detection start position error during cell replacement. Cells with an error will not be used for the assay. The cell may be tilted. Check the cell placement and replace the cell again. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE]: Close error display
	Detection start position error	
1442	Usable cells ran out	Usable cells ran out. After closing this error message, replace the cell on the Cell replacement screen. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE]: Close error display
	Usable cells ran out	
1443	Purified water volume 0	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE]: Close error display
	Purified water volume 0	
1444	Washing solution volume 0	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE]: Close error display
	Washing solution volume 0	
1445	Reagent double barcode	There are multiple reagents with the same barcode. *P1 to P8 Presence of double barcode at installation positions 1 to 8 (0: Normal, 1: Double barcode)
	Reagent double barcode	
1446	LED deterioration detected	LED has deteriorated. Check that there are no foreign objects on the table. If the issue persists, please contact the seller. LED wavelength (nm): Status Wavelength nm 660, 800, 600, and 340 Status 0: Normal, 1: Caution about deterioration, 2: Deterioration detected <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE] Close error display
	LED deterioration detected	
1447	Caution about LED deterioration	LED may be deteriorated. Be careful. LED wavelength (nm): Status Wavelength nm 660, 800, 600, and 340 Status 0: Normal, 1: Careful about deterioration <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE] Close error display
	Caution about LED deterioration	

Appendix

Error No. ERR#0-	Screen Message (Upper) / Printed Message (Lower)	Error Description and Cancelling Procedure
1448	Cell blank range value error	Cell blank range value error occurred for some cells during cell replacement. Cells with an error will not be used for the assay.
	Cell blank range value error	Check the cell condition on the Cell replacement screen. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE] Close error display
1449	Measurement interruption occurred	The measurement was interrupted. INF1: Causes of interruptions No. 1 to 18 No.01: All cells were used No.11: Container check results error No.02: Cell shortage (for one test) No.12: Order error
	Measurement interruption occurred	No.03: Cell shortage No.13: Puncture error (for one consecutive sample) No.04: Empty cell No.14: Sample dispense error No.05: Double BC error No.15: Reagent dispense error No.06: Reagent shortage No.16: Mixing error No.07: Buffer shortage No.17: Temperature error (reagent refrigerator) No.08: Purified water shortage No.18: Temperature error (reaction table) No.09: Washing solution shortage No.19: No usable reagent No.10: LED deterioration error <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE] Close error display
1450	Temperature error at reagent refrigerator during analysis	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE] Close error display
	Temperature error at reagent refrigerator during analysis	

Error No. ERR#0-	Screen Message (Upper)	Error Description and Cancelling Procedure
	Printed Message (Lower)	
1452	Cell presence check error	In priming before the assay, some cells output the cell presence error.
	Cell presence check error	Blocks containing cells with an error will not be used for the assay. Check the cell condition on the Cell replacement screen. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE] Close error display
1453	Rack error	Set rack error.
	Rack transfer error	INF1: Reason for the stop No.05: Rack barcode reading error No.06: Rack setting outside the range <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [CLOSE] Close error display
1454	Sampling volume check error	(Not displayed on screen)
	Sampling check error	Operation continues automatically.
1455	Temperature error of reaction table during analysis	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	Temperature error of reaction table during analysis	[CLOSE] Close error display
1456	Usable reagent is not installed.	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	Usable reagent is not installed.	[CLOSE] Close error display

Appendix

Error No. ERR#0-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
ERR# 0-1500 -		
1501	Startup failed	(Not displayed on screen) Unable to start the system.
	Startup failed	Touch [SHUT DOWN] to turn off the power.
1502	Analysis end processing failed	(Not displayed on screen) Unable to complete testing.
	Analysis end processing failed	Touch [SHUT DOWN] to turn off the power.
1503	Program end processing failed	(Not displayed on screen) Unable to end the system.
	Program end processing failed	Touch [SHUT DOWN] to turn off the power.
1504	A required file cannot be found.	FILE MISSING

	No file	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.

1505	func.ini is abnormal or cannot be found	(Not displayed on screen) The file is missing.
	func.ini is abnormal	Touch [SHUT DOWN] to turn off the power.
1506	kinou.dat is abnormal or cannot be found	(Not displayed on screen) The file is missing.
	kinou.dat is abnormal	Touch [SHUT DOWN] to turn off the power.
1509	Necessary common memory cannot be found.	(Not displayed on screen) Memory cannot be found.
	Necessary common memory cannot be found.	Operation continues automatically.

Error No. ERR#0-	Screen Message (Upper) / Printed Message (Lower)	Error Description and Cancelling Procedure
1511	Common memory initialization failed	PROGRAM ERROR (MEMORY) due to file setting failure INF1 : MEMORY No.1 - 53–01: Sample barcode (SysTBcr.txt) 11: Sample cup (SysTube.txt) 02: Rack information (SysRack.txt) 12: Order test (SysOdrAna.txt) 03: Environment setting (SysEnv.txt) 13: Sample/QC protocol (PrtSmpQc.txt) 04: Data output (SysDtOut.txt) 14: CC1-CC6 protocol (PrtCC.txt) 05: Output format (SysForm.txt) 15: Common protocol 1 (PrtCom1.txt) 06: RS232C setting (SysRS.txt) 16: Common protocol 2 (PrtCom2.txt) 07: Analysis method (SysSoku.txt) 17: Analysis (AnaInf.dat) 08: Alarm setting (SysAlm.txt) 18: Test mode (SokuMode.dat) 09: Screen saver (SysScrn.txt) 19: Reagent CC (SiyakuCC.dat) 10: STD/QC run (SysStdQc.txt) 20: Reagent volume (SiyakuZan.dat) <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [SHUT DOWN] Shutdown the system.
		PROGRAM ERROR (MEMORY) due to file setting failure INF1 : MEMORY No.1 to 53 21: Buffer volume (KBufZan.dat) 31: System status (-------- ----) 22: Shift register (--------) 32: Error information (----) 23: Supply units (KUnitinf.dat) 33: Subsystem (----) 24: Unload units (HUnitinf.dat) 34: Additional analysis (----) 25: Rack・Sample (RackInf.dat) 35: Test result (----) 26: Analysis data (AnaRslt.dat) 36: STD・QC result (----) 27: STD result data (StdRslt.dat) 37: Instrument information (----) 28: Cell blank analysis (CellBlnk.dat) 38: CC information (----) 29: Temperature information (--------) 39: Printer (----) 30: Protocol DWLD (--------) 40: Spare parts (U_Parts.dat) <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [SHUT DOWN] Shutdown the system.
	(Messages will not be printed.)	PROGRAM ERROR (MEMORY) due to file setting failure INF1 : MEMORY No.1 to 53 41: Spare parts (S_Parts.dat) 51: Washing solution information (WashSol.dat) 42: Additional analysis recovery (-----) 52: Retest order information (----) 43: Reagent・CC (-----) 53: Switch display language (SysLang.txt) 44: Auto Startup (AutoStart.txt) 45: Log in information (----) 46: Cell management information (CellMng.dat) 47: Rack lane information (RackLane.dat) 48: Reagent history information (SRireki.dat) 49: Buffer information (KRireki.dat) 50: Purified water information (Water.dat) <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR. [Shutdown] Shutdown the system.

Appendix

Error No. ERR#0-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
ERR# 0-1600 -		
1601	COM port is not properly connected	PRINT ERROR COM PORT CONNECTION FAIL. CHECK CONNECTION. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	COM port error	[CLOSE] Close error display
ERR# 0-2000 -		
2003	Replace the purified water with the washing solution	Replace from purified water to washing solution. After the replacement, press [Close] button. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	(The message is not printed.)	[CLOSE] Close error display
2004	Shutdown error Warning	The system was shut down abnormally last time. The hard disk may be damaged. If there is something wrong with the hard disk after system startup, please contact our seller. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	Shutdown error Warning	[CLOSE] Start up the system.

Error No. ERR#0-	Screen Message (Upper)	Error Description and Cancelling Procedure
	Printed Message (Lower)	
ERR# 0-3000 -		
3001	Reagent shortage	Reagent shortage. Finish analysis. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	Reagent shortage	[CLOSE] Close error display
3002	Empty cell shortage	Analyzing cell shortage. Finish analysis. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	Empty cell shortage	[CLOSE] Close error display
3003	STD or QC installation error	STD or QC installation error Finish analysis. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	Installation error	[CLOSE] Close error display
3004	QC expiration date expired	QC expiry date expired. Finish analysis. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	QC expired	[CLOSE] Close error display
3005	Test item is undecided	Test item setting error Finish analysis. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR.
	Test item is undecided	[CLOSE] Close error display

Appendix

3.2   ERR# 1-001 - 1-200(SS1)

Error No. ERR#1-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
ERR# 1-001 -		
002	Sample nozzle Z-axis origin error (Test) SAMP Z ORG error	The Z-axis of the sample nozzle could not be moved to the origin on the reaction table. Analyze the sample currently under analysis again. <ERROR CANCELLATION> Press [ABORT]. The assay ends.
003	Sample nozzle Z-axis origin error (Test) SAMP Z ORG error	The Z-axis of the sample nozzle could not be moved to the origin on the rack or on the overflow cell. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. The Error screen closes.
004	Sample nozzle Z-axis origin error (Out of test) SAMP Z ORG error	The Z-axis of the sample nozzle could not be moved to the origin. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
005	Sample nozzle Theta-axis origin error (shaft origin error (Test) SAMP θ ORG error	The Theta-axis of the sample nozzle could not be moved to the origin. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. The Error display closes.
006	Sample nozzle Theta-axis origin error (Out of test) SAMP θ ORG error	The Theta-axis of the sample nozzle could not be moved to the origin. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
007	Sample dispensing pump origin error (Test) SAMP P ORG error	The syringe of the sample dispensing pump could not be moved to the origin. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. The Error display closes.

Error No. ERR#1-	Screen Message (Upper) / Printed Message (Lower)	Error Description and Cancelling Procedure
008	Sample dispensing pump origin error (Out of test) / SAMP P ORG error	The syringe of the sample dispensing pump could not be moved to the origin. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
009	Rack installation lane origin error (Out of test) / Rack installation lane ORG error	The rack lane could not be moved to the origin. <ERROR CANCELLATION> 1. Press [ABORT]. Stop the process.
010	Rack conveyance lane origin error (Out of test) / Rack conveyance lane ORG error	The rack lane could not be moved to the origin. <ERROR CANCELLATION> 1. Press [ABORT]. Stop the process.
011	Sample nozzle Z-axis jam error (Test) / SAMPZ JAM error	The Z-axis of the sample nozzle jammed while descending. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. Close Error display.
012	Sample nozzle Z-axis jam error (Out of test) / SAMPZ JAM error	The Z-axis of the sample nozzle jammed during descending. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
013	Sample nozzle jam sensor error (Test) / SAMP jam sensor error	The jam sensor did not work correctly at the sample nozzle. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. Close Error display.
014	Sample nozzle jam sensor error (Out of test) / SAMP jam sensor error	The jam sensor did not work correctly at the sample nozzle. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.

Appendix

Error No. ERR#1-	Screen Message (Upper) / Printed Message (Lower)	Error Description and Cancelling Procedure
022	Rack conveyance error / Rack conveyance error	The rack could not be pulled into the end in the equipment during the rack transfer. A rack or other obstacle may exist on the transfer line. <ERROR CANCELLATION> 1. Press [ABORT]. 2. Remove the rack on the transfer line.
023	Rack detection error / Rack detection error	While the rack transfer, the rack could not be detected. The result of this rack is not output. After the analysis is completed, remove any racks in the rack set position and initialize with the Prep functions. Check the rack orientation and analyze again. <ERROR CANCELLATION> 1. Press [Close]. Close Error display.
024	Rack discharge error / Rack discharge error	While unloading the rack, the rack could not be transferred to the set position. Or the rack could not be provided correctly. An obstacle may exist on the transfer line. The result for this rack is not output. Analyze again. If the analysis result of the previous rack is output, close the Error screen and abort. <CANCELLATION> Press [Close]. Close Error display.
031	Sample nozzle No liquid error (Test) / SAMP No liquid	The liquid level could not be detected. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. Close Error display.
032	Sample nozzle No liquid error (Out of test) / SAMP No liquid	The liquid level could not be detected. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
033	Sample nozzle Erroneous liquid level detection error (Test) / SAMP nozzle Erroneous liquid level detection error	The position which the liquid level was detected was not the expected position. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. Close Error display.

Error No. ERR#1-	Screen Message (Upper) / Printed Message (Lower)	Error Description and Cancelling Procedure
034	Sample nozzle Erroneous liquid level detection error (Out of test) / SAMP nozzle Erroneous liquid level detection error	The position which the liquid level was detected was not the expected position. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
041	Squeeze mechanism Operation error (Test) / Squeeze error	The squeeze DC motor did not work correctly. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. Close Error display.
042	Squeeze mechanism Operation error (Out of test) / Squeeze error	The squeeze DC motor did not work correctly. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. Restart the process. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
043	Puncturing mechanism Operation error (Test) / Puncture error	The puncture DC motor did not work correctly. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. Close Error display.
044	Puncturing mechanism Operation error (Out of test) / Puncture error	The puncture DC motor did not work correctly. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
071	Sample and rack barcode reader error (Test) / SAMP barcode reader error	The communication with the barcode reader did not work correctly. Analyze the sample currently under analysis again. <ERROR CANCELLATION> Press [ABORT]. The assay ends.
072	Sample and rack barcode reader error (Test) / SAMP barcode reader error	The communication with the barcode reader did not work correctly. Wait for the results for samples currently the analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> ① Press [ABORT]. ② The assay ends when [ABORT] is pressed on the displayed dialog. When [Close] is pressed, the current sample is analyzed through the end, but no additional samples will be analyzed.

Appendix

Error No. ERR#1-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
073	Sample and rack barcode reader error (Out of test) SAMP barcode reader error	The communication with the barcode reader did not work correctly. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
074	Sample and rack barcode reader Communication timeout error (Test) Barcode communication timeout	Reading the barcode did not complete within the specified time. Analyze the sample currently under analysis again. <ERROR CANCELLATION> Press [ABORT]. The assay ends.
075	Sample and rack barcode reader Communication timeout error (Test) Barcode communication timeout	The reagent could not be detected. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> ① Press [ABORT]. ② The assay ends when [ABORT] is pressed on the displayed dialog. When [Close] is pressed, the current sample is analyzed through the end, but no additional samples will be analyzed.
076	Sample and rack barcode reader Communication timeout error (Out of test) Barcode communication timeout	Reading the barcode did not complete within the specified time. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.

Appendix

Error No. ERR#1-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
ERR#1-101 -		
101	Set the rack.	<CANCELLATION>
	(The message is not printed.)	1. Set the rack on the lane and press [Continue]. The process continues.
		2. When aborting the process, press [ABORT].
105	Close the rack setting cover.	The process temporarily stops.
	(The message is not printed.)	<CANCELLATION>
		1. Close the rack lane cover and press [Retry]. The process restarts.
		2. If the message is issued again, press [ABORT]. Stop the process.
108	Remove the rack from the displayed lane No. (Test)	The rack could not be ejected.
		<CANCELLATION>
		1. Remove the racks on the displayed lane No. and press [Retry]. Restart the process.
	(The message is not printed.)	2. When aborting the process, press [ABORT].
109	Remove the rack from the displayed lane No. (Out of test)	The rack transfer motor was returned to the origin.
		<CANCELLATION>
		1. Remove the rack of lane 1 or lane 2 and press [Continue]. The process continues.
	(The message is not printed.)	2. When aborting the process, press [ABORT].

Appendix

3.3   ERR# 2-001 - 2-200(SS2)

Error No. ERR#2-	Screen Message (Upper) / Printed Message (Lower)	Error Description and Cancelling Procedure
ERR#2-001 -		
002	Reagent nozzle Z-axis origin error (Test)	The Z-axis of the reagent nozzle could not be moved to the origin on the reaction table. Analyze the sample currently under analysis again. <ERROR CANCELLATION> Press [ABORT]. The assay ends.
	REAGZ ORG error	
003	Reagent nozzle Z-axis origin error (Test)	The Z-axis of the Reagent nozzle could not be moved to the origin on the reagent refrigerator or on the overflow cell. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. The Error display closes.
	REAGZ ORG error	
004	Reagent nozzle Z-axis origin error (Out of test)	The Z-axis of the reagent nozzle could not be moved to the origin. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
	REAGZ ORG error	
005	Reagent nozzle Theta-axis origin error (Test)	The Theta-axis of the reagent nozzle could not be moved to the origin. Wait for the results for samples currently under the analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. The Error display closes.
	REAG θ ORG error	
006	Reagent nozzle Theta-axis origin error (Out of test)	The Theta-axis of the reagent nozzle could not be moved to the origin. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
	REAG θ ORG error	
007	Reagent dispensing pump Origin error (Test)	The syringe of the reagent dispensing pump could not be moved to the origin. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. The Error display closes.
	REAGP ORG error	

Error No. ERR#2-	Screen Message (Upper) / Printed Message (Lower)	Error Description and Cancelling Procedure
008	Reagent dispensing pump Origin error (Out of test) / REAGP ORG error	The syringe of the reagent dispensing pump could not be moved to the origin. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
010	Reaction table Origin error / Reaction table ORG error	The motor on the reaction table could not move to the origin. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
012	Reagent refrigerator Origin error / REAG rotation ORG error	The motor of the reagent refrigerator could not be moved to the origin. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
013	Reagent nozzle Z-axis jam error (Test) / REAGZ JAM error	The Z-axis of the reagent nozzle jammed during descending. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. Close Error display.
014	Reagent nozzle Z-axis jam error (Out of test) / REAGZ JAM error	The Z-axis of the reagent nozzle jammed during descending. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
015	Reagent nozzle Jam sensor error (Test) / REAG jamming sensor error	A jam sensor error was detected at the reagent nozzle. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close].
016	Reagent nozzle Jam sensor error (Out of test) / REAG jamming sensor error	A jam sensor error was detected at the reagent nozzle. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.

Appendix

Error No. ERR#2-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
017	Reaction table Step-out error	The pulse motor on the reaction table stepped out.
	Table motor step-out	<ERROR CANCELLATION>
		1. Press [ABORT]. End the assay.
018	Reagent refrigerator Step-out error	The pulse motor of the reagent refrigerator stepped out.
		Wait for the results for samples currently under analysis.
	Refrigerator motor step-out	Re-analyze the errored samples and unmeasured samples.
		<ERROR CANCELLATION>
		Press [Close].
019	Pulse motor Step-out error	The pulse motor stepped out.
	Motor step-out	<Motor>
		1: Reaction table
		6: Reagent refrigerator
		<ERROR CANCELLATION>
		1. If there is no error at the mechanical movement, press [Retry]. It is initialized, and the process restarts.
		2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
031	Reagent nozzle No liquid error (Test)	The liquid level could not be detected.
		Wait for the results for samples currently under analysis.
	REAG No liquid	Re-analyze the errored samples and unmeasured samples.
		<ERROR CANCELLATION>
		Press [Close]. Close Error display.
032	Reagent nozzle No liquid error (Out of test)	The liquid level could not be detected.
		<ERROR CANCELLATION>
	REAG No liquid	1. If there is no error at the mechanical movement, press [Retry]. The process restarts.
		2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. The process stops.
033	Reagent nozzle Erroneous liquid level detection error (Test)	The position which the liquid level was detected was not the expected position.
		Wait for the results for samples currently under analysis.
	REAG Liquid level error	Re-analyze the errored samples and unmeasured samples.
		<ERROR CANCELLATION>
		Press [Close]. Close Error display.
034	Reagent nozzle Erroneous liquid level detection error (Out of test)	The position which the liquid level was detected was not the expected position.
		<ERROR CANCELLATION>
	REAG Liquid level error	1. If there is no error at the mechanical movement, press [Retry]. The process restarts.
		2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. The process is aborted.

Appendix

Error No. ERR#2-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
035	Overflow cell (for reagent nozzle) Liquid level detection error (Test)	An error was detected while supplying the purified water to the overflow cell. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples.
	OF Liquid level error	<ERROR CANCELLATION> Press [Close].
036	Overflow cell (for reagent nozzle) Liquid level detection error (Out of test)	An error was detected while supplying the purified water to the overflow cell. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts.
	OF Liquid level error	2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
041	Reagent refrigerator Shutter operation error (Test)	The shutter of the reagent refrigerator did not work correctly. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples.
	Reagent refrigerator Shutter operation error	<ERROR CANCELLATION> Press [Close]. Close Error display.
042	Reagent refrigerator shutter operation error (Out of test)	The shutter of the reagent refrigerator did not work correctly. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts.
	Reagent refrigerator shutter error	2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
043	Reagent refrigerator barcode reader error	The communication with the barcode reader did not work correctly <ERROR CANCELLATION>
	REAG barcode reader error	1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
044	Mixer operation error (Test)	The mixer arm DC motor did not work correctly above the reaction table. Wait for the result for the currently testing sample. Retest error samples and untested samples.
	Mixer operation error	<ERROR CANCELLATION> Press [ABORT]. The test ends.

Appendix

Error No. ERR#2-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
046	Mixer operation error (Out of test)	The mixer arm DC motor did not work correctly above the reaction table. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
	Mixer operation error	
047	Mixing operation error (Test)	The mixer DC motor did not work correctly. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION> Press [Close]. The Error screen closes.
	Mixing error	
048	Mixing operation error (Out of test)	The mixer DC motor did not work correctly. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts. 2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
	Mixing error	
051	Temperature control error	An error was detected in the temperature control. Analyze the sample currently under analysis again. <ERROR CANCELLATION> 1. Press [ABORT]. If an analysis is ongoing, such analysis will be ended. If any process other than analysis is ongoing, such process will be aborted.
	Temperature control error	
052	Detection control error	An error was detected in the detection control. Analyze the sample currently under analysis again. <ERROR CANCELLATION> 1. Press [ABORT]. If an analysis is ongoing, such analysis will be ended. If any process other than analysis is ongoing, such process will be aborted.
	Detection control error	

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Error No. ERR#2-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
053	Liquid level detection control error	An error was detected in the liquid level detection control.
	Liquid level detection control error	Analyze the sample currently under analysis again.
		<ERROR CANCELLATION>
		1. Press [ABORT].
		If an analysis is ongoing, such analysis will be ended.
		If any process other than analysis is ongoing, such process will be aborted.
054	DC pump control error	An error was detected in the DC pump control.
	DC pump control error	Analyze the sample currently under analysis again.
		<ERROR CANCELLATION>
		1. Press [ABORT].
		If an analysis is ongoing, such analysis will be ended.
		If any process other than analysis is ongoing, such process will be aborted.
061	Purified water set position Purified water shortage (Test)	Lack of solution in the purified water bottle was detected.
		Wait for the results for samples currently under analysis.
		Re-analyze the errored samples and unmeasured samples.
	Purified water shortage	<ERROR CANCELLATION>
		Press [Close].
062	Purified water set position Purified water shortage (Out of test)	Lack of solution in the purified water bottle was detected.
		<ERROR CANCELLATION>
		1. When the bottle is replaced, press [Retry]. The process restarts.
	Purified water shortage	2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.
063	Washing solution set position Washing solution shortage (Test)	Lack of solution in the washing solution bottle was detected.
		Wait for the results for samples currently under analysis.
		Re-analyze the errored samples and unmeasured samples.
		<ERROR CANCELLATION>
	Washing solution shortage	Press [Close].
064	Washing solution set position Washing solution shortage (Out of test)	Lack of solution in the washing solution bottle was detected.
		<ERROR CANCELLATION>
		1. When the bottle is replaced, press [Retry]. Restart the process.
		2. If there is an error at the mechanical movement or if an error is
	Washing solution shortage	issued again, press [ABORT]. Stop the process.
071	Safety guard error	The analysis was ended because the safety guard was opened during an analysis.
	Safety guard open error	Analyze the sample currently under analysis again.
		<ERROR CANCELLATION>
		Press [ABORT]. The assay ends.

Error No. ERR#2-	Screen Message (Upper) Printed Message (Lower)	Error Description and Cancelling Procedure
072	Mixer nozzle Presence sensor error (Test)	The mixer nozzle could not be detected in the overflow cell. Wait for the results for samples currently under analysis. Re-analyze the errored samples and unmeasured samples. <ERROR CANCELLATION>
	Mixer nozzle Presence sensor error	Press [Close].
073	Mixer nozzle Presence sensor error (Out of test)	The mixer nozzle could not be detected in the overflow cell. <ERROR CANCELLATION> 1. If there is no error at the mechanical movement, press [Retry]. The process restarts.
	Mixer nozzle Presence sensor error	2. If there is an error at the mechanical movement or if an error is issued again, press [ABORT]. Stop the process.

ERR#2-101 -

101	Close the safety guard.	The process temporarily stops. <CANCELLATION>
	(The message is not printed.)	1. Close the safety guard and press [Retry]. Restart the process. 2. If the error is issued again, press [ABORT]. Stop the process.
102	Close the reagent refrigerator cover.	The process temporarily stops. <CANCELLATION>
	(The message is not printed.)	1. Close the reagent refrigerator and press [Retry]. Restart the process. 2. If the error is issued again, press [ABORT]. Stop the process.
103	Check the reagent again.	<CANCELLATION>
	(The message is not printed.)	Close the reagent refrigerator cover and press [Continue].
107	Remove the pipes of purified water and washing solution.	<CANCELLATION> 1. Remove pipes and press [Continue]. The process continues.
	(The message is not printed.)	2. When aborting the process, press [ABORT].
111	Replace the washing solution line to the purified water.	<CANCELLATION> 1. Replace the washing solution line to the purified water. Disconnect the pipe connected to the washing solution bottle and connect the bottle to the purified water container.
	(The message is not printed.)	2. Press [Continue]. When aborting the process, press [ABORT].

4 Saving to External Media

The following data can be saved to external media: Sample measured data information, Sample replication information, QC measured data information, QC replication information, STD measured data information, STD replication information, and Time course data information.

Output data are variable-length.

4.1   Sample Measured Data Information

Sample Measured Data Information is saved.

■   File name: ocsamp.csv

No.	Item name	Note (△ is a blank [20H]))	Output setting
1	Data type	Analysis date, re-measurement data: 'N △' Retest data (buffer retest included): 'A △' If the data is edited, set "E" to △. Example) Analysis data edited: 'NE'	Yes
2	Date of analysis	Date of analysis Example) September 23, 2020 -> 2020/09/23	―
3	Time of analysis	Time of analysis (24-hour notation) Example: 2:05 P.M. -> 14:05	―
4	Rack No.	Barcode information put on the rack	―
5	Position in rack	Positions in the rack: 1 - 10	―
6	Sample ID	Barcode information put on the sampling bottle (*1)	Yes
7	Sample sequence No.	Measurement sequence number: 1 to 99999	―
8	Measurement method counter	Unused. ",," is output.	Yes
9	Number of replications	Number of replications in the replication measurements: 1 - 10	―
10	DA value	Value obtained by No. 3 detection – No. 1 detection See "Appendix 1.2 Calculation of DA Value."	Yes

No.	Item name	Note (△ is a blank [20H])	Output setting
11	Measured data	Calculated measured data: Up to 7 digits in the integer part and 1 digit in the decimal part (the number of digits in the decimal part can be changed in the "Output Format Settings.")	Yes
12	Judgment result	Qualitatively converted result of measured data by the cut off value △ -, △ +, 1+, 2+, and 3+	Yes
13	SD value	SD value of measured data (statistic)	Yes
14	CV value	CV value of measured data (statistic)	Yes
15	Error code	See "Appendix 4.8 List of Error Codes for External Media Output."	Yes
16	Test item code	Measured item code Not output in order error (CSV format. Thus, it is displayed as , ,).	―
17	Test item name	Name of measured item Not output in order error (CSV format. Thus, it is displayed as , ,).	Yes
18	Units of inspection result	Units of measure inspection result	Yes
19	Normal value range 1	Set cut off 1 value	Yes
20	Normal value range 2	Set cut off 2 value ("*" when not set)	Yes
21	Normal value range 3	Set cut off 3 value ("*" when not set)	Yes
22	Operator ID	ID of logged-in operator	Yes
23	R1 reagent lot	Lot of used R1 reagent	Yes
24	R1 reagent expiration date	Expiration date of used R1 reagent lot	Yes
25	R2 reagent lot	Lot of used R2 reagent	Yes
26	R2 reagent expiration date	Expiration date of used R2 reagent lot	Yes
27	Buffer expiration date	Lot of used buffer (, , is output when brand new)	Yes
28	Buffer expiration date	Expiration date of used buffer (, , is output when the expiration date is unknown)	Yes
29	Dilution factor	Sample dilution factor in a retest (0 is output in regular tests) 0, 1, 10, 20, 100, 200, 400	Yes

(Note)
· The item name is placed at the head of a file name as a header followed by data.
· Each item is separated by a comma (,).
· Output order and content depend on the setting of output item selection of the output format setting.
· Zero suppression is performed for items other than date of analysis, time of analysis, rack number, test item code, and test item name.
* 1   A maximum of 50 digits are output for sample IDs when 2D code is used (option).

4.2   Sample Replication Information

Sample replication information is saved.

■   File name: ocrsamp.csv

No.	Item name	Note	Output setting
1	Data type	See "Appendix 4.1 Sample Measured Data Information."	Yes
2	Date of analysis	See "Appendix 4.1 Sample Measured Data Information."	─
3	Time of analysis	See "Appendix 4.1 Sample Measured Data Information."	─
4	Relative cell No.	Used cells No.: 1 - 55	Yes
5	Rack No.	See "Appendix 4.1 Sample Measured Data Information."	─
6	Position in rack	See "Appendix 4.1 Sample Measured Data Information."	─
7	Sample ID	See "Appendix 4.1 Sample Measured Data Information."(* 1)	Yes
8	Sample sequence No.	See "Appendix 4.1 Sample Measured Data Information."	─
9	Replication counter	Number of replications in replication measurement: 1 - 10	─
10	A1 value	See "Appendix 1.2 Calculation of DA Value."	Yes
11	A2 value	See "Appendix 1.2 Calculation of DA Value."	Yes
12	A3 value	See "Appendix 1.2 Calculation of DA Value."	Yes
13	DA1 value	See "Appendix 1.2 Calculation of DA Value."	Yes
14	DA2 value	See "Appendix 1.2 Calculation of DA Value." It is output when there is no measured data.	Yes
15	Measured data	See "Appendix 4.1 Sample Measured Data Information."	Yes
16	Judgment result	See "Appendix 4.1 Sample Measured Data Information."	Yes
17	Error code	See "Appendix 4.1 Sample Measured Data Information."	Yes
18	Test item code	Measured item code	─
19	Test item name	Measured item name	Yes
20	Units of inspection result	Measured test result units	Yes

Appendix

No.	Item name	Note	Output setting
21	Normal value range 1	Set cut off 1 value	Yes
22	Normal value range 2	Set cut off 2 value ("*" when not set)	Yes
23	Normal value range 3	Set cut off 3 value ("*" when not set)	Yes
24	Operator ID	See "Appendix 4.1 Sample Measured Data Information."	Yes
25	R1 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
26	R1 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
27	R2 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
28	R2 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
29	Buffer expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
30	Sample dilution factor	See "Appendix 4.1 Sample Measured Data Information."	Yes
31	Dilution factor	See "Appendix 4.1 Sample Measured Data Information."	Yes

(Note)
- The item name is placed at the head of a file name as a header followed by data.
- Each item is separated by a comma (,).
- Output order and content depend on the setting of output item selection of the output format setting.
- Zero suppression is performed for items other than date of analysis, time of analysis, rack number, test item code, and test item name.
- Sample uninstallation" is not output for Sample Replication Information.
- Sample Replication Information is not output for no order and order error.

* 1   The maximum of 50 digits are output for sample IDs when 2D code is used (option).

Appendix

4.3   QC Measured Data Information

QC measured data information is saved.

■   File name: ocqc.csv

No.	Item name	Note	Output setting
1	Data type	QC data:'Cx' x: 1 – 4 QC numbers	Yes
2	Date of analysis	See "Appendix 4.1 Sample Measured Data Information."	Yes
3	Time of analysis	See "Appendix 4.1 Sample Measured Data Information."	Yes
4	Rack No.	See "Appendix 4.1 Sample Measured Data Information."	Yes
5	Position in rack	See "Appendix 4.1 Sample Measured Data Information."	Yes
6	Sample sequence No.	See "Appendix 4.1 Sample Measured Data Information."	Yes
7	QC lot	QC lot	Yes
8	Number of replications	See "Appendix 4.1 Sample Measured Data Information."	Yes
9	DA value	See "Appendix 4.1 Sample Measured Data Information."	Yes
10	Measured data	See "Appendix 4.1 Sample Measured Data Information."	Yes
11	Judgment result	Not output	Yes
12	SD value	See "Appendix 4.1 Sample Measured Data Information."	Yes
13	Error code	See "Appendix 4.8 List of Error Codes for External Media Output."	Yes
14	Test item code	Measured item code	Yes
15	Test item name	Measured item name	Yes
16	QC ID	Barcode information put on the QC container (*1)	Yes
17	Units of inspection result	Units of measured inspection result	Yes
18	Operator ID	See "Appendix 4.1 Sample Measured Data Information."	Yes
19	Control expiration date	QC expiration date	Yes
20	R1 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
21	R1 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
22	R2 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
23	R2 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes

Appendix

Note   ·   The item name is placed at the head of a file name as a header followed by data.
         ·   Each item is separated by a comma (,).
         ·   Output order and content depend on the setting of output item selection of the output format setting.
         ·   Zero suppression is performed for items other than date of analysis, time of analysis, rack number, test item code, and test item name.

* 1   A maximum of 50 digits are output for sample IDs when 2D code is used (option).

Appendix

4.4　QC Replication Information

Information for each QC replication is saved.

■　File name: ocrqc.csv

No.	Item name	Note	Output setting
1	Data type	See "Appendix 4.3 QC Measured Data Information."	Yes
2	Date of analysis	See "Appendix 4.1 Sample Measured Data Information."	Yes
3	Time of analysis	See "Appendix 4.1 Sample Measured Data Information."	Yes
4	Relative cell No.	See "Appendix 4.2 Sample Replication Information."	Yes
5	Rack No.	See "Appendix 4.1 Sample Measured Data Information."	Yes
6	Position in rack	See "Appendix 4.1 Sample Measured Data Information."	Yes
7	Sample sequence No.	See "Appendix 4.1 Sample Measured Data Information."	Yes
8	QC lot	See "Appendix 4.3 QC Measured Data Information."	Yes
9	Replication counter	See "Appendix 4.2 Sample Replication Information."	Yes
10	A1 value	See "Appendix 1.3 DA Value Calculation."	Yes
11	A2 value	See "Appendix 1.3 DA Value Calculation."	Yes
12	A3 value	See "Appendix 1.3 DA Value Calculation."	Yes
13	DA1 value	See "Appendix 1.3 DA Value Calculation."	Yes
14	DA2 value	See "Appendix 1.3 DA Value Calculation."	Yes
15	Measured data	See "Appendix 4.1 Sample Measured Data Information."	Yes
16	Judgment result	Not output.	Yes
17	Error code	See "Appendix 4.8 List of Error Codes for External Media Output."	Yes
18	Test item code	Measured item code	Yes
19	Test item name	Measured item name	Yes
20	QC ID	Barcode information put on the QC container (*1)	Yes
21	Units of inspection result	Units of measured sample result	Yes

Appendix

No.	Item name	Note	Output setting
22	Operator ID	See "Appendix 4.1 Sample Measured Data Information."	Yes
23	Control expiration date	QC expiration date	Yes
24	R1 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
25	R1 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
26	R2 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
27	R2 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes

Note
- The item name is placed at the head of a file name as a header followed by data.
- Each item is separated by a comma (,).
- Output order and content depend on the setting of output item selection of the output format setting.
- Zero suppression is performed for items other than date of analysis, time of analysis, rack number, test item code, and test item name.

* 1   A maximum of 50 digits are output for sample IDs when 2D code is used (option).

Appendix

4.5   STD Measured Data Information

STD Measured Data Information is saved.

■   File name: ocstd.csv

No.	Item name	Note	Output setting
1	Date of analysis	See "Appendix 4.1 Sample Measured Data Information."	Yes
2	Time of analysis	See "Appendix 4.1 Sample Measured Data Information."	Yes
3	Rack No.	See "Appendix 4.1 Sample Measured Data Information."	Yes
4	Position in rack	See "Appendix 4.1 Sample Measured Data Information."	Yes
5	STD point No.	Measurement point No. (STD1 - STD6): 1 - 6	Yes
6	DA1 value	See "Appendix 1.2 DA Value Calculation."	Yes
7	DA2 value	See "Appendix 1.2 DA Value Calculation."	Yes
8	DA1 applying value	Concentration acquired by applying DA1 to CC	Yes
9	DA1CV value	DA1 CV value (statistic)	Yes
10	DA2CV value	DA2 CV value (statistic)	Yes
11	DA1SD value	DA1 SD value (statistic)	Yes
12	DA2SD value	DA2 SD value (statistic)	Yes
13	Theoretical value	STD concentration	Yes
14	Number of replications	STD Number of replications	Yes
15	Error code	See "Appendix 4.8 List of Error Codes for External Media Output."	Yes
16	Test item code	Measured item code	Yes
17	Test item name	Measured item name	Yes
18	R1 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
19	R1 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
20	R2 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
21	R2 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
22	Cal. lot	Calibrator lot	Yes
23	Cal. expiration date	Calibrator expiration date	Yes

(Note)
・   The item name is placed at the head of a file name as a header followed by data.
・   Each item is separated by a comma (,).
・   Output order and content depend on the setting of output item selection of the output format setting.
・   Zero suppression is performed for items other than date of analysis, time of analysis, rack number, test item code, and test item name.

Appendix

4.6   STD Replication Information

Information for each STD replication is saved.

■   File name: ocrstd.csv

No.	Item name	Note	Output setting
1	Date of analysis	See "Appendix 4.1 Sample Measured Data Information."	Yes
2	Time of analysis	See "Appendix 4.1 Sample Measured Data Information."	Yes
3	Relative cell No.	See "Appendix 4.2 Sample Replication Information."	Yes
4	Rack No.	See "Appendix 4.1 Sample Measured Data Information."	Yes
5	Position in rack	See "Appendix 4.1 Sample Measured Data Information."	Yes
6	STD point No.	See "Appendix 4.5 STD Measured Data Information."	Yes
7	Replication counter	See "Appendix 4.2 Sample Replication Information."	Yes
8	A1 value	See "Appendix 1.2 Calculation of DA Value."	Yes
9	A2 value	See "Appendix 1.2 Calculation of DA Value."	Yes
10	A3 value	See "Appendix 1.2 DA Value Calculation."	Yes
11	DA1 value	See "Appendix 1.2 DA Value Calculation."	Yes
12	DA2 value	See "Appendix 1.2 DA Value Calculation."	Yes
13	Error code	See "Appendix 4.8 List of Error Codes for External Media Output."	Yes
14	Test item code	Measured item code	Yes
15	Test item name	Measured item name	Yes
16	R1 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
17	R1 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
18	R2 reagent lot	See "Appendix 4.1 Sample Measured Data Information."	Yes
19	R2 reagent expiration date	See "Appendix 4.1 Sample Measured Data Information."	Yes
20	Cal. lot	Calibrator lot	Yes
21	Cal. expiration date	Calibrator expiration date	Yes

(Note)
- The item name is placed at the head of a file name as a header followed by data.
- Each item is separated by a comma (,).
- Output order and content depend on the setting of output item selection of the output format setting.
- Zero suppression is performed for items other than date of analysis, time of analysis, rack number, test item code, and test item name.

Appendix

4.7   Time Course Data Information

Information for the time course data is saved.

■   File name: tcourse.csv

No.	Item name	Note	Output setting
1	Cell information 1	Time course information of relative cell 1	—
	. . .	. . .	. . .
n	Cell information n	Time course information of relative cell n	—

■   Cell information #

No.	Item name	Note	Output setting
1	Date of analysis	See "Appendix 4.1 Sample Measured Data Information."	—
2	Time of analysis	See "Appendix 4.1 Sample Measured Data Information."	—
3	Relative cell No.	See "Appendix 4.2 Sample Replication Information."	—
4	Test item code	Measured item code	—
5	Test item name	Measured item name	—
6	Cell blank ABS value		
7	ABS value of 1st cycle	See "Appendix 1.2 DA Value Calculation."	—
8	ABS value of 2nd cycle	See "Appendix 1.2 DA Value Calculation."	—
	. . .	. . .	. . .
26	ABS value of 20th cycle	See "Appendix 1.2 DA Value Calculation."	—

Note
·   The file contains only data without a header.
·   Each item is separated by a comma (,).
·   CR/LF is added as a delimiter, and EOF is added at the end of the file.
·   Zero suppression is performed for items other than date of analysis, time of analysis, rack number, test item code, and test item name.

Appendix

4.8   List of Error Codes for External Media Output

Code	Error content	Measured data (*3)	Note
10	Sample barcode read error	Yes	
01	Sample shortage, No sample	—	Dispensing is not conducted.
02	No reagent error	—	*2
03	RBC (Prozone)	Yes	
04	PRC (Prozone)	Positive/Negative judgment only	
05	OR (Over Range)	Positive/Negative judgment only	
06	UR (Under Range)	—	
07	Sample dispense error (Sample nozzle jamming, etc.)	—	Dispensing is not conducted.
08	Reagent dispense error (Reagent nozzle jamming, etc.)	—	Dispensing of R1 reagent or R2 reagent is not conducted. Dispensing of buffer can also cause this error.
09	Mixer error (Mixer jamming, etc.)	—	No mixing (agitation) is conducted.
0A	Reagent blank error (A1 check)	—	The reagent blank is abnormal.
0B	No CC	—	Includes mismatch of CC lot.
0D	QC control limit check error	—	
11	Combination error of "10" + "01" errors	—	*1
12	Combination error of "10" + "02" errors	—	*1
13	Combination error of "10" + "03" errors	Yes	*1
14	Combination error of "10" + "04" errors	—	*1
15	Combination error of "10" + "05" errors	—	*1
16	Combination error of "10" + "06" errors	—	*1
17	Combination error of "10" + "07" errors	—	*1
18	Combination error of "10" + "08" errors	—	*1
19	Combination error of "10" + "09" errors	—	*1
1A	Combination error of "10" + "0A" errors	—	*1
1B	Combination error of "10" + "0B" errors	—	*1

* 1   11 - 1B is a combined error with two errors overlapped. No other error is overlapped.

* 2   "No reagent error" is output if the reagent volume could not be detected when dispensing the reagent is attempted.

* 3   For errors with "Yes" in the "Measured data" field outputs the measured data and the judgment result.

For errors with "-" in the "Measured data" field outputs blank (20H) to the measured data and the judgment result.

Appendix

5 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.
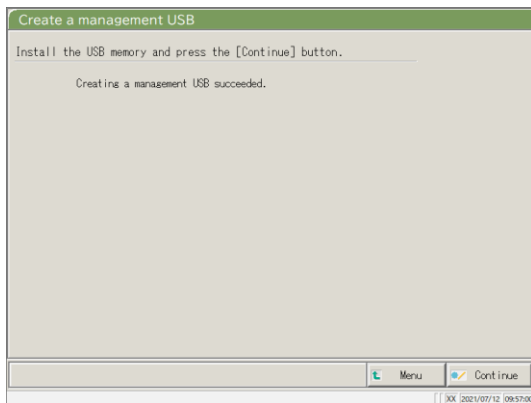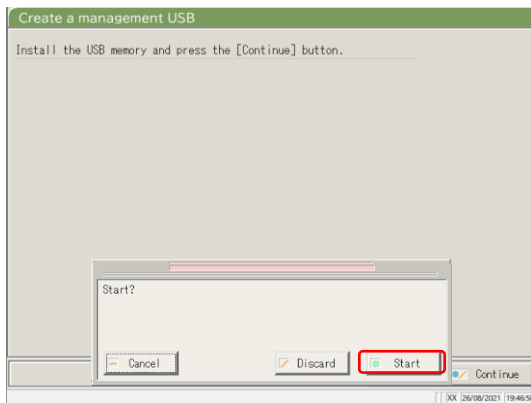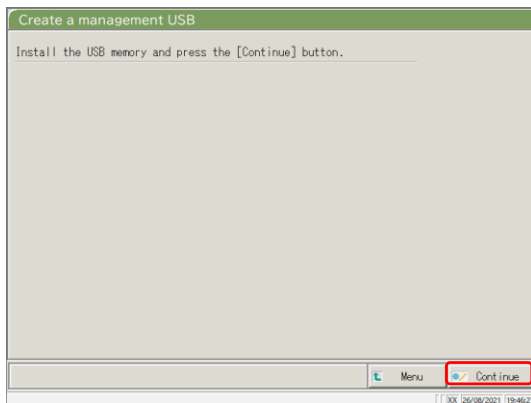
5.1 How to Set a Management USB Stick
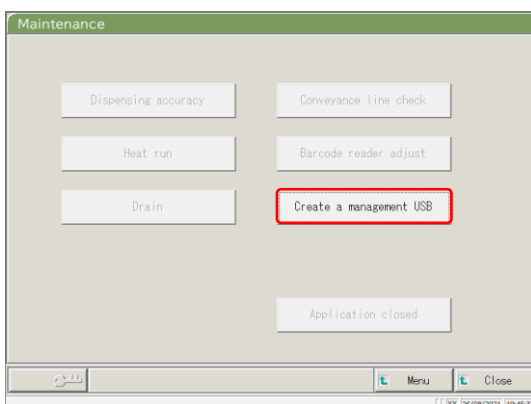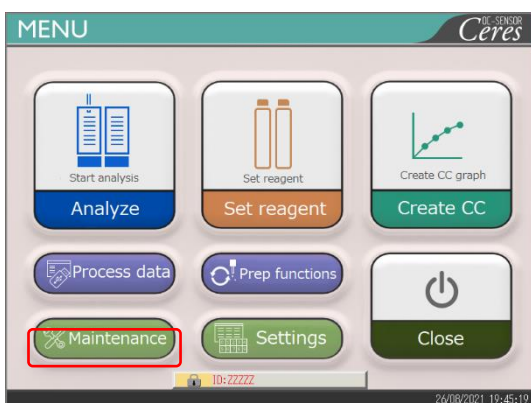
1 Set an administrator ID.
☞ For setting an administrator ID, see "6.1.10 User Account Settings" on page 206.

2 Select "ON" for [Operator management].

☞ For operator management setting, see "6.1.12 Operator Mode" on page 212.

3 Log in using the administrator ID.
☞ See "2.3 Logging In" on page 28.

4 Touch [Maintenance] on the [MENU] screen.

* [Maintenance] screen opens.

5 {Create a management USB} button.

* [Create a management USB] screen opens.

6 Insert the USB stick.

7 Touch {Continue}.

8 Touch {Start}.

{Cancel}: Closes the dialog box.

{Discard}: Aborts setting and returns to [Maintenance] screen.

{Start}: Set the inserted USB stick as a management USB stick.

9 The inserted USB stick has been successfully set as a management USB stick.

10 Remove the USB stick from the system.

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R

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Glossary

A

ABS

> A1, A2, and A3
>
> Logarithm of the ratio of the strength of incident light striking a sample (Io) and the strength of the transmitted light (I) (i.e. Io/I).

Analysis mode

> Used when the sample is analyzed for the first time. One of the measurement modes.

B

Back fit value

> The value obtained by fitting absorbance to a calibration curve.

D

DA value

> Absorbance difference. Calculated as the amount of change in absorbance. For example,
>
> DA1 = A3-A1 [ABS]
>
> DA2 = A2-A1 [ABS]

Data

> The concentration value of a target, such as hemoglobin.
>
> Measured data (concentration values) calculated using DA values and calibration curves.

J

Jam error

> An error indicating that something is touching the sample nozzle or mixer.

P

PRC method

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 a reference sample.

QC value check

Check based on the control limit values set on the [QC process] screen.
Specification:
When less than Min Value +1: Abnormal
When Max Value +1 or more: Abnormal

R

RBC method

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 of the measure modes.
Remeasured samples are handled in the same manner as first test samples.

Retest mode

Retests samples measured in the analysis mode. However, they are not punctured again. One of the measurement modes.

Glossary

S

STD (sample)

The calibrator sample. Also referred to as standard material or standard sample.

T

Time course

Results (graph) of measuring/recording changes in absorbance as time passes.

*C*eres OC-SENSOR

OC-SENSOR
Ceres

Eiken Chemical Co., Ltd.