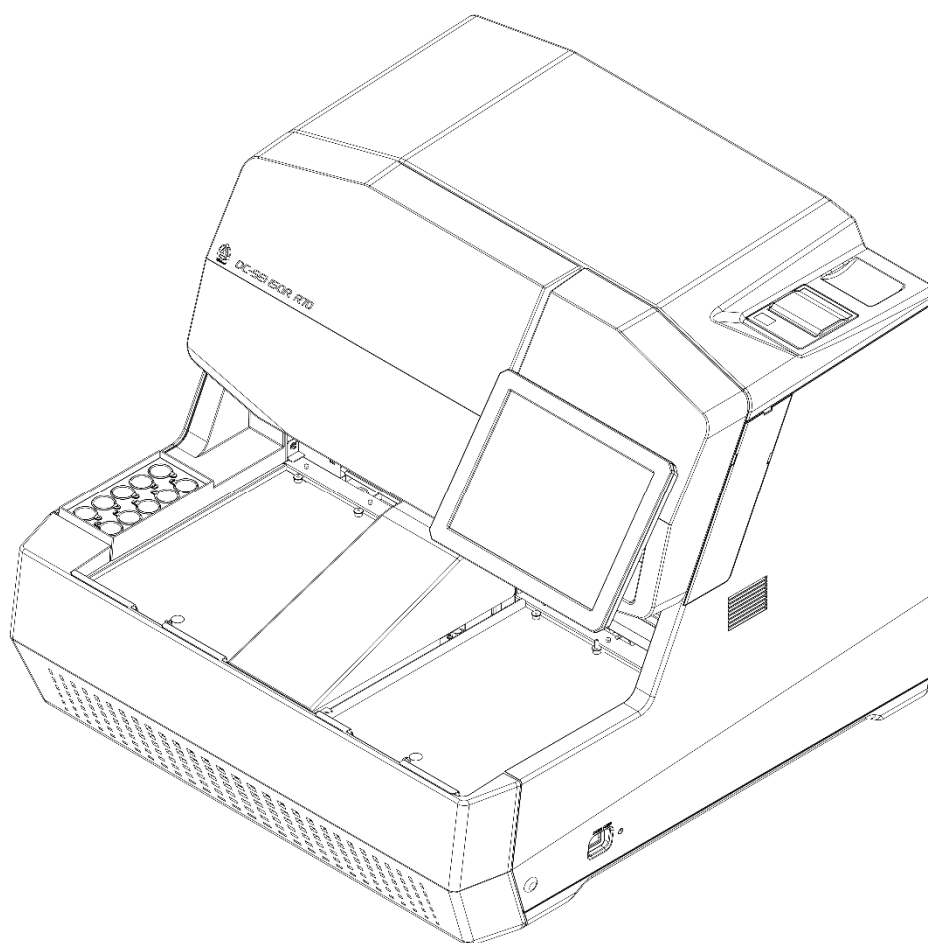


OC-SENSOR R70

Operation Manual



Version 2
August 2026

Attention

Only persons who have fully understood the contents of this Operation Manual shall operate this system.
Store this Operation Manual near this system so that it can be referred to when necessary.



EIKEN CHEMICAL CO., LTD.

Important

- Copyright for this Operation Manual belongs to EIKEN CHEMICAL CO., LTD. Use, reprinting, duplication, and modification of its contents in part or entirely without permission is strictly prohibited.
- 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 damage or the like if the System is not used in accordance with this Operation Manual.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- For technical support, please contact EIKEN CHEMICAL CO., LTD. (hereinafter referred to as the "manufacturer") via "<https://www.eiken.co.jp/en/>".

Introduction

Prior to reading this Operation Manual

OC-SENSOR R70 is an automated immunochemistry analyser—that is, it is a movable and discrete clinical chemistry automatic analysis system (hereinafter referred to as the “System”).

This System is classified as an In Vitro Diagnostic medical device.

The System and its Operation Manual is meant for doctors, clinical laboratory technicians, and those who have received specialized education or training in test procedures that use In Vitro Diagnostic medical devices.

Read this Operation Manual carefully prior to use the System properly.

Note that using the System in a manner not described in this Operation Manual or in conditions outside the System specifications could negatively impact the System’s safety and performance.

Be sure to use the System according to the instructions in this Operation Manual.

Operation Manual organization

This Operation Manual consists of the following chapters:

Introduction	Describes the organization and notation of this Operation Manual, as well as “Safety Precautions” when using the System.
1. Overview	Gives an overview of the System, including measurement principles, analysis flow, as well as the names and functions of each part.
2. Operation (Basic)	Gives an overview of initial settings prior to use, and describes basic operation of the System, such as daily operation.
3. Operation (Applied)	Describes applied operation of the System, such as searching measured data, recalculation, output, and deletion of test data, as well as quality control.
4. Auxiliary Functions	Describes auxiliary functions run prior to analysis, such as priming and cell blanking.
5. Maintenance	Describes inspection and maintenance methods users should follow in order to safely use the System, maintain performance, and discover malfunctions and the like as early as possible.
6. Settings	Describes details on various settings for operating the System.
7. Quick Help	Describes quick help functions.
8. Printed Information	Describes printed content.
9. External Media Output	Describes configuration of files to be output to external media.
10. Calculation Processing	Describes calculation processing related to the analysis.
11. Error Handling	Describes how to read and clear the error screen.
12. Technical Explanation Related to EMC	Provides technical explanations related to EMC.
13. Information on Trademarks and Software	Describes information regarding trademarks and software.
14. Glossary	Describes terms related to the Operation Manual.

Operation Manual notation

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

■ “Warnings,” “Cautions,” and “Requests”



Warning

Indicates a possibility that improper use of the System will cause **death or severe personal injury to the user**.



Caution

Indicates a possibility that improper use of the System will cause **personal injury to the user 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.

Personal 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



High temperature

Prohibition symbols: Indicate prohibited actions.



Prohibited



**Disassembly
prohibited**

Instructional symbol: Indicates Instructions users must follow.



Required

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 insert or remove the power plug with wet hands.
- Do not damage or alter the power cord.
- Do not apply excessive force to the power cord.
- Do not fasten the power cord using metal fixtures or the like.
- Do not use power cords other than that provided.
Failure to observe this precaution may lead to electric shock or fire.



Warning



Required

- Make sure that the System is grounded.
Failure to observe this precaution may lead to electrical shock.



Required

- Connect to the appropriate power supply.
Power supply voltage: AC100 V-240 V
Frequency: 50/60 Hz
Power consumption: ≤500 VA
Socket: The power plug uses a protective earth terminal.
Use a fixed power socket (electrical outlet for medical use)
that is correctly grounded.
Failure to observe this precaution may lead to electric shock or fire.
- Install the attached power cord in a location where the power plug can be easily removed as it is less than 3 m.

■ Installation conditions



Caution



Required

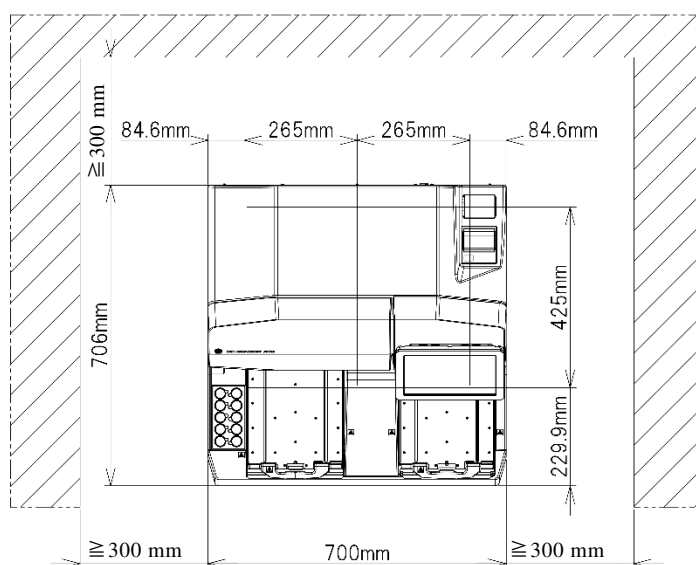
- Use indoors.
- Install and store in a location where it is not exposed to water.
- Ensure the System is installed in a location free from extreme environmental conditions such as unusual pressure, temperature or humidity, poor ventilation, direct sunlight, dust, salt air, or corrosive gases.
- Install in an appropriate lighting environment. Avoid installation in environments where ambient lighting creates a strobe effect, or where glare or shadows reduce the visibility of the display or controls.
- Install in a location that is flat and free of vibration or impact.
- Avoid installing the unit in areas where chemicals are stored or where gases are generated.
- Ensure that the installation location is leveled.

Caution



Required

- Do not move the System.
This system should only be installed or moved by a maintenance person who has been certified by the manufacturer.
- Use a platform that can support the weight of the System. Make sure that the platform is stable.
If the System falls, it could cause unexpected injury.
- Install the System in a location with plenty of space, so as to not hinder operation or maintenance.
(Refer to the following diagram.)
- Make sure the desk is at least 425 mm deep and 530 mm wide so that all six legs can be placed on it.



- Size (mm) and weight (kg) of system
Width 700 x Length 706 x Height 589 ($\pm 2\%$)
 - Weight: 70 kg $\pm 4\%$
 - Dissipated heat: 882 kJ/h (211 kcal/h) at AC 240 V ^{*1}
1800 kJ/h (430 kcal/h) at Max Power ^{*2}
 - ^{*1}. Calculated value based on a measured power consumption of 245 W.
 - ^{*2}. Calculated value based on the maximum power consumption of 500 W.
 - Sound power level: 67 dB (A) (Benchmark) ^{*3}
 - ^{*3}. All drive units were operated and measured according to ISO 3746:2010.
- Do not place the System near the exhaust ports of heating and cooling equipment.
Doing so could result in incorrect analytical results.

■ Environmental conditions

 Caution				
 Required	Adhere to the following environmental conditions.			
	<table border="0"> <tr> <td>• Usage conditions</td> <td> Temperature: 15 °C to 30 °C Humidity: 20 % to 80 % (no condensation) Atmospheric pressure: 800 hPa to 1060 hPa Height of 2000 m or less* Pollution degree 2* Overvoltage Category II* </td> </tr> <tr> <td>• Storage/Transport conditions</td> <td> Temperature: -10 °C to 50 °C Humidity: 10 % to 90 % (no condensation) </td> </tr> </table>	• Usage conditions	Temperature: 15 °C to 30 °C Humidity: 20 % to 80 % (no condensation) Atmospheric pressure: 800 hPa to 1060 hPa Height of 2000 m or less* Pollution degree 2* Overvoltage Category II*	• Storage/Transport conditions
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• Storage/Transport conditions	Temperature: -10 °C to 50 °C Humidity: 10 % to 90 % (no condensation)			

Explanatory note: * Standardized conditions are based on EN61010-1:2010 "Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements."

■ EMC (Electromagnetic Compatibility)

 Caution	
 Required	Do not make connections to this system other than those specified. Such connections may increase electromagnetic emissions or reduce electromagnetic immunity.
	This device is designed for use in professional healthcare facility environments (hospitals, clinical laboratories, blood banks, donation centres, examination rooms, intensive care units, surgery centres, emergency rooms, operating rooms, clinics, patient rooms, dental offices, confined care facilities, nursing homes, pharmacies with trained operators, and urgent care rooms). Do not use in home healthcare environments (other than the professional healthcare facility environments listed above). It may cause malfunction. - Do not use this system in a dry environment. In particular, the presence of chemical fibers (synthetic fiber clothing, carpets, etc.) may cause harmful electrostatic discharge, which could result in incorrect measurement results. - Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

■ 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.
- Please review your users and passwords regularly.
- Regularly protect your data by storing it on external media. There is a possibility of data corruption due to cyber attacks, disasters, etc."
- 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.
- Check the USB flash drive in advance for viruses and make sure that no viruses have been detected"
 - 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 equipment when handling samples, reagents, or wash solution. - Wash your hands well after using the System. Failure to observe this precaution may lead to infection from samples.
 Biohazard	- Dispose of drainage after using the System. - The unit periodically drains condensate. To prevent spillage, please transfer the condensate to a separate container when removing the full-level sensor and hose. - Make sure that drainage does not leak into the area surrounding the device when detaching the drain tank hose. - Make sure that drain tank is empty prior to using the System. Failure to observe this precaution may lead to infection from samples.
 Biohazard	- Be careful not to let the sample container fall over when attaching/detaching the sample rack or tray. Failure to observe this precaution may lead to infection/contamination from samples. Failure to observe this precaution may lead to loss of samples. - In the unlikely event that the sample splattered, wipe and disinfect with 70% ethanol.
 Biohazard	Be careful of sample splattering when removing the sample bottle from the rack. Failure to observe this precaution may lead to infection from samples.
 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 electrical shock.
 Prohibited	- Do not spill any samples or reagents inside the System. If any product is spilled, do not use the System and contact the manufacturer immediately. - Do not touch the System with wet hands. Failure to observe this precaution may lead to electrical shock.
 Prohibite	Do not mix the wash solution with acid washing solution. Failure to observe this precaution may damage the operator's health.
 Electrical shock	Do not operate the System while touching external input/output ports such as USB. Failure to observe this precaution may lead to electrical shock.

 Caution	
 Pinching hazard	- Do not open the protective cover during operation. - Keep out of the operational range of the System during operation. Failure to observe this precaution may lead to injury or damage.
 Required	- Do not use racks that are dirty, damaged, or deformed. - Do not move the rack while it is conveying. If the rack is accidentally moved, remeasure (retest) all samples in the rack. If the rack is misaligned, it could result in incorrect measurements.
 Required	- Use only the specified reagents, consumables, and wash solutions. - Connect each tank (purified water, wash solution, and drainage) correctly with each hose. - Monitor the quality control function and positive rate change periodically. Failure to observe this precaution may lead to a false diagnosis.
 Required	- Use only recommended external media (such as USB flash drive). Contact the manufacturer for details on recommended products. - Do not connect encrypted USB devices. The storage may not be recognized. - Manage external media appropriately. Check for viruses periodically. Failure to observe this precaution may lead to infection by a computer virus.
 Required	Use only reagents that have not expired. Failure to observe this precaution may lead to a false diagnosis.
 Required	If the reagent storage temperature becomes abnormal, dispose of the reagent that was set. Failure to observe this precaution may lead to a false diagnosis.
 Required	- Do not turn off the power during measurement. - Do not turn off the main power switch until the System has completely shut down. Failure to observe this precaution may lead to memory corruption and data loss.
 Required	Do not press the touch panel strongly. Failure to observe this precaution may lead to system malfunction.

■ Maintenance, inspections, and cleaning

 Warning
 Biohazard ▪ Wear protective equipment when maintaining, inspecting, and cleaning the System. Failure to observe this precaution may lead to infection from samples. ▪ Do not place liquids on the top of the System or handle liquids above the System.
 Pinching hazard ▪ The tips of the nozzle and puncture needles are sharp. Use caution when handling them. Failure to observe this precaution may lead to injury.

 Caution
▪ Back up the data of the System regularly.

 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 should be satisfied. ▪ Be sure to maintain and inspect the System daily, and keep it clean. ▪ If the System has not been used for some time, check that the System is operating properly prior to use. ▪ If the System does not turn on, there is a possibility that the fuse is blown. In that case, contact the manufacturer. ▪ If system failure is suspected, attach a failure notice or other notification to the System and do not operate or touch the System. Immediately contact the manufacturer or a legal representative.

■ Disposing of drainage and other waste



Warning



Biohazard

Dispose of drainage and other waste (reagent containers, reaction cells, sample bottles, and sample cups) appropriately in accordance with facility safety management procedures and the instructions of the person in charge of infectious medical waste management.

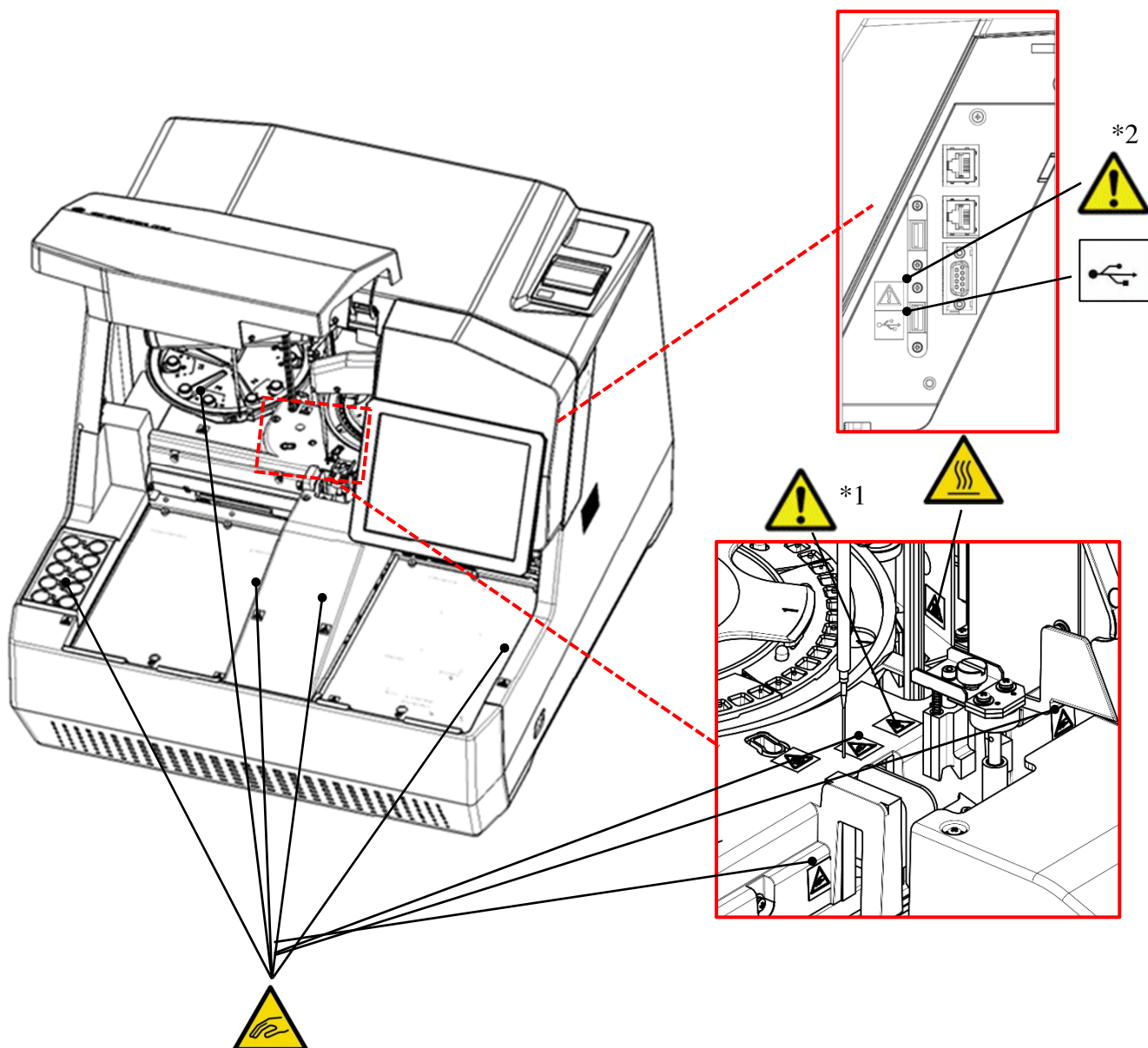
- Some examples of infectious medical waste include reagent containers, reaction containers, sample bottles, and sample cups.)
- Refer to the usage instructions attached to the reagent for information on how to dispose of reagent containers and drainage.
- Contact the manufacturer for information on disposing of the System.
- Wear protective equipment during disposal.

Failure to observe this precaution may lead to infection.

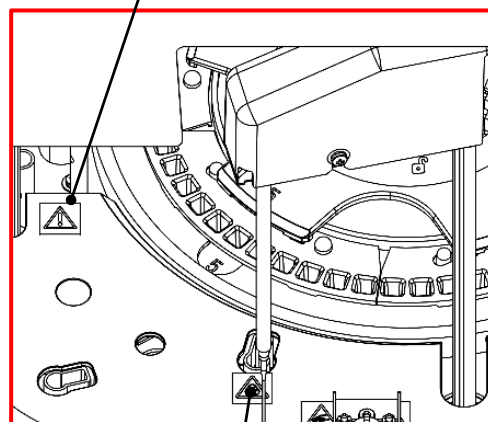
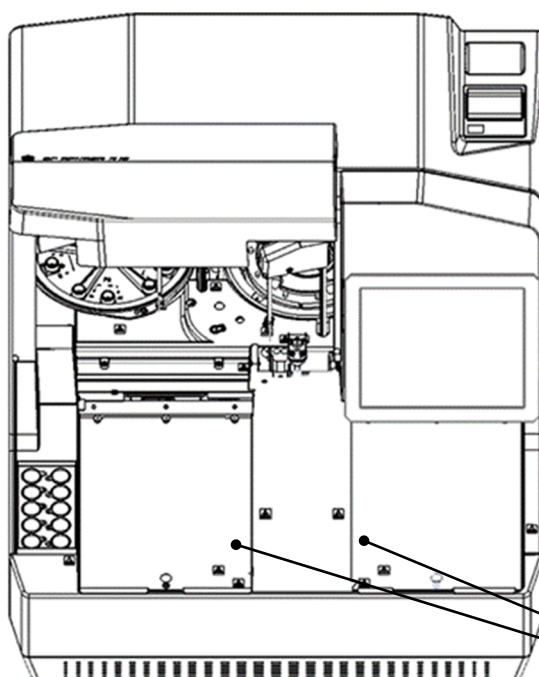
Caution labels and where they are affixed

The following caution labels are affixed to the System. Understand where the caution labels are and what they mean before using the System.

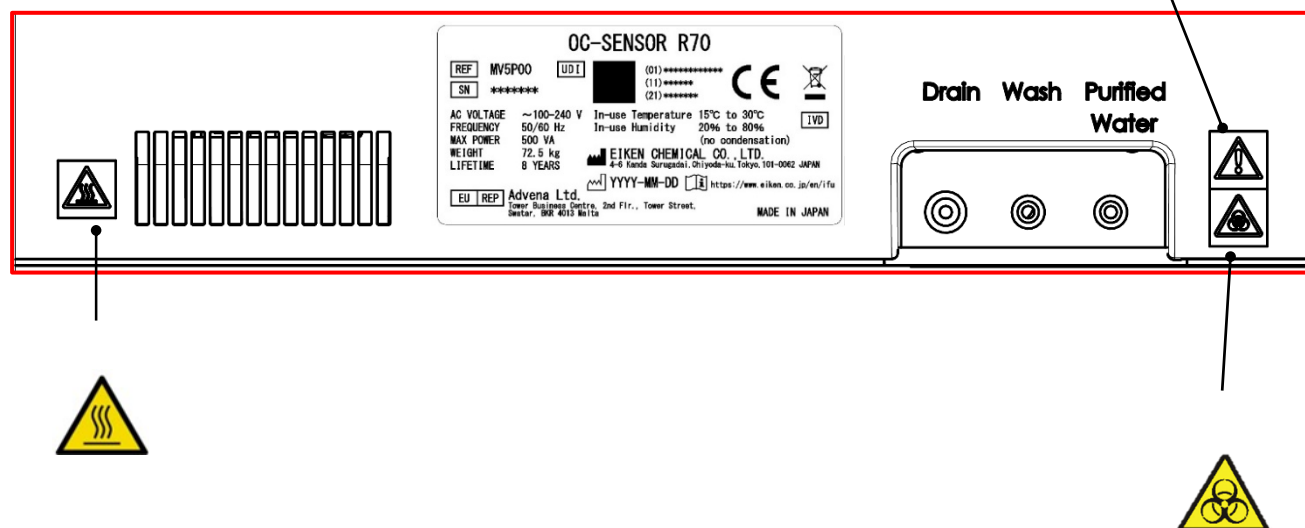
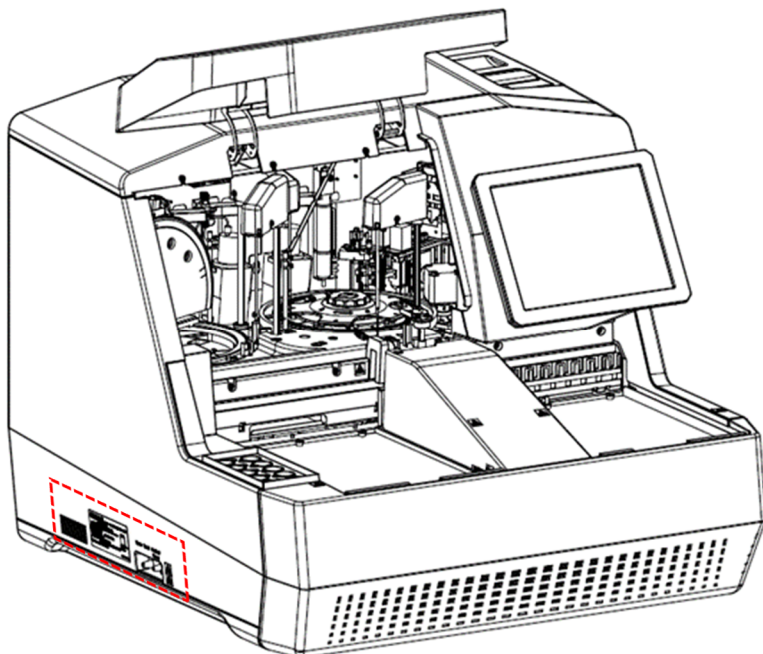
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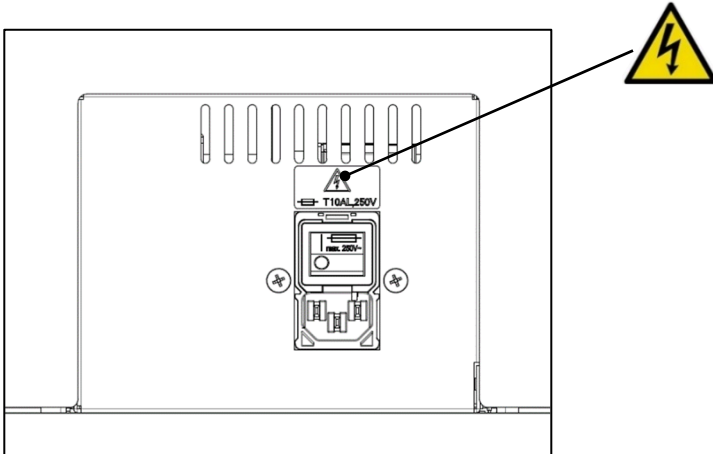
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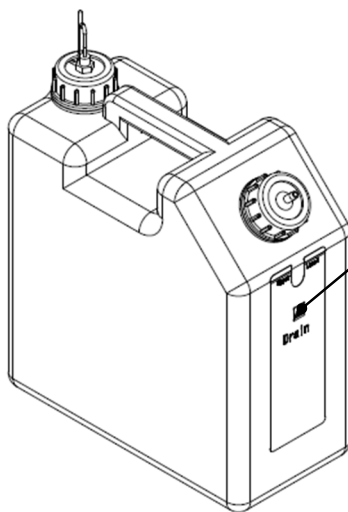
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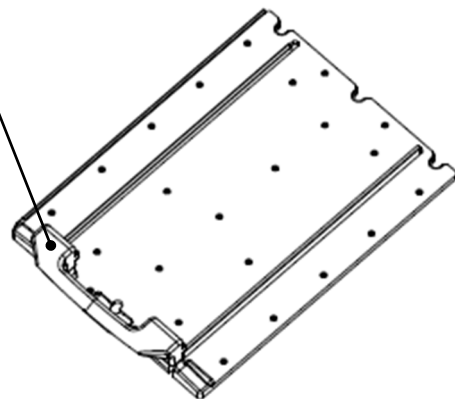
<System body (power supply)>



<Accessories>



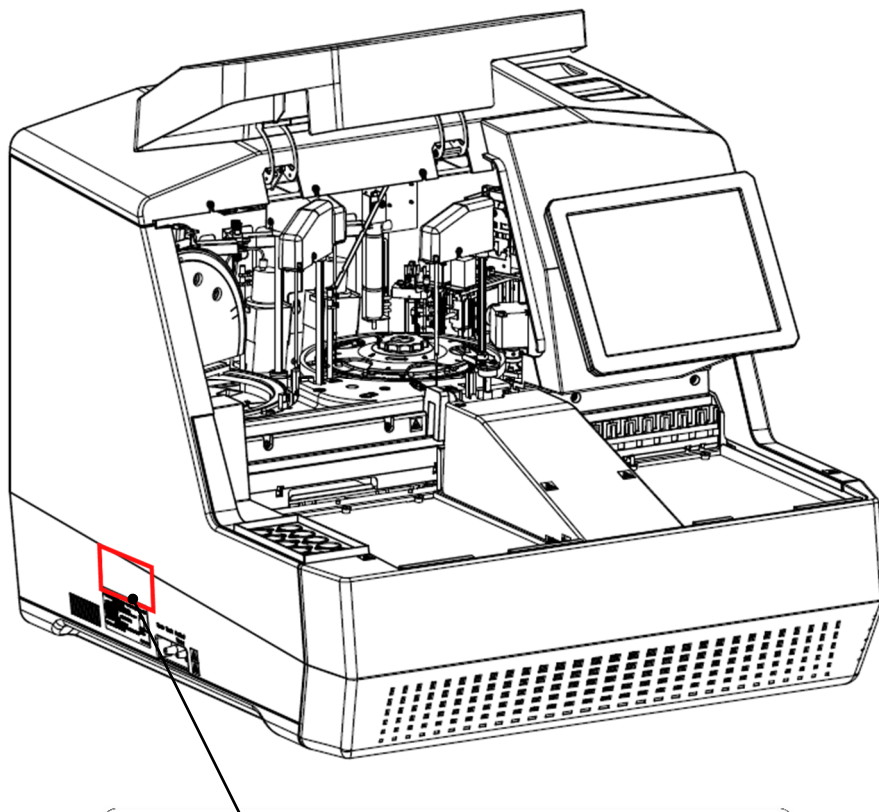
Drain tank



Rack tray

Caution Label	Meaning
 Pinching hazard	- Keep out of operational range during system operation. - Failure to observe this precaution may lead to injury.
 Biohazard	- Do not handle drainage or samples with bare hands. - Failure to observe this precaution may lead to infection or contamination.
 High temperature	- Do not touch as this part reaches high temperature. - Failure to observe this precaution may lead to burns.
 Electrical shock	- Do not open due to high voltage inside the power supply. - Failure to observe this precaution may lead to electrical shock.
	*1 Puncture/Squeeze system Keep out during operation. Failure to observe this precaution may lead to injury such as fingers being caught.
	*2 Connection port Connect the authorized device. If an unauthorized device is connected, the System may malfunction.
	*3 Dispensing nozzle Do not touch the dispensing nozzle. Failure to observe this precaution may lead to injury with to the tip of the nozzle.
	*4 Drain tank hose connection Do not touch drainage with bare hands. Failure to observe this precaution may risk infection or contamination.
 USB	Connect the USB flash drive at this location.

Identification plate and where affixed



OC-SENSOR R70			
REF	MV5P00	UDI	(01) ***** (11) ***** (21) *****
SN	*****		CE
AC VOLTAGE	~100-240 V	In-use Temperature	15 °C to 30 °C
FREQUENCY	50/60 Hz	In-use Humidity	20 % to 80 % (no condensation)
MAX POWER	500 VA		
WEIGHT	70 kg		
LIFETIME	8 YEARS		
EIKEN CHEMICAL CO.,LTD. 4-8 Kanda Su nagah, Chiyoda-ku, Tokyo, 101-0062 JAPAN			
YYYY-MM-DD https://www.eiken.co.jp/en/ifu			
EU REP	Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta		MADE IN JAPAN

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1. Overview

This section gives a general outline of the System and describes the configuration of OC-SENSOR R70, an automated immunochemistry analyser (movable and discrete clinical chemistry automatic analysis system).

1.1. OC-SENSOR R70 Features

- OC-SENSOR R70 (hereinafter referred to as the “System”) is equipped with functions required for immunoanalytical equipment, such as automatic sample dilution, a wide range of measurements, carryover countermeasures, and prozone checking.
- The System always keeps the reagents refrigerated, allowing for sample measurement at any time.

1.2. Intended Purpose

- The System is designed to be used together with dedicated reagents as an immunoassay test system. It is used by qualified personnel in clinical laboratories and hospitals.

1.3. Measurement Principles

- Latex turbidimetry
 - An antigen-antibody reaction is a specific reaction that occurs between an antigenic determinant and the active group of an antibody. The amount of bonding depends on the concentrations of the antigen and antibody.
 - A latex agglutination reaction is the clumping of antigen- or antibody-sensitized polystyrene latex particles caused by an antigen-antibody reaction. A light beam is passed through the reaction liquid to measure changes in the intensity of the transmitted light beam. This method is called “latex turbidimetry.” This system makes use of this “latex turbidimetry.”

1.4. System Configuration

Check the configuration prior to using the System.

Name		Quantity	Remarks
Body	Automated immunochemistry analyser (movable and discrete clinical chemistry automatic analysis system) OC-SENSOR R70	1	
Accessories	(1) Software package		
	1. Software program	1	Preinstalled on SSD
	(2) Racks		
	2. Sample Rack	20	
	3. STD/QC Rack	2	
	4. Retest Rack	1	
	5. Dilute test Rack	1	
	6. Rack Tray	2	
	7. Barcode Labels for Rack	3 sheets	
	(3) Tanks		
	8. Purified Water Tank (10L)	1	10 L tank w/sensor
	9. Wash Solution Tank (5L)	1	5 L tank w/ sensor
	10. Drain Tank (10L)	1	10 L tank w/ sensor
	11. Auxiliary Tank	2	5 L tank
	12. Beaker	1	For wash solution preparation
	13. Tank Nozzle	2	
	14. Cap Spacer	4	For 10 L tank
	15. Cap Spacer	2	For 5 L tank
	16. Tank Label	1	Affixed to tank

Name		Quantity	Remarks
Accessories	(3) Others		
	17. Sample Cups	1 bag	100 pieces
	18. Measurement Cells	1 box	5 pieces/box
	19. Printer Paper	1 roll	
	20. Power Cable	1	
	21. End Ring	1	
	22. Cable Ties	5	
Document	23. Operation Manual	1	
	24. Windows License Terms	1	Included in the instruction manual binder

■ **Sold separately**

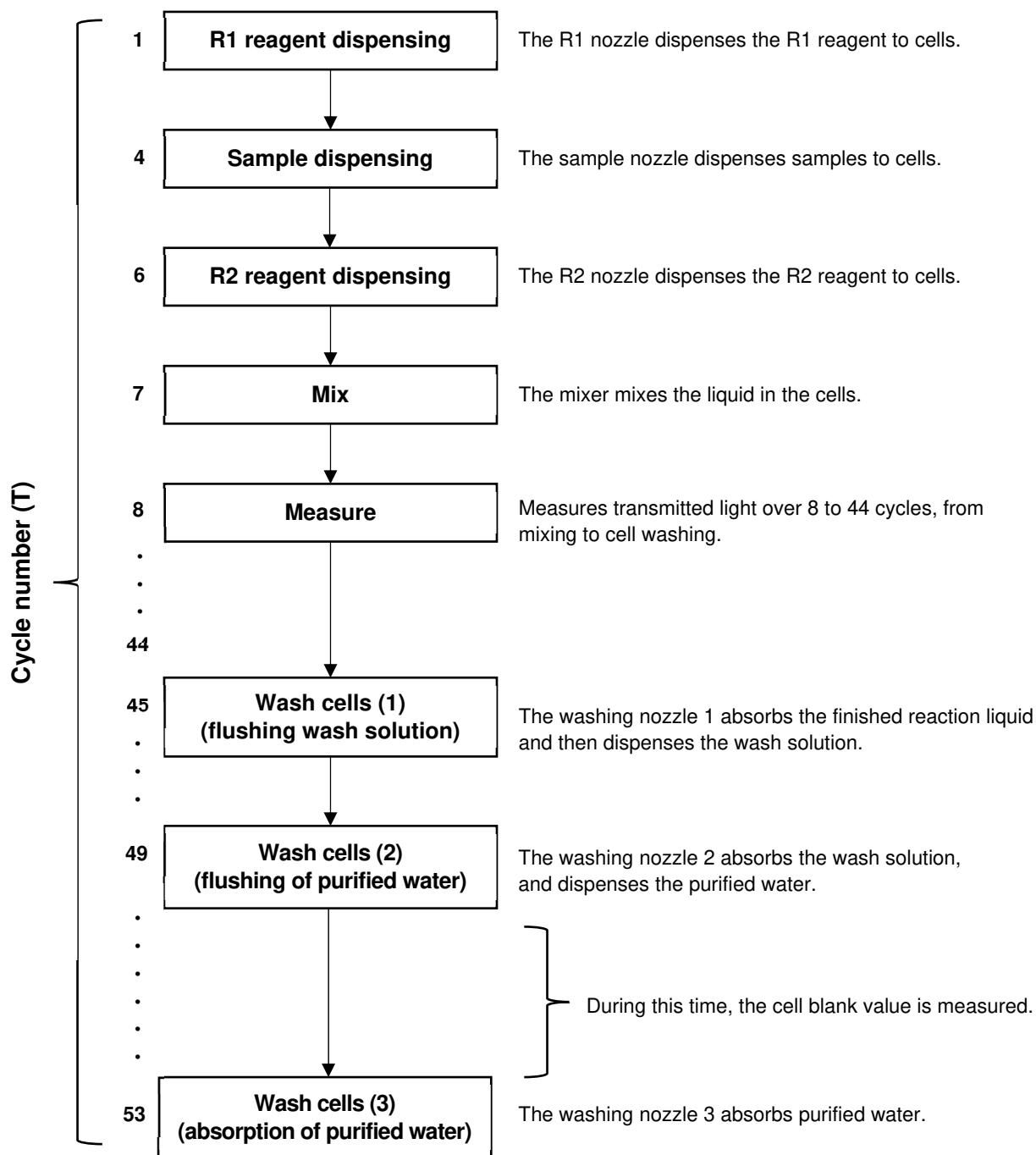
Product Name	Product Code	Quantity	Remarks
Sample Rack	M-5P01	1 box	10 units
STD/QC Rack	M-5P02	1 box	1 unit
Retest Rack	M-5P03	1 box	1 unit
Dilute Retest Rack	M-5P04	1 box	1 unit
Rack Tray	M-5P05	1 box	2 units
Measurement Cell	M-5P06	1 box	5 units
End Ring	M-5P07	1 box	1 unit
Purified Water Tank (10L)	M-5P08	1 box	
Wash Solution Tank (5L)	M-5P09	1 box	
Drain Tank (10L)	M-5P10	1 box	
Tank Cap Spacer Set	M-5P11	1 set	10L:4 units 5L:2 units
Tank Cap Spacer (10L)	M-5P15	1 set	10L:2 units
Tank Cap Spacer (5L)	M-5P16	1 set	5L:2 units
Printer Paper	M-5P21	1 box	10 rolls
Sample Cup	M-1U83	1 box	1000 units

■ Options

Product Name	Product Code	Quantity	Remarks
Wash Solution Tank (10L) With Sensor	M-5P12	1 box	
Handy Barcode Reader	M-5P13	1 set	Used to import barcode information for calibrators, QCs, and reagents into the analyser. Model: L-22X-V-WHT-USB
2D Code Reader	M-5P14	1 set	Used for scanning 2D codes on specimen labels. Model: NLV-5201-HD46K00997

1.5. Analysis Flow

The analysis flow for this system is as follows:



11.25 seconds are required for a single cycle.

1.6. System Specifications

■ Basic specifications

Item	Specification
Measurement principles	Latex turbidimetry
Method	Discrete method, random access method
Analysis mode	1-Step rate
Samples	Faeces
Processing capacity	320 tests/hour Analysis time: 11.25s cycle
Measurement method	1 sample, 2 sample, 3 sample
Sample setting	200 samples: 10-sample racks × 20
Sample bottle	OC-Auto Sampling Bottle 3 or OC-Auto Sampling Bottle 4 (EIKEN CHEMICAL special bottle) Sample cup (DSP-SC-20B)
Calibration curve generation	Automatic generation of calibration curves
STAT sample setting	Up to 10 samples
Dilute test	Automatic dilute test (10x, 20x, 100x, 200x, 400x)
Measurement cells	Semi-disposable, 11-cell plastic holder (up to five loadable), automatic washing with wash solution and purified water
Sample dispensing	Non-disposable sampling (with a nozzle washing function)
Sample dispensing range	3.0 to 21.0 μ L (0.1 μ L increments) However, set the protocol to the dispensing volume set by the manufacturer.
Reagent dispensing	Non-disposable reagent sampling (with a nozzle washing function)
Reagent dispensing range	30 to 210 μ L (1 μ L increments) However, set the protocol to the dispensing volume set by the manufacturer.
Mix	Mixer (with washing function)
Barcode reading	Rack barcodes, sample barcodes, reagent barcodes
Prozone check	PRC method, RBC method
Check reagent blank	Detection using A1 value check
Number of test items	Haemoglobin, Calprotectin

Item	Specification
Carryover	Haemoglobin: Carryover rate $\leq 0.005\%$ Calprotectin: Below the lower limit of the measuring range
Cooling system	Reagent installation section (24-hour control), Peltier cooling system Liquid temperature in reagent bottles (Storage): $10 \pm 3\text{ }^{\circ}\text{C}$
Heating system	Reaction table, air bath system Reaction cell liquid temperature: $40 \pm 2\text{ }^{\circ}\text{C}$
Light source	LED (Wavelength: 660 nm)
Detector	Photo diode
Operation control/data processing	Multi-CPU system on internal network connection
External online	RS-232C, Ethernet
Sample dispensing accuracy	When 10 μL , CV 0.5 % or less (dye method)
Reagent dispensing accuracy	When 30 μL , CV 0.5 % or less (gravimetric method)
Input method	Colour LCD screen (10.4-inch), touch panel, barcode reader
Output method	Thermal printer (thermal paper width: 58 mm) Internal SSD External media over USB connection
Dimensions	700 mm $\times$ 706 mm $\times$ 589 mm (W $\times$ D $\times$ H) Tolerance: $\pm 2\%$
Weight	70 kg Tolerance: $\pm 4\%$
Insulation rating	Basic insulation: 1500 V (RS-232C, LAN)
Power	$\sim 100\text{-}240\text{ V } 50/60\text{ Hz } 500\text{ VA}$ or less
Usable life	8 years (self-certified [based on manufacturer data]) from start of use (installation) * Assuming periodic inspection/maintenance, part replacement, and repairs/overhaul (when required after inspection) are conducting.

■ Rack barcode specifications

Type	No. of Digits	Check Digit
ITF	3 digits	Modulus 10/3 weight

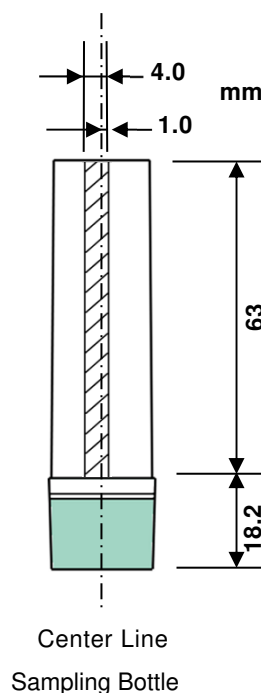
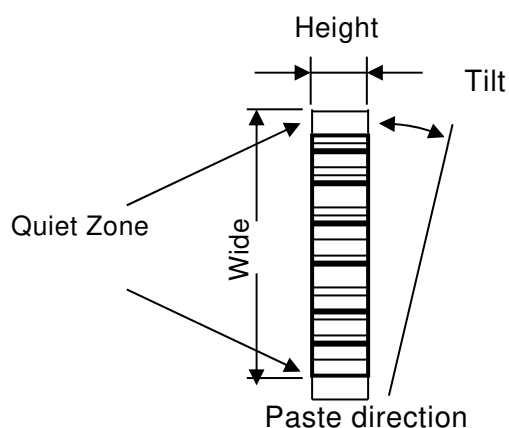
■ Sample barcode specifications (1D code)

Type	No. of Digits	Check Digit
NW-7	5-17 digits (Delete start/stop character.) 5 - 15 digits (Do not delete start/stop character.)	Modulus 10/3 weight Modulus 16 7 check DR Weighted modulus 11
ITF	6-14 digits	Modulus 10/3 weight (fixed)
IND 2 of 5	6-15 digits	Modulus 10/3 weight (fixed)
CODE39	5-15 digits (including start/stop characters)	Modulus 43 (fixed)
JAN	8 or 13 digits	Modulus 10/3 weight
CODE128	5-15 digits	None

■ 1D barcode reader specifications

Items	Specifications
Readable Size	Bar height 6 mm or more
Narrow bar width	0.19 mm to 1.0 mm
Quiet Zone	More than 10 times the size of a narrow bar
Digits	5 or more digits (maximum 15 digits)
PCS	0.45 or higher (white reflectance 75% or higher) PCS= (white bar reflectance - black bar reflectance) / white bar reflectance
Bar (label) slope	±4° or less

■ 1D barcode placement



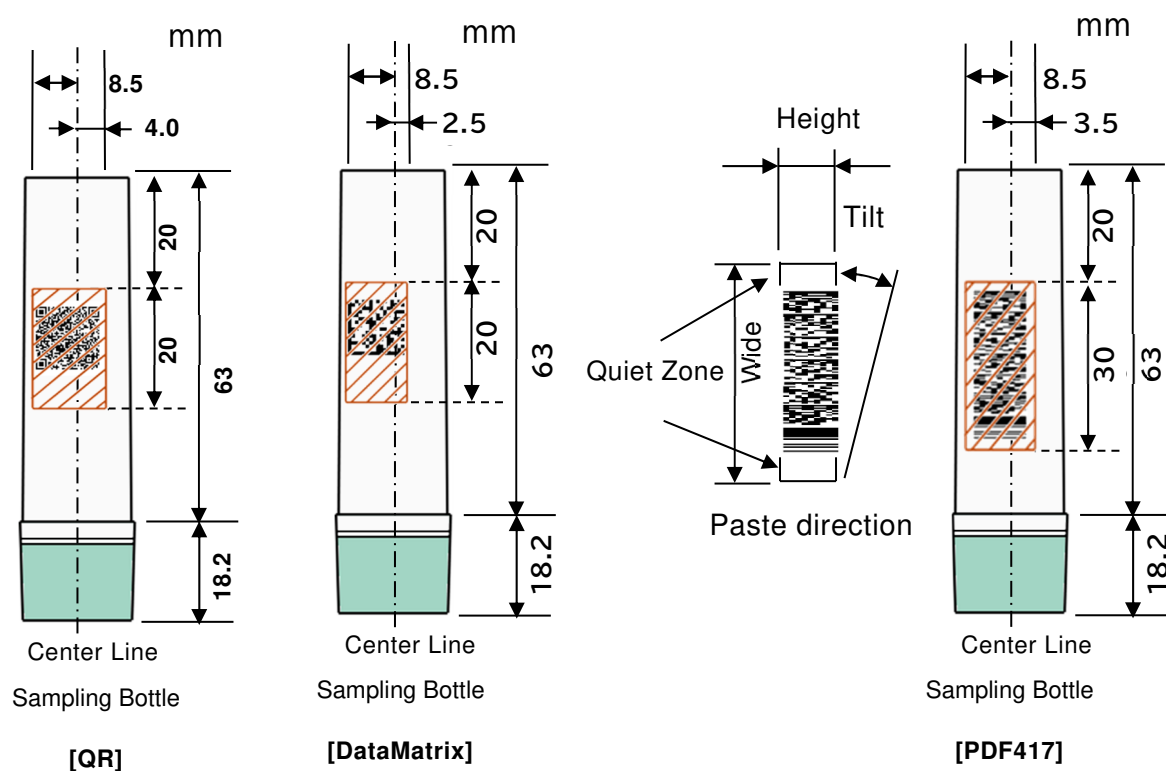
■ Sample barcode specifications (2D code)

Type	No. of Digits	Check Digit
QR	6-50 digits	None
DataMatrix	6-50 digits	None
PDF417	6-50 digits	None

■ 2D barcode reader specifications

Type	Standards/Models	Symbol size	Cell Size
QR	Model 2/Ver.4	33×33	0.25 mm
DataMatrix	ECC200	24×24	0.25 mm
Type	Items	Specifications	
PDF417	Size(mm)	Sideways 25~30、Height 10~ 12	
	Quiet Zone	At least 0.40 mm in both the vertical and horizontal directions	
	Bar (label) slope	±4° or less	

■ 2D barcode placement



1.7. Reagents Used by System

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

■ Reagents for haemoglobin measurement

Product Name	Product Code	Package
OC-SENSOR FIT	V-PZ05	4 × 16 mL 4 × 64 mL
OC-FIT Calibrator	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

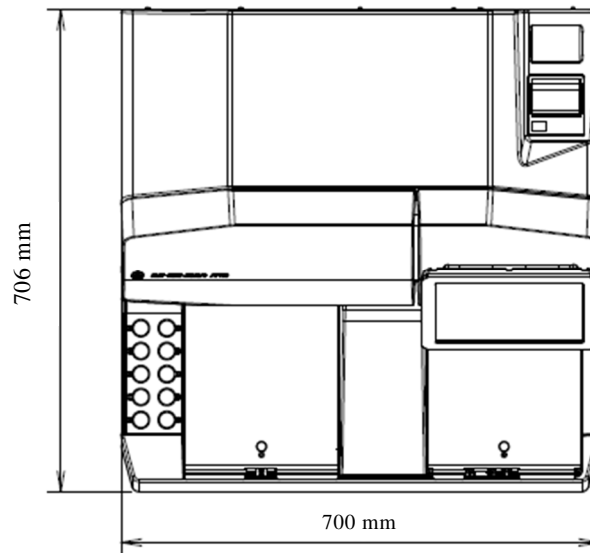
■ Reagents for calprotectin measurement

Product Name	Product Code	Package
OC-FCa Reagent	V-PH09	2 × 8 mL 2 × 15 mL
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

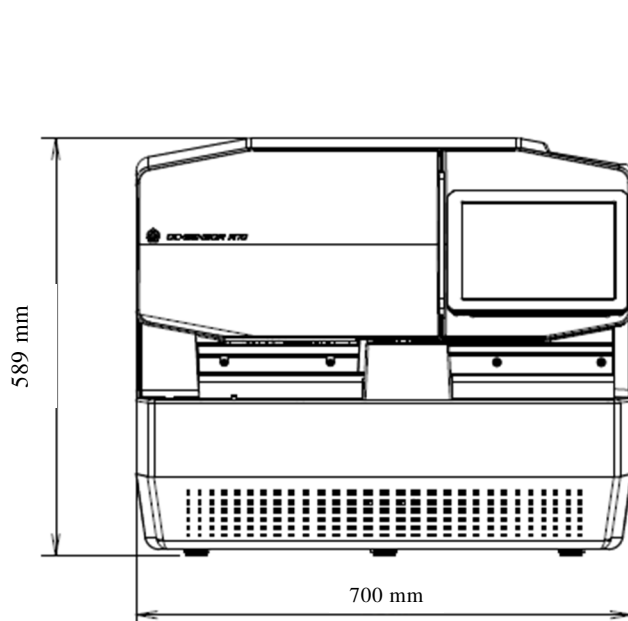
■ Common reagent (sample diluent)

Product Name	Product Code	Package
OC-SENSOR Sample Diluent	V-PH08	2 × 20 mL

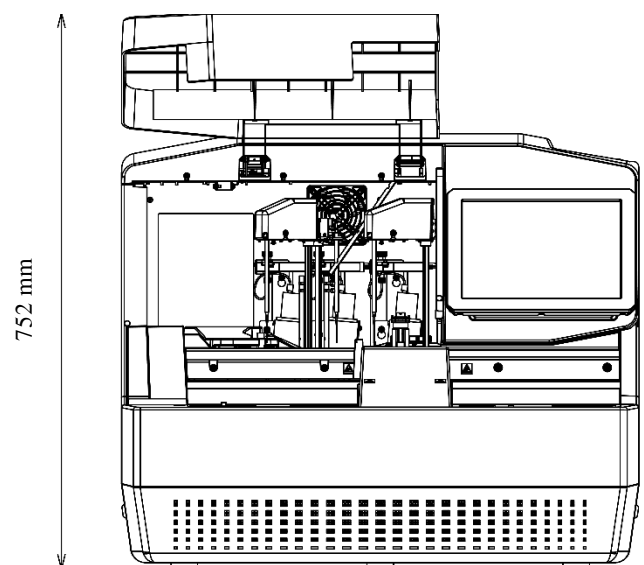
1.8. System Dimensions



Top view



Front view (cover closed)

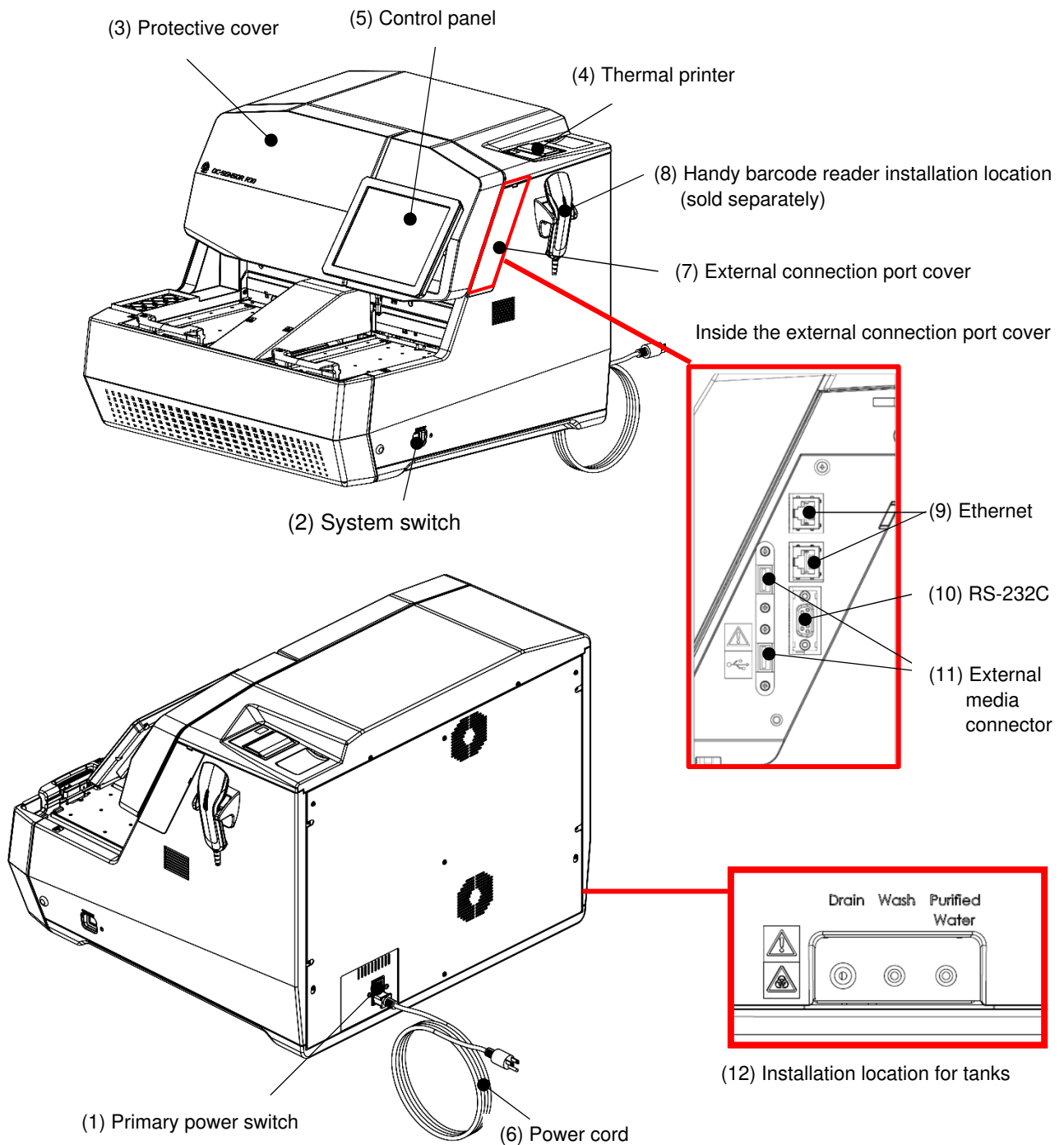


Front view (cover opened)

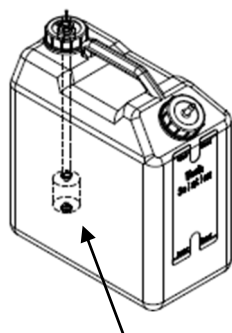
1.9. Names and Functions of Parts

The names of each part and their functions are described.

1.9.1. Exterior parts

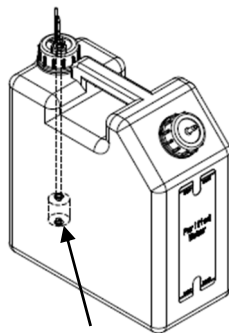


(13) Wash solution tank



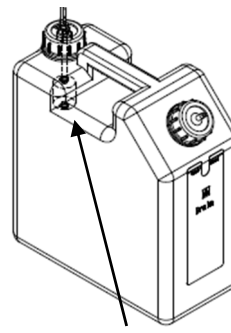
Sensor

(14) Purified water tank



Sensor

(15) Drain tank

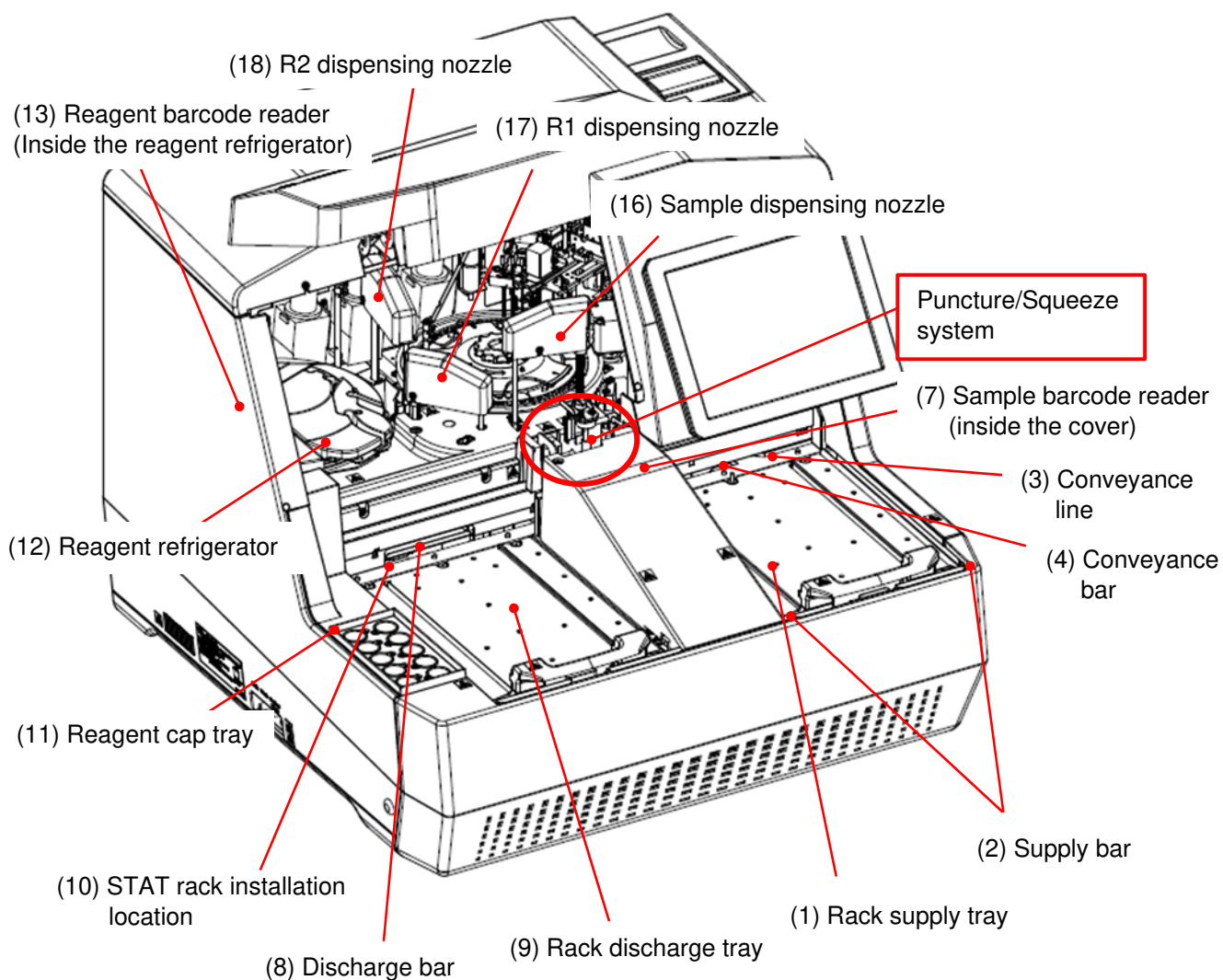


Sensor

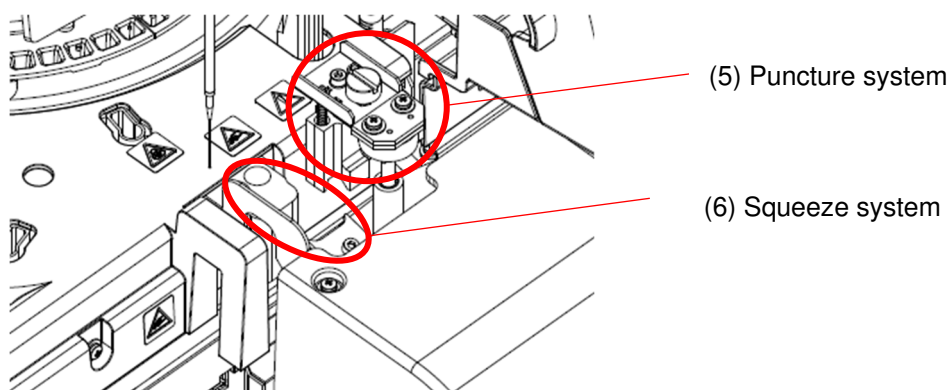
Name	Function
(1) Primary power switch	If the primary power switch is turned on, the System controls the temperature of the reagent refrigerator . The primary power switch should normally be left on.
(2) System switch	If the system switch is turned on, the System starts and controls the temperature of the reaction table.
(3) Protective cover	Safety feature to prevent accidents during system operation. The lock will be engaged during system operation.
(4) Thermal printer	Prints setup conditions, analysis results, error messages, or other data.
(5) Control panel	Shows operation screens and analytical results. The screen can be touched directly to operate.
(6) Power cord	The power cord for this system.
(7) External connection port cover	The cover of the external connection port. Attach it when the external connection port is not in use.
(8) Handy barcode reader installation location	Attach the separately sold handy barcode reader to the right side of the System.
(9) Ethernet	Connects to the host computer.
(10) RS-232C	Connects to the host computer.
(11) Port to external media	Allows connection to external media for storage of measured data.
(12) Installation location for tanks (left side of system)	Connects piping and wiring to the tanks (for wash solution, purified water, and drainage). (Piping and wiring connections are to be performed by service personnel.)
(13) Wash solution tank (Wash Solution)	Filled with wash solution. (Colour: Yellow)
(14) Purified water tank (Purified Water)	Filled with purified water. (Colour: Blue)
(15) Drain tank (Drain)	Stores liquid disposed by washing each nozzle (sample, R1, R2, and mixer) and cells. (Colour: White)

1.9.2. Internal parts

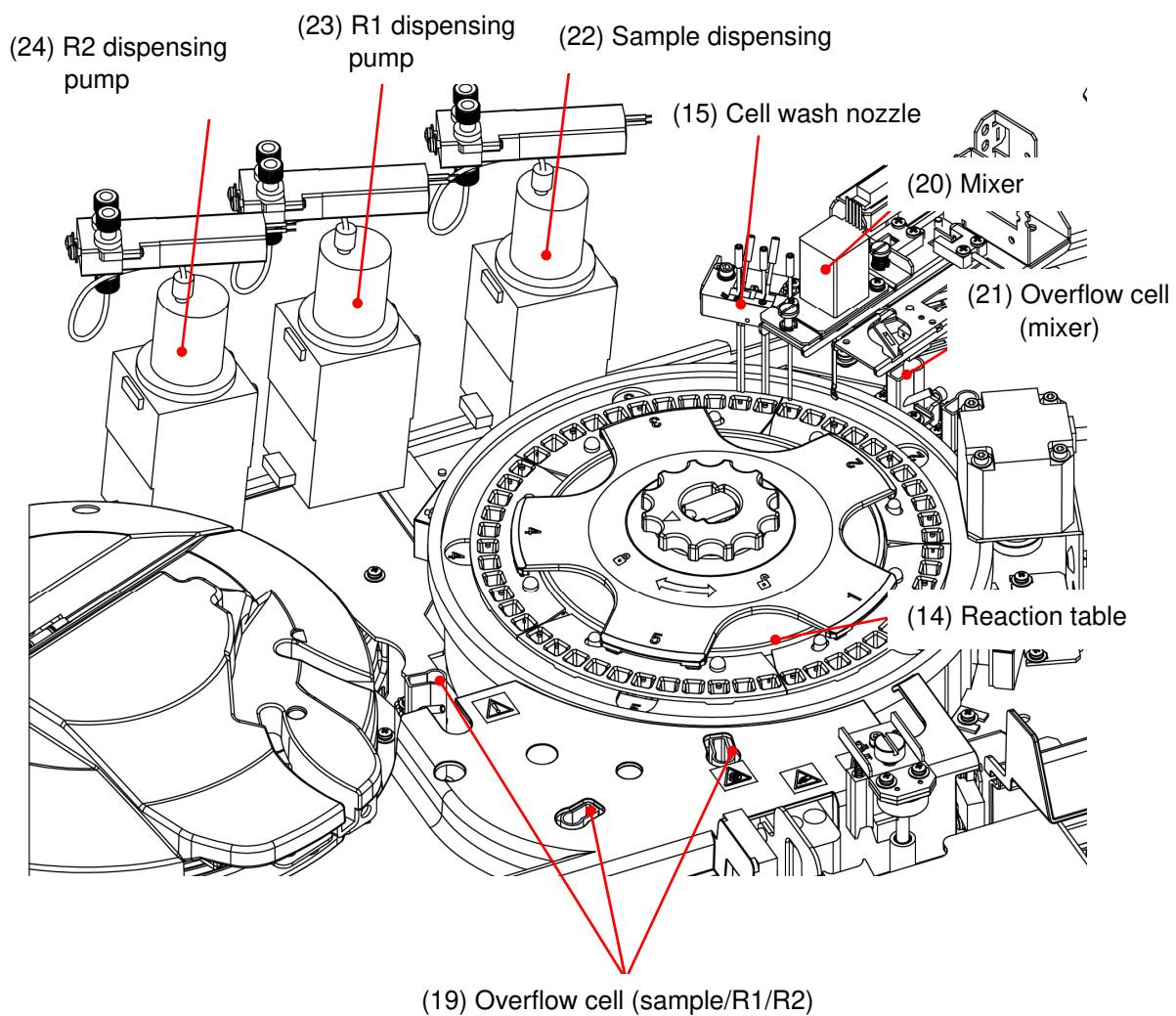
<Internal parts (1)>



<Puncture/Squeeze system (enlarged)>



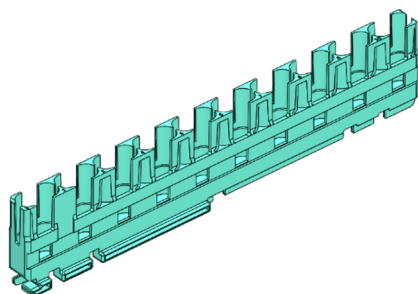
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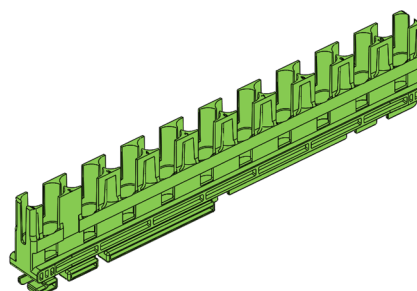
Name	Function
(1) Rack supply tray	Location where racks are placed. Up to 20 racks can be placed.
(2) Supply bar	Pushes the rack placed on the rack tray to the conveyance line.
(3) Conveyance line	Location where the rack moves during rack conveyance.
(4) Conveyance bar	Conveys a rack along the conveyance line.
(5) Puncture system	Punctures the double-layered aluminum seal attached to sample bottles.
(6) Squeeze system	Pushes up the liquid surface of the sample in the sample bottles.
(7) Sample barcode reader	Scans the barcodes of the sample bottles and the rack.
(8) Discharge bar	Feeds a rack to the rack discharge tray at the end of analysis.
(9) Rack discharge tray	Location where the rack is discharged.
(10) STAT rack installation location	Location where the rack is installed when performing STAT analysis.
(11) Reagent cap tray	Location where the cap of the reagent bottle is placed during installation.
(12) Reagent refrigerator	Location to set the reagents. Constantly maintained at 7 °C to 13 °C.
(13) Reagent barcode reader	Scans the reagent barcodes.
(14) Reaction table	Performs antigen-antibody reaction and photometry.
(15) Cell wash nozzle	Washes the measurement cells.
(16) Sample dispensing nozzle	Dispenses samples.
(17) R1 dispensing nozzle	Dispenses the R1 reagent.
(18) R2 dispensing nozzle	Dispenses the R2 reagent.
(19) Overflow cell (Sample/R1/R2)	<u>For sample nozzles</u> Washes the inner and outer wall of sample nozzles using purified water and wash solution. Drainage is sent to the drain tank. <u>For R1, R2 nozzles</u> Washes the inner and outer wall of R1 and R2 nozzles using purified water. Drainage is sent to the drain tank.
(20) Mixer	Mix samples and reagents.
(21) Overflow cell (mixer)	Washes mixer blades using purified water and wash solution. Drainage is sent to the drain tank.
(22) Sample dispensing pump	Absorbs and flushes samples.
(23) R1 dispensing pump	Absorbs and flushes the R1 reagent.
(24) R2 dispensing pump	Absorbs and flushes the R2 reagent.

1.9.3. Accessories/Others

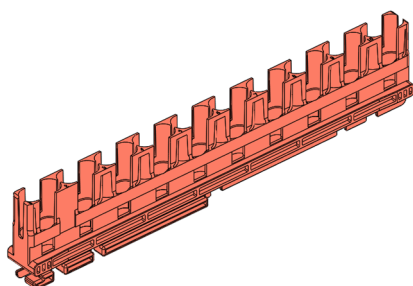
(1) Sample Rack



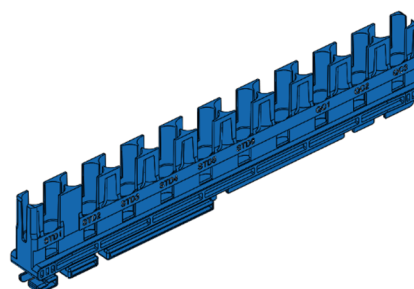
(2) Retest Rack



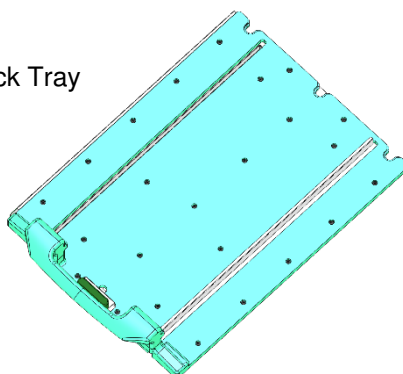
(3) Dilute Retest Rack



(4) STD/QC Rack



(5) Rack Tray



Name	Function
(1) Sample Rack	Only the sample bottles can be placed.
(2) Retest Rack	Holds sample bottles and sample cups.
(3) Dilute Test Rack	
(4) STD/QC Rack	
(5) Rack Tray	Used to place each rack.

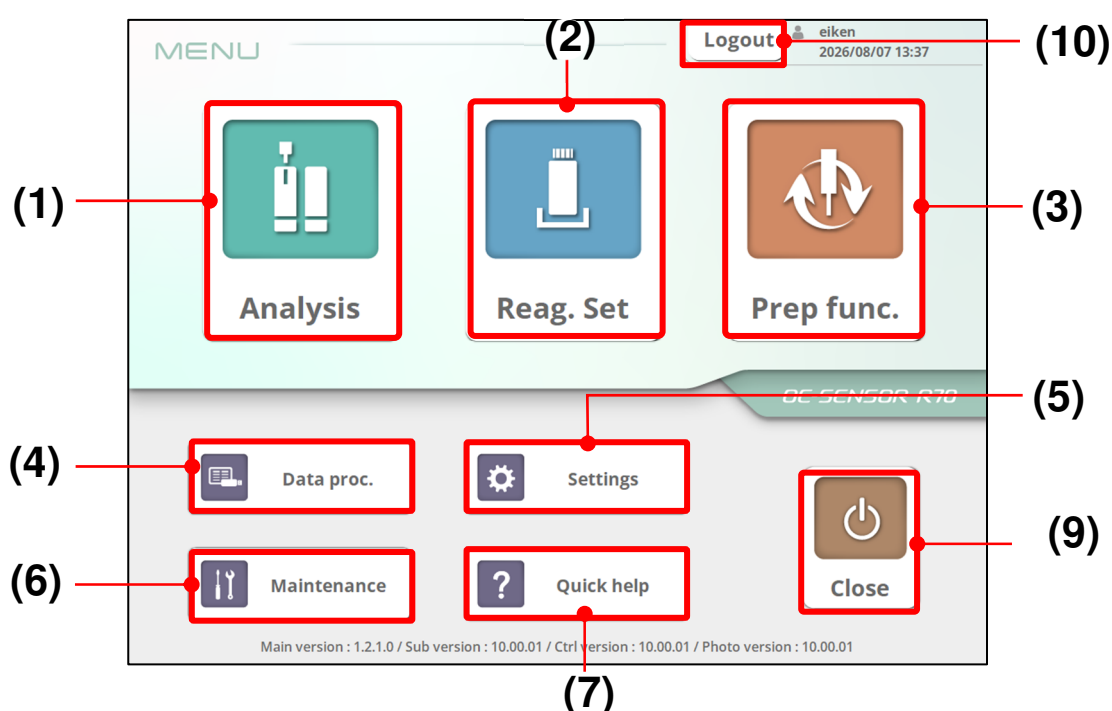
2. Operation (Basic)

2.1. Basic Screen Operation

This section describes functions that can be run on each screen, as well as buttons displayed on the screen and their basic operations.

2.1.1. Menu screen and functions

When the System is started and login is completed, the "MENU" screen is displayed. The details of each button are as follows.

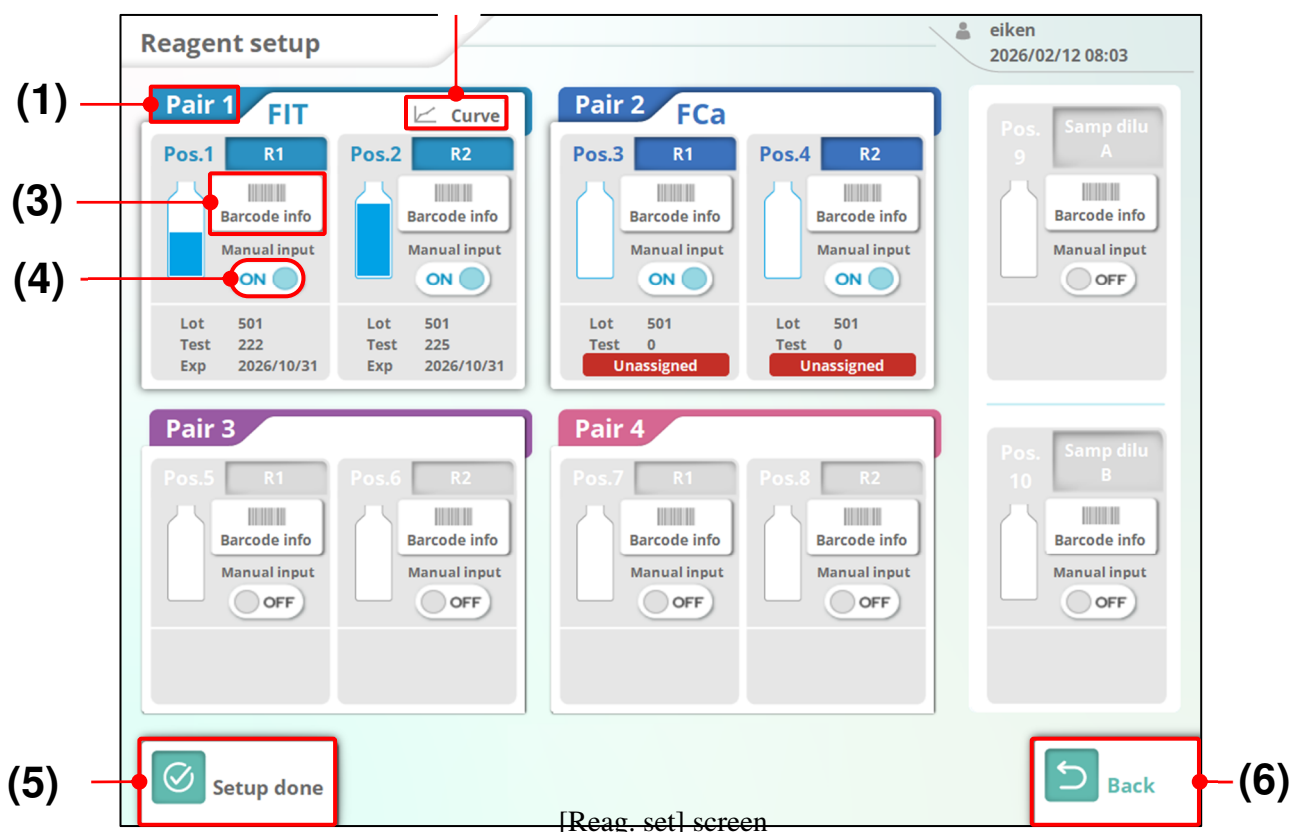


Name	Details
(1) Analysis	Performs the analysis.
(2) Reag. set	Installs reagents.
(3) Aux func.	Performs auxiliary functions (initialization, priming, cell blank).
(4) Data proc.	Performs "measurement data processing" and "quality control processing."
(5) Settings	Performs various settings of the System.
(6) Maintenance	Performs inspection and maintenance.
(7) Quick help	Checks the quick help screen.
(8) Exit	Turn off the device. Executing 'Shut down process' will automatically shut down the System.
(9) Logout	Logs out from the currently logged-in account and displays the login screen.

2.1.2. [Reag. set] screen and functions

When installing reagents, operate using [Reag. set]. This section describes the functions of each button.

(2)

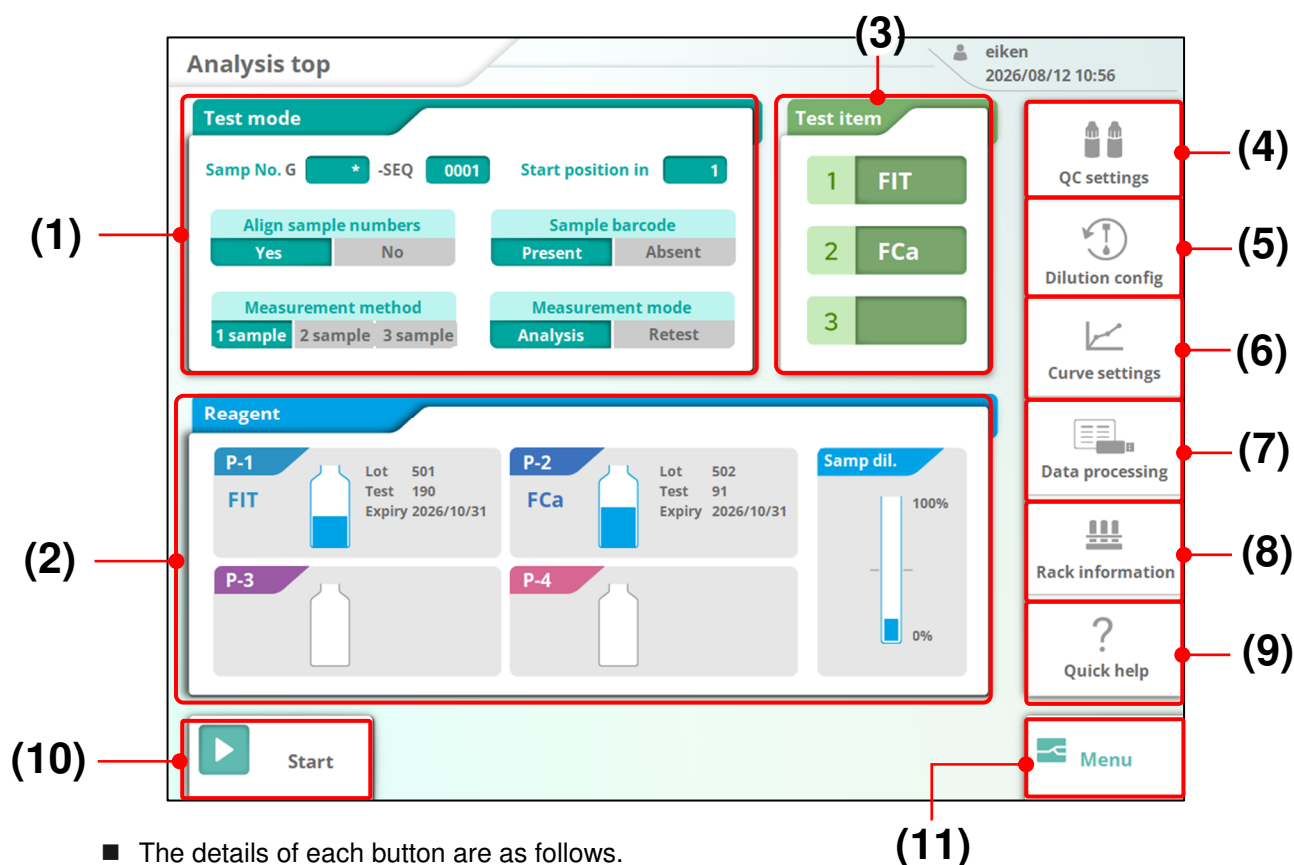


[Reag. set] screen

Name	Details
(1) Installation position	The installation positions in the refrigerator are displayed as [Pair 1 to 4]. When the area is touched, the touched Pair position is oriented toward the front of the System by the automatic movement of the reagent table.
(2) Calibration curve	If a calibration curve corresponding to the reagent lot is registered, the calibration curve information can be confirmed. If a calibration curve is not registered, "No calibration curve" is displayed.
(3) Barcode info	Reagent barcode information is displayed and can be edited. When edited, "Manual input" is set to "ON". Reagent barcode information can only be edited by users with "Administrator" login accounts.
(4) Manual input	The manually entered barcode information is prioritized and saved. Reagent barcodes are not read.
(5) Setup done	Reagent barcode reading and the measurement of the remaining reagent volume are performed.
(6) Back	Returns to the menu screen/analysis top screen.

2.1.3. [Analysis top] screen and functions

When [MENU] screen is displayed, touch {Analysis} to display the analysis top screen.

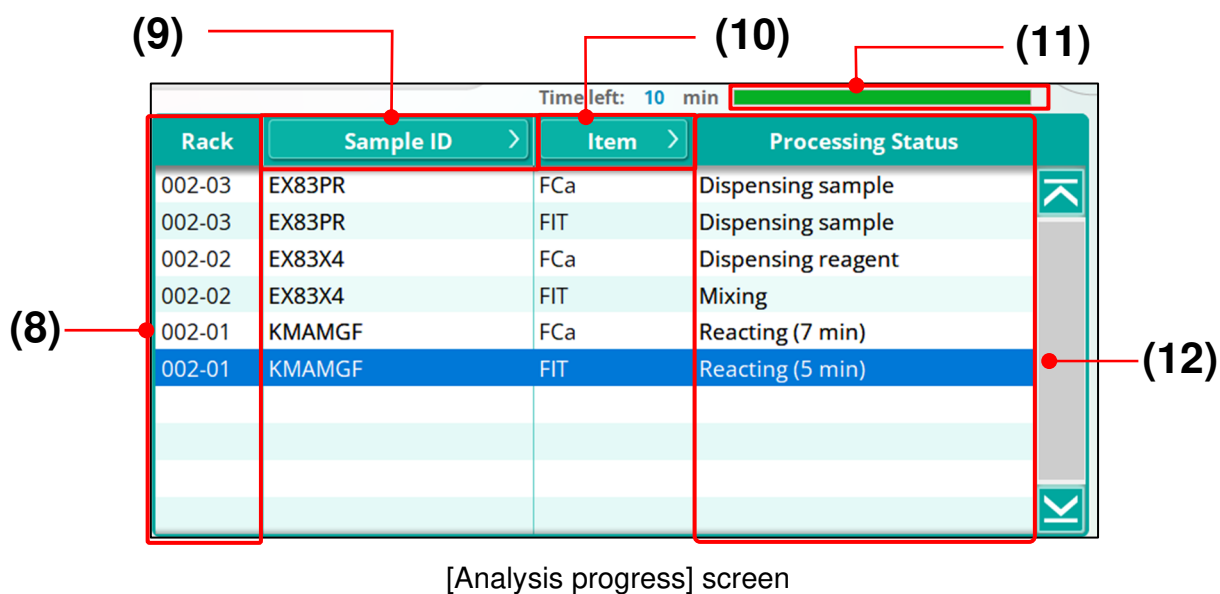
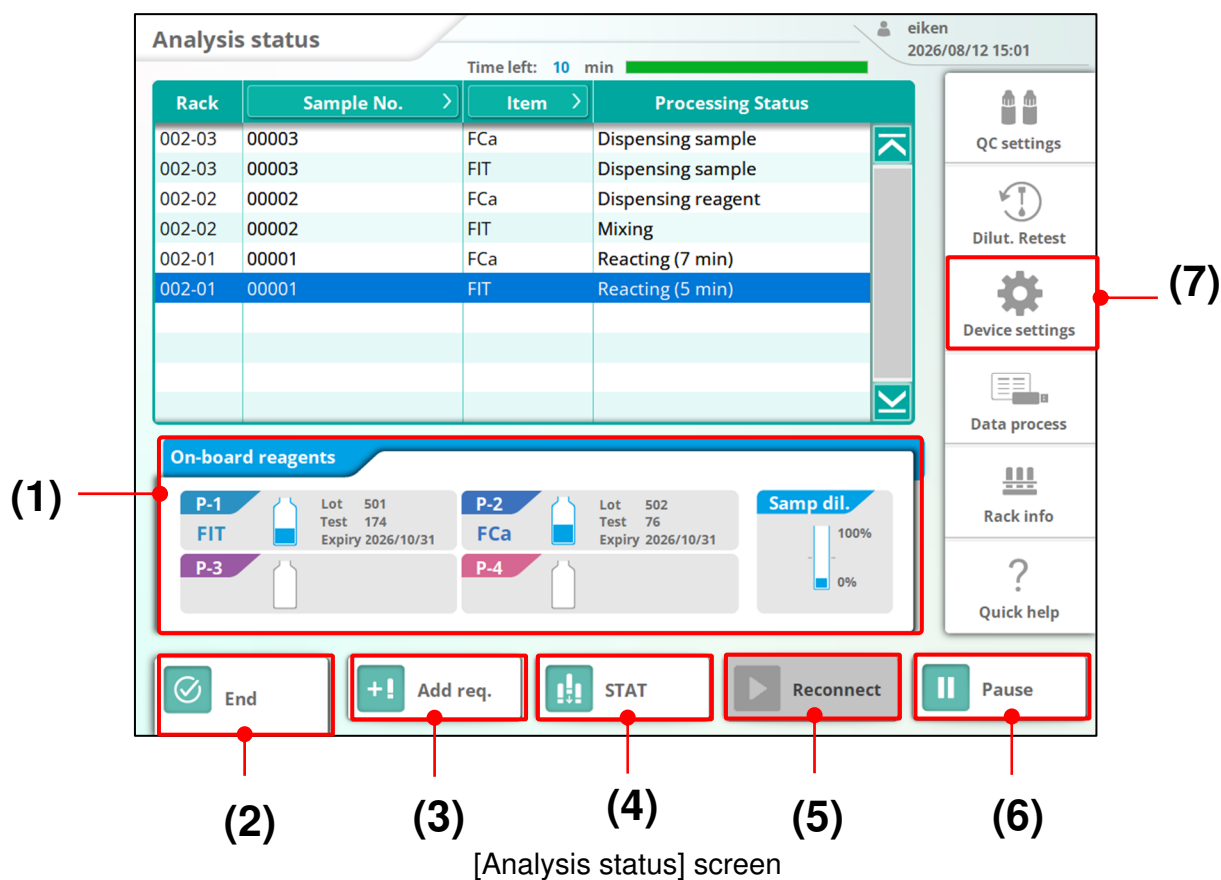


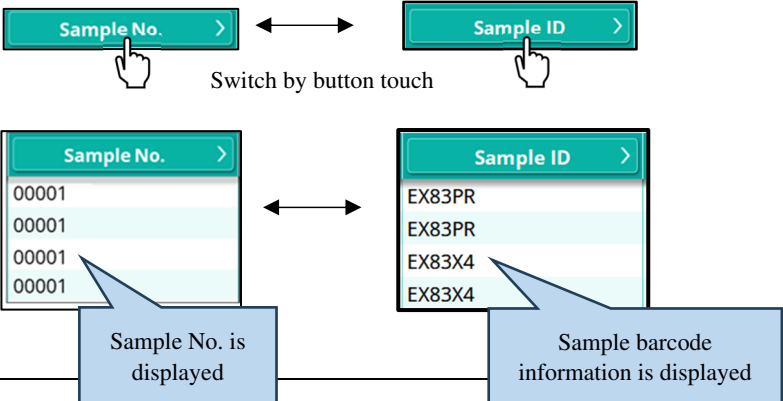
■ The details of each button are as follows.

Name	Details
(1) Test mode	Configures various conditions for analysis.
(2) Reagent	Displays information of reagents installed in the reagent refrigerator.
(3) Test item	Selects the analysis item.
(4) QC settings	Configures settings for QC measurement.
(5) Dilution config	Configures settings for dilution retest.
(6) Curve settings	Configures settings for calibration curves.
(7) Data processing	Checks measured data.
(8) Rack information	Checks rack information.
(9) Quick help	Checks simple help.
(10) Start	Starts the analysis.
(11) Menu	Returns to the menu screen.

2.1.4. [Analysis status] screen and functions

During analysis, the following [Analysis status] screen is displayed.



Name	Details
(1) Reagent	The information of the reagent in use is displayed. When the area is touched, additional reagents can be installed.
(2) End ana.	Ends the analysis.
(3) Add req.	Changes "Test mode" during analysis.
(4) STAT	Inserts the sample rack and STD/QC rack during analysis for priority analysis.
(5) Reconn.	If an abnormality communicating with an outside computer is detected and the communication is disconnected, the {Reconn.} button is displayed. ■ Resume communication using the following method. (1) Resolve the communication error. (2) Touch the {Reconn.} button. * Communication resumes and remaining data that was not output during the interruption is output.
(6) Pause	Pauses the analysis. * The sample being processed will continue to be analyzed.
(7) System settings	The System setting information can be viewed. * It cannot be edited.
(8) Rack info	The rack number and position in the rack of the sample (including STAT samples, STD samples, and QC samples) being tested are displayed.
(9) Sample No./Sample ID	[Sample No./Sample ID] - Sample No. The samp No. of the samples (including STAT samples, STD samples, and QC samples) being tested are displayed. - Sample ID The sample barcode information is displayed. The display switching between sample No. and sample ID is switched by touching the button. The Sample ID is displayed upon startup. 

Name	Details																																																								
(9) [Item]	The item being analyzed is displayed. When measuring multiple items, the displayed items can be narrowed down by touching the button. Each time the [Item] button is touched, the item to be narrowed down changes. After filtering, touch the [Item Name] button to return to the full list. <table><tr><th>Rack</th><th>Sample ID</th><th>Item</th><th>Processing Status</th></tr><tr><td>002-03</td><td>EX83PR</td><td>FCa</td><td>Dispensing sample</td></tr><tr><td>002-03</td><td>EX83PR</td><td>FIT</td><td>Dispensing sample</td></tr><tr><td>002-02</td><td>EX83X4</td><td>FCa</td><td>Dispensing reagent</td></tr><tr><td>002-02</td><td>EX83X4</td><td>FIT</td><td>Mixing</td></tr><tr><td>002-01</td><td>KMAMGF</td><td>FCa</td><td>Reacting (7 min)</td></tr><tr><td>002-01</td><td>KMAMGF</td><td>FIT</td><td>Reacting (5 min)</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr></table> ↓ <table><tr><th>Rack</th><th>Sample No.</th><th>Item</th><th>Processing Status</th></tr><tr><td>008-09</td><td>00009</td><td>FIT</td><td>Dispensing sample</td></tr><tr><td>008-08</td><td>00008</td><td>FIT</td><td>Dispensing reagent</td></tr><tr><td>008-07</td><td>00007</td><td>FIT</td><td>Reacting (5 min)</td></tr></table> Filter the items to be displayed by FIT	Rack	Sample ID	Item	Processing Status	002-03	EX83PR	FCa	Dispensing sample	002-03	EX83PR	FIT	Dispensing sample	002-02	EX83X4	FCa	Dispensing reagent	002-02	EX83X4	FIT	Mixing	002-01	KMAMGF	FCa	Reacting (7 min)	002-01	KMAMGF	FIT	Reacting (5 min)													Rack	Sample No.	Item	Processing Status	008-09	00009	FIT	Dispensing sample	008-08	00008	FIT	Dispensing reagent	008-07	00007	FIT	Reacting (5 min)
Rack	Sample ID	Item	Processing Status																																																						
002-03	EX83PR	FCa	Dispensing sample																																																						
002-03	EX83PR	FIT	Dispensing sample																																																						
002-02	EX83X4	FCa	Dispensing reagent																																																						
002-02	EX83X4	FIT	Mixing																																																						
002-01	KMAMGF	FCa	Reacting (7 min)																																																						
002-01	KMAMGF	FIT	Reacting (5 min)																																																						
Rack	Sample No.	Item	Processing Status																																																						
008-09	00009	FIT	Dispensing sample																																																						
008-08	00008	FIT	Dispensing reagent																																																						
008-07	00007	FIT	Reacting (5 min)																																																						
(10) Remaining time	The remaining time display shows the time from after the last sample dispensing until the washing of all reaction cells is completed.																																																								
(11) [Processing status]	The processing status of the sample is displayed. The following information is displayed. Dispensing sample Dispensing reagent Mixing Reacting (○ min) : The number in ○ indicates the remaining minutes until the value is Value output. OR/PRC/RBC : When the measurement is completed normally If the value is equal to or exceeds the upper measurement limit or meets the PRC/RBC check criteria, “OR” or “PRC, RBC” is displayed, and the text background turns yellow. Various errors : When measurement did not complete normally The error is displayed, and the text background turns red.																																																								

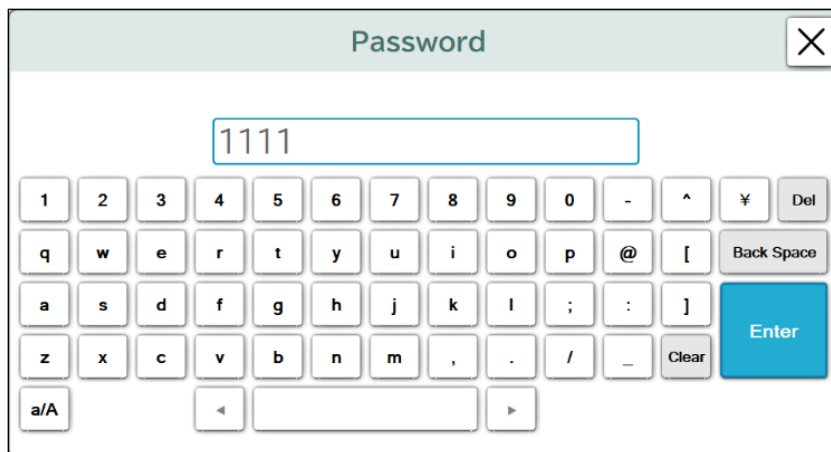
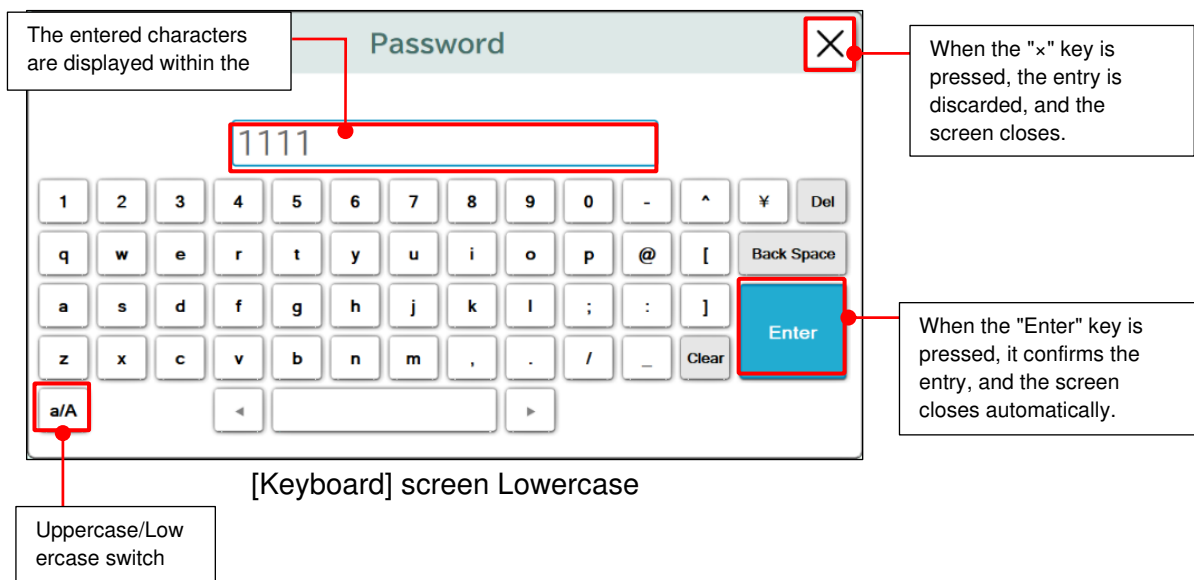
2.1.5. How to enter characters

When it is necessary to enter characters or numbers, a keyboard or numeric keypad is displayed on the screen.

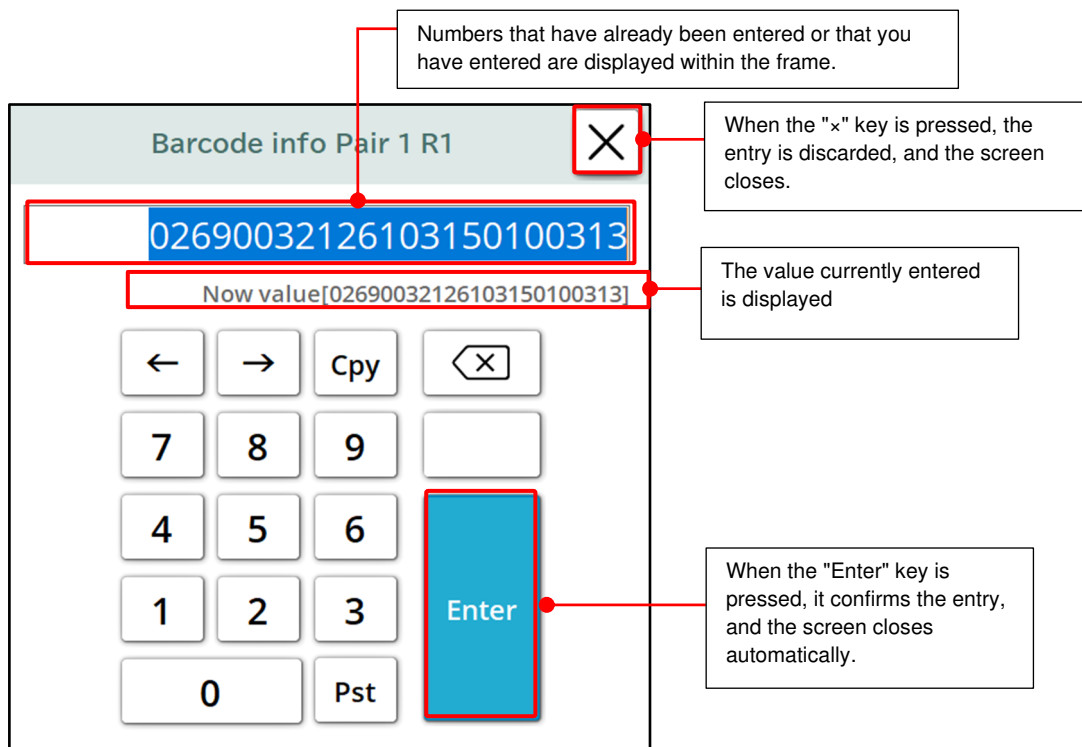
This section describes the operation method for each.

<Keyboard>

Used to enter characters and numbers. Switching between uppercase and lowercase changes the characters that can be entered.



< Numeric keypad >
Used to enter numbers.

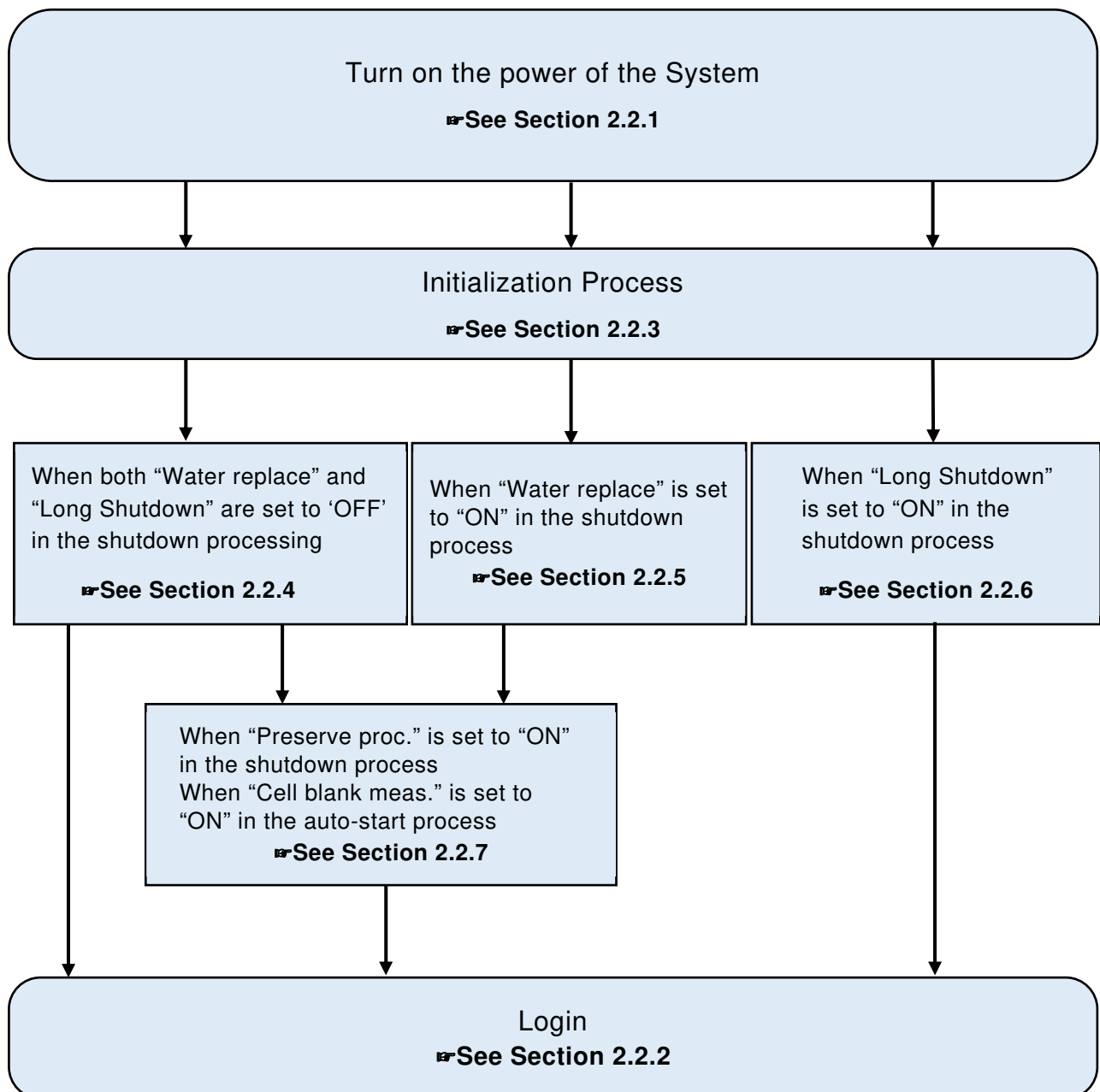


[Numeric Keypad] Screen

2.2. Starting the System

This section describes the procedure for starting the System. Note that the flow after starting differs depending on the shutdown process/startup process. The flow after startup is as shown in the figure below.

* If nothing is configured, the "Login" screen is displayed after startup.



When starting the System for the first time, register a new account.

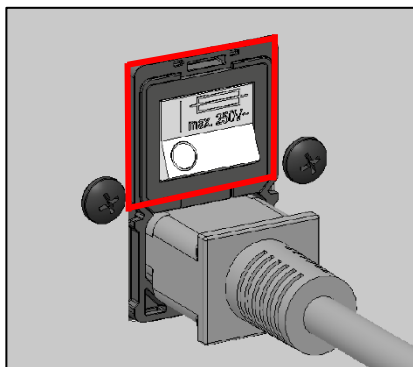
☛ See Section 2.3.1

2.2.1. Turn on the power of the System

The section describes the procedure for turning on the power of the System.

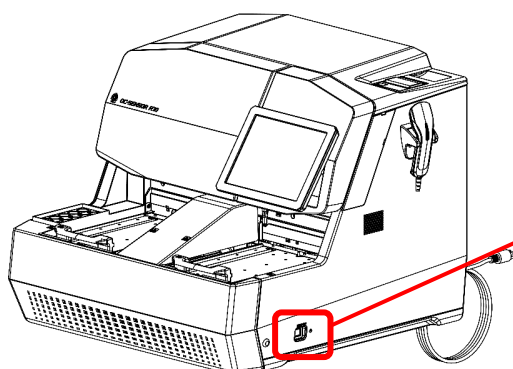
- * If automatic startup is set at system shutdown, the power is automatically turned on at the set day/time, so these operations are not necessary.

➤ See Section 2.11

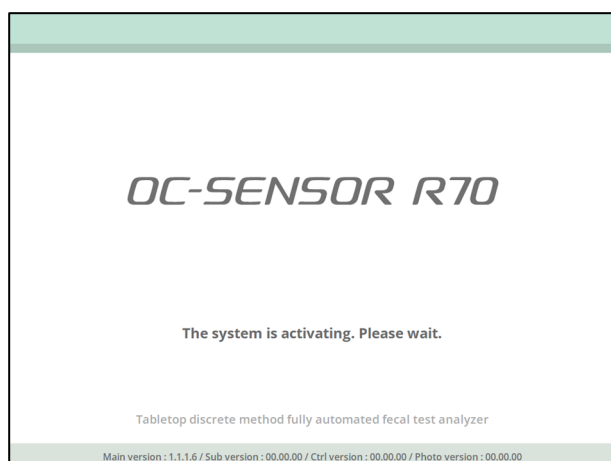
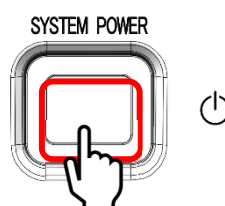


Primary power switch (system rear end)

- (1) Confirm that the primary power switch on the back of the System is set to "ON".
 - Normally, keep the primary power switch in the "ON" position.



- (2) Press the standby switch on the right side of the System.



- (3) The power is supplied to the System, and the startup screen is displayed. After a while, the login screen is displayed.

2.2.2. Login/Logout

After system startup, login is required to begin various operations.
This section describes the login procedure and the logout procedure.

The screenshot shows the 'Login' screen with the title 'Select a user and enter the password.' At the top right, the date and time are '2026/08/19 12:53'. Below the title is a table with columns: 'Select', 'Permission', 'Operator ID', and 'Operator name'. The first row is highlighted with a red box and contains a selected radio button, 'Admin', 'eiken', and 'eiken'. Below this table are three more rows for 'User' with IDs 'User', 'user2', and an empty field. A red box labeled '(1)' is around the 'User' row. Below the table is a 'Password' field with a red box labeled '(2)' around it. At the bottom left is a 'Login' button with a checkmark icon.

■ Login procedure

- (1) After the System is started, the [Login] screen is displayed.

* The [Account registration] screen is displayed at initial startup.

➡ See Section 2.3.1

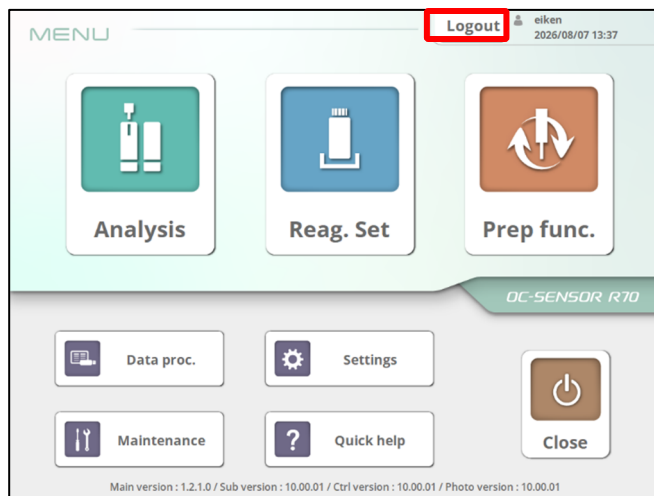
- (2) Select the user for login and touch the password entry field.

The screenshot shows the 'Password' entry screen. At the top, it says 'Select a user and enter the password.' and '2026/08/19 12:53'. Below is a 'Password' field containing 'Eiken000000'. Below the field is an on-screen keyboard with letters, numbers, and symbols. A red box is around the keyboard area. At the bottom left is a 'Login' button with a checkmark icon.

- (3) Enter the password linked to the operator ID using the on-screen keyboard.

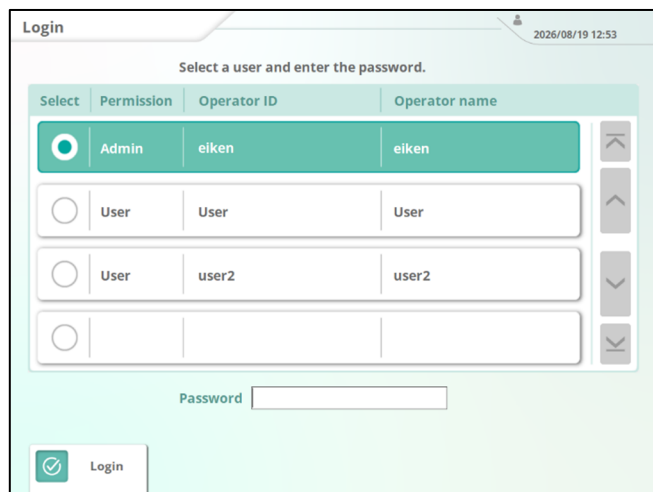
The screenshot shows the 'Login' screen again, similar to the first one. The 'Admin' user is selected. The 'Password' field is empty. A red box is around the 'Login' button at the bottom left.

- (4) Touch Login.
After login is completed, the main menu is displayed.



■ Logout procedure

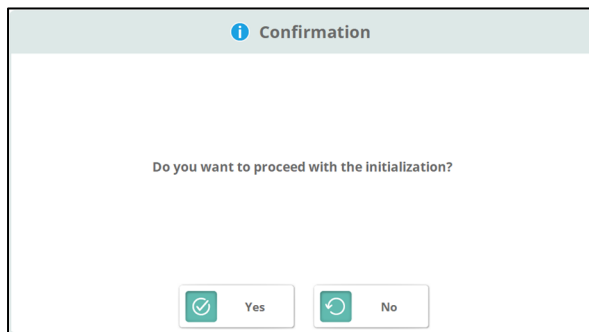
- (1) On the [MENU] screen, touch the {Logout} button.



- (2) Logout from the currently logged-in account, and the [Login] screen is displayed again.

2.2.3. Initialization Process

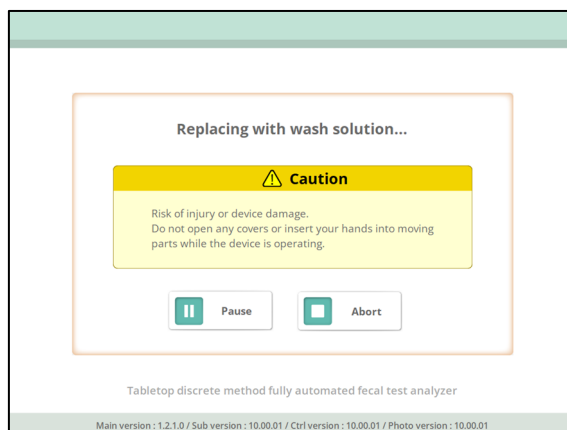
Once the device has started up, the initialization process will be carried out.



- (1) Once the device has started up, a message asking 'Do you want to proceed with the initialization?' will appear. Please tap 'Yes' to run the initialization process, or 'No' if you do not wish to do so. If you do not select either option, the initialization process will run automatically after 10 seconds.

2.2.4. When both “Water replace” and “Long Shutdown” are set to ‘OFF’ in the shutdown processing

2.2.4. When both “Water replace” and “Long Shutdown” are set to ‘OFF’ in the shutdown processing, the system will perform a detergent flush and normal prime upon restart.



- (1) Once the initialization process is complete, a cleaning fluid replacement process will be carried out to fill the pipework with cleaning fluid.

<Operations during the replacing with wash solution>

{Pause}: Replacing with wash solution is temporarily paused.

{Start}: Resume processing.

If the {Pause} button is touched, it changes to the {Start} button.

{Abort}: Abort processing

- (2) Once the cleaning solution replacement process is complete, the normal priming procedure will commence.

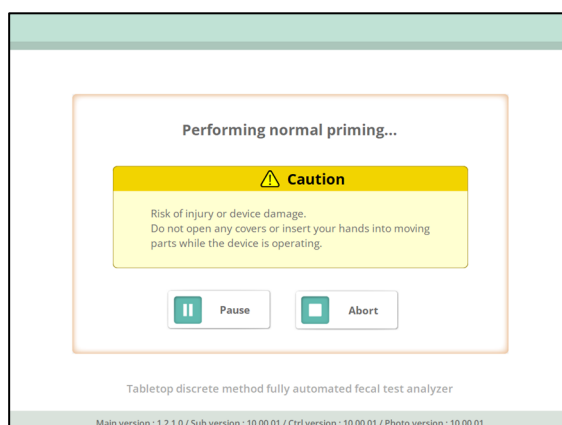
<Operation during activate priming>

{Pause}: Priming is temporarily paused.

{Start}: Resume processing.

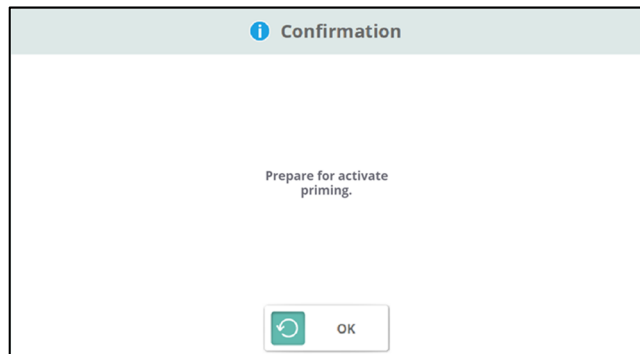
If the {Pause} button is touched, it changes to the {Start} button.

{Abort}: Abort processing

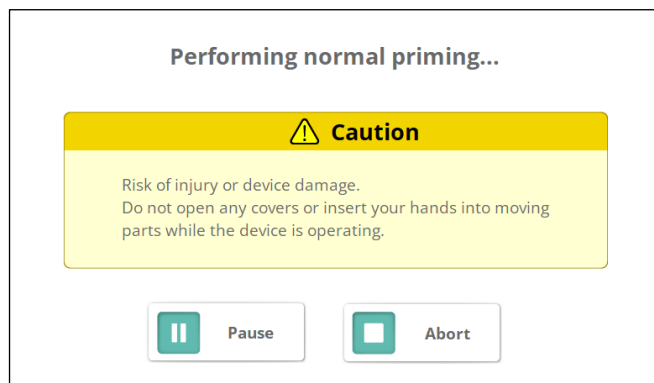


2.2.5. When “Water replace” is set to “ON” in the shutdown process

When “Water replace” is set to “ON” in the System shutdown process, activate priming is executed after startup.



- (1) After starting the device, the message "Please prepare for induction prime" will be displayed. Check each tank (see sections 2.6.1 to 2.6.3 for tank checking instructions) and press the [OK] button.



- (2) The activate priming starts automatically.

<Operation during activate priming>

{Pause}: Priming is temporarily paused.

{Start}: Resume processing.

If the {Pause} button is touched, it changes to the {Start} button.

{Abort}: Abort processing.

- (3) If cell blank measurement is set to “ON” during the shutdown process, cell blank measurement starts after activate priming is completed.

➡ **See Section 2.2.7**

- * After cell blank measurement is completed, the login screen is displayed.
- * If the cell blank measurement is set to “OFF,” the login screen is displayed after activate priming is completed.

2.2.6. When Long Shutdown is set in the shutdown process

When “Long Shutdown” is set to “ON” in the shutdown process, activate priming is executed after startup, in the same way as when “Water replace” is set to “ON.”

➡ **See Section 2.2.5**

2.2.7. When “Preserve proc.” is set to “ON” in the shutdown process, or When “Cell blank meas.” is set to “ON” in the auto-start process

This procedure is carried out after the procedures in Section 2.2.4 or Section 2.2.5 have been completed. **Refer to Section 2.2**

When “Preserve proc.” is set to “ON” in the shutdown process, or when “Cell blank meas.” is set to “ON” in the auto-start process, cell blank measurement is executed automatically after startup.

For cell blank measurement settings at auto-start **Refer to Section 2.11**

The login screen displays a table for user selection. The 'Admin' user is selected. Below the table is a password field and a 'Login' button.

Select	Permission	Operator ID	Operator name
☒	Admin	eiken	eiken
☐	User	User	User
☐	User	user2	user2
☐			

Password:

Login

[Startup screen]

The 'Measuring cell blank...' screen displays a table with 55 rows of data (No., ADC, ABS). At the bottom, there are 'Pause' and 'Abort' buttons.

No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS
01			12	25877	526	23	26223	468	34			45		
02			13	26209	470	24	26178	475	35			46		
03			14	26332	450	25	26365	444	36			47		
04			15	26287	457	26	26319	452	37			48		
05	26054	496	16	25375	611	27			38			49		
06	26032	500	17	26298	456	28			39			50		
07	26292	457	18	26365	445	29			40			51		
08	25820	535	19	26257	462	30			41			52		
09	26174	476	20	25834	533	31			42			53		
10	26357	446	21	26304	455	32			43			54		
11	26279	459	22	26281	458	33			44			55		

Pause Abort

[Cell blank measurement screen]

The 'Cell blank measurement finished.' screen displays a table with 55 rows of data (No., ADC, ABS). At the bottom, there are 'Print' and 'Close' buttons.

No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS
01	26222	468	12	25877	526	23	26223	468	34	26310	454	45	26110	487
02	26223	468	13	26209	470	24	26178	475	35	26096	489	46	26186	474
03	26084	491	14	26332	450	25	26365	444	36	26131	483	47	26312	453
04	26234	466	15	26287	457	26	26319	452	37	26193	473	48	26096	489
05	26054	496	16	25375	611	27	26083	491	38	26248	464	49	26000	505
06	26032	500	17	26298	456	28	25549	581	39	26233	466	50	25808	537
07	26292	457	18	26365	445	29	26308	454	40	26293	456	51	26302	455
08	25820	535	19	26257	462	30	26348	447	41	26221	468	52	26289	457
09	26174	476	20	25834	533	31	25781	542	42	26107	487	53	26174	476
10	26357	446	21	26304	455	32	26094	489	43	26269	460	54	26130	483
11	26279	459	22	26281	458	33	26280	459	44	26217	469	55	26299	455

Print Close

<Startup flow>

- (1) The System automatically starts at the time of the set day of the week.
* The startup screen is displayed.

- (2) Cell blank measurement starts automatically.

<Operation during cell blank measurement>

{Pause}: Cell blank measurement pauses.

{Start} : Resumes cell blank measurement.

If the {Pause} button is touched, it changes to the {Start} button.

{Abort}: Aborts cell blank measurement.

- (3) When the {Close} button is touched, the login screen is displayed.

When printing the cell blank results with the printer, touch the {Print} button.

Refer to Section 2.6.7

2.3. Account Registration

When starting the System for the first time, new account registration is required. This section describes the procedure for new account registration and the differences in functions that can be used depending on permissions.

2.3.1. New account registration

The screenshot shows the 'User account settings' interface. At the top, it says 'eiken 2026/02/12 12:36'. Below is the 'Account Information' section with a red box labeled (1) around the input fields. The fields are: Operator ID (eiken-2), Operator name (eiken-2), Password (*****), Permission (Admin selected, User button), and Auto logout time (10 m). At the bottom, there is a 'Register' button with a green checkmark icon, highlighted with a red box labeled (2). Other buttons include 'Delete account' and 'Back'.

- At the initial startup of the System, the "New account registration" screen is displayed.

- Enter each item, and press {Register}.

After the initial login is completed, the login screen is displayed at the next startup.

➡ See Section 2.2.2

The registered account can be edited, added, or deleted from the settings screen.

➡ See Section 6.2.2

Setting Item	User Account Setting Item	Contents
Operator ID	1 character or more Alphanumeric characters/symbols	Set the operator ID at login.
Operator name	1 character or more Alphanumeric characters/symbols	Set the operator name at login.
Password	8 character or more Alphanumeric characters/symbols	Set the password for login.
Permission	Admin	At the initial startup, only the "Admin" can be registered. ("User" cannot be selected.) If you wish to register an additional account, register after completing the initial login. ➡ See Section 6.2.2
Auto logout time	1-99	Set the automatic logout time when no screen transition occurs from the main menu for a specified period. * If set to 0 minutes, automatic logout does not occur.

2.3.2. Account permissions

The functions that can be used differ depending on the account permissions at the time of login.

List of access restrictions by account permissions

Items	Available functions	Account permission	
		User	Admin
Settings	Protocol	○	○
	Sample barcode	○	○
	Rack No.	○	○
	Environment	○	○
	User account	○	○
	Screen saver	○	○
	Alarm	○	○
	Output format	×	○
	Data output	×	○
	Backup	×	○
	Restore	×	○
Analysis	Editing calibration curve information	×	○

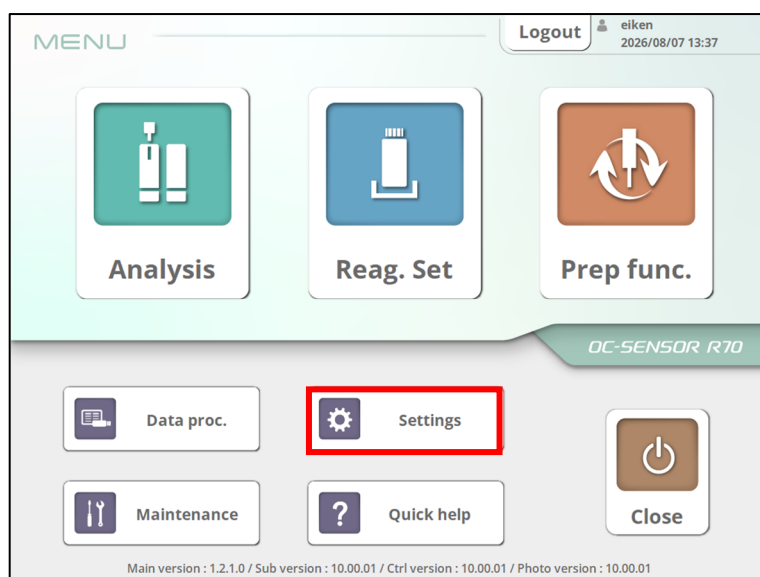
2.4. Initial Settings

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

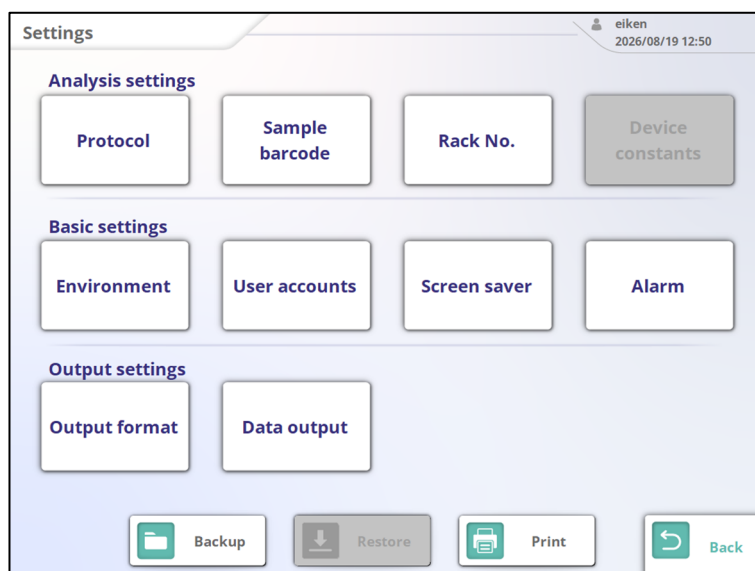
Initial settings are broadly classified into three categories: “analysis settings,” “basic settings,” and “output settings.”

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

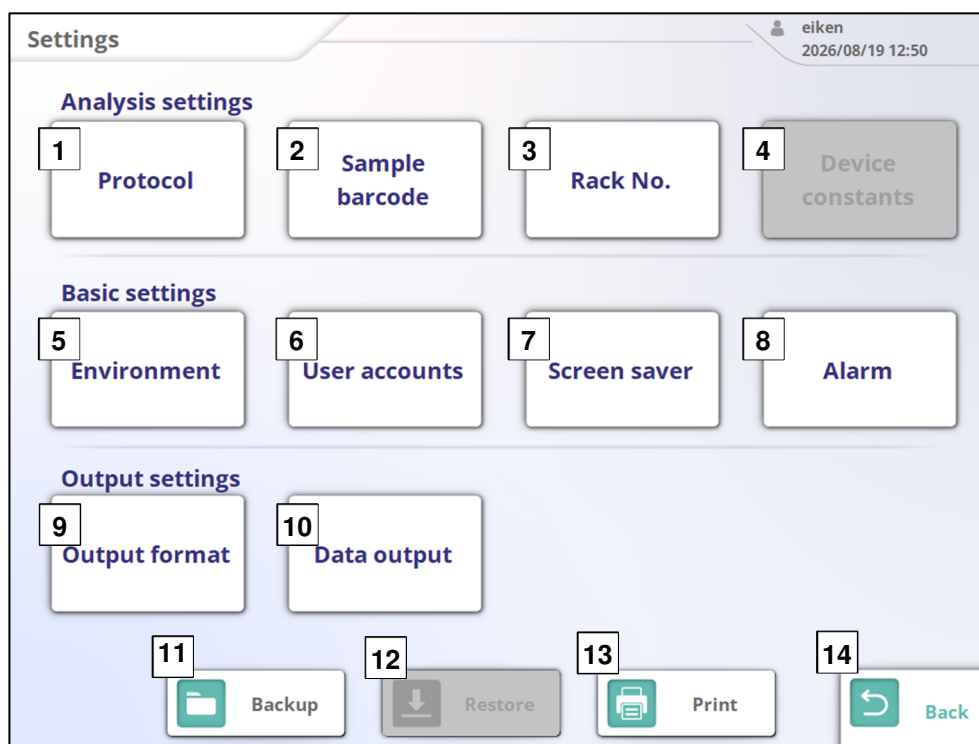
This section gives an overview of each setting. See **Chapter 6** for details.



(1) Touch the {Settings} button.



(2) The settings menu screen is displayed.



[Settings menu screen]

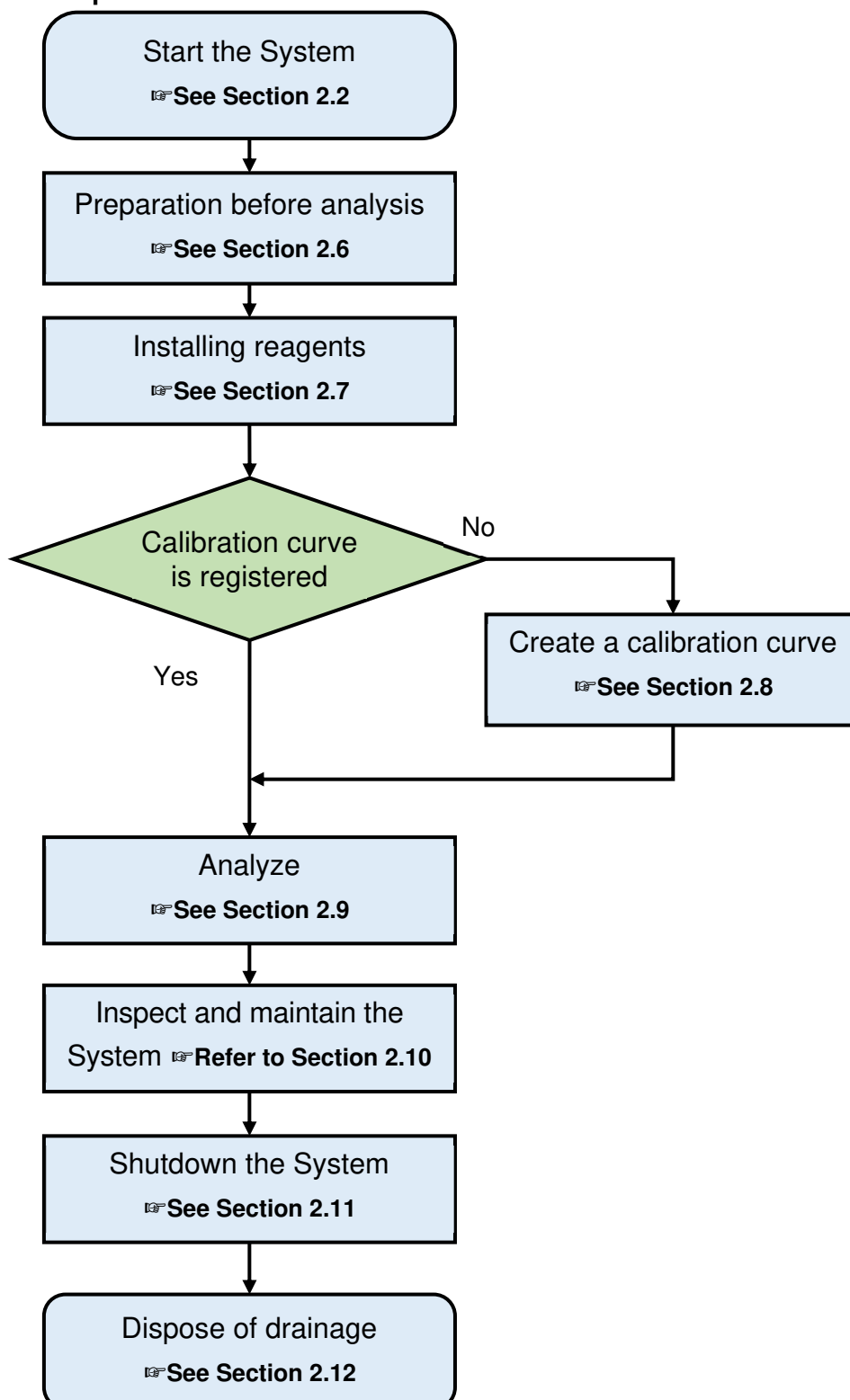
Name	Details
1 Protocol	Configures the protocol for each analysis item.
2 Sample barcode	Configures the sample barcode.
3 Rack No.	Registers STD/QC racks, QC racks, retest racks, and dilution retest racks.
4 System constants	Configures the System-specific constants.
5 Environment	Configures the following. ▪ Date and time ▪ Water supply method and drainage method ▪ Automatic rack supply waiting time ▪ Volume ▪ Language ▪ Sample No. at startup
6 User account	Sets the operator ID and password at login.
7 Screen saver	Sets the screen saver.
8 Alarm	Sets the alarm.
9 Output format	Selects the output format of the measurement data. Selects the output items for the printer and online output. Sets the display method by analysis item and the output order.

Name	Details
10 Data output	Sets the output destination for measurement data. Selects whether to output data to the printer, external media, or online. Configures the online communication interface. Configures the output items for external media output.
11 Backup	Outputs the registered setting information to external media.
12 Restore	Imports the setting information saved on external media to the System.
13 Print	Prints the setting information.
14 Menu	Returns to the [MENU] screen.

2.5. Daily Operation Procedure

The section describes basic operation processes and procedures.

<Operation flow>



2.6. Preparation before Analysis

Prepare the System before analysis.

2.6.1. Empty the drain tank (connection with the body is performed during installation)

Empty the drain tank.



Warning



Biohazard

- Wear protective equipment when handling the drain tank. Failure to observe this precaution may lead to infection.

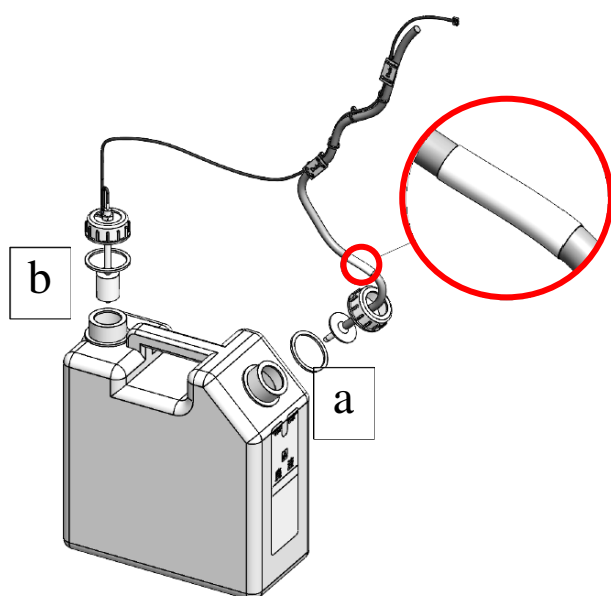


Caution



Required

- Ensure to empty the drain tank before using the System. Failure to observe this precaution may lead to infection.
- Install the drain tank below the System. If the drain tank is positioned above the System, drainage may not be performed correctly.



- Empty the drain tank, and attach the drain hose (a) and the maximum-level sensor (b) to the two openings of the drain tank.
 - Do not install the hose and the maximum-level sensor in reverse.

Ensure that both the tube attached to the piping and the tank label are white. (See the figure to the left)

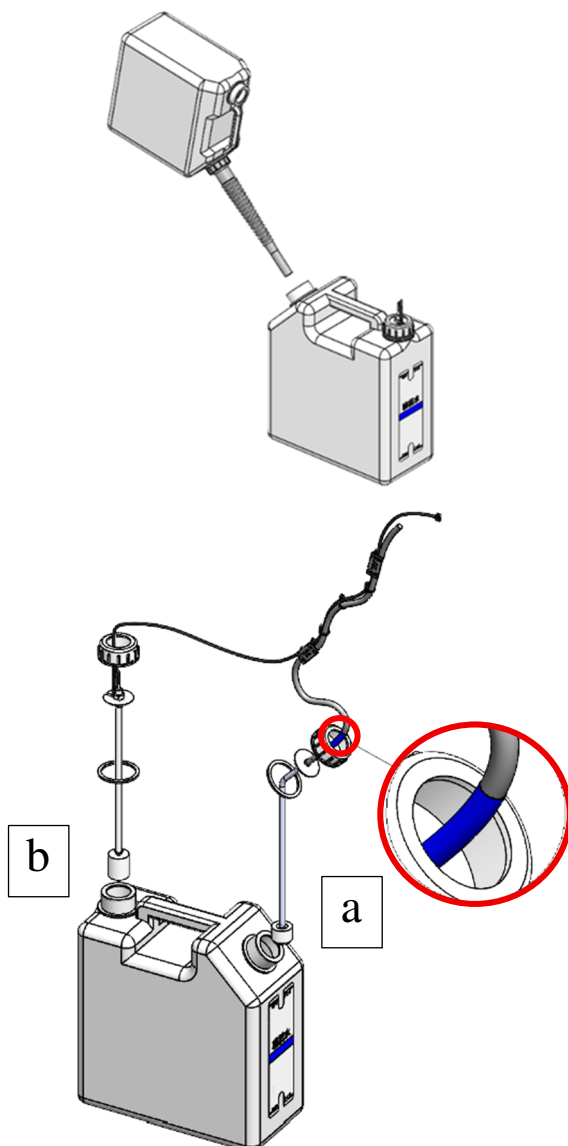
2.6.2. Refill the tank with purified water (connection with the body is performed during installation)

Refill the tank with purified water.



Request

- After setting the purified water tank, be sure to perform priming.
 "2.6.6. Priming (normal priming/activate priming)"
- Use only the accessories provided for the purified water tank.
- When supplying purified water directly from an external source by connecting piping to the System without using the purified water tank, check that the water supply pressure is less than 0.1 MPa. High water supply pressure may cause pipe disconnections, water leaks, or damage to the equipment.



- (1) Remove the hose from the tank and refill the purified water.



Check that it is the purified water tank before refilling.

- (2) Attach the hose (a) and the zero-level sensor (b) to the two openings of the purified water tank.



Do not install the hose and the zero-level sensor in reverse.

Ensure that both the tube attached to the piping and the tank label are blue. (See the figure to the left)

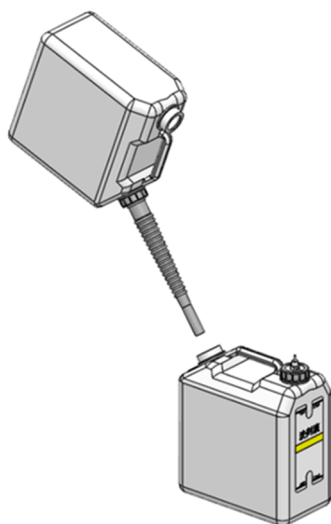
2.6.3. Refill the tank with wash solution (connection with the body is performed during installation)

Refill the tank with wash solution.



Request

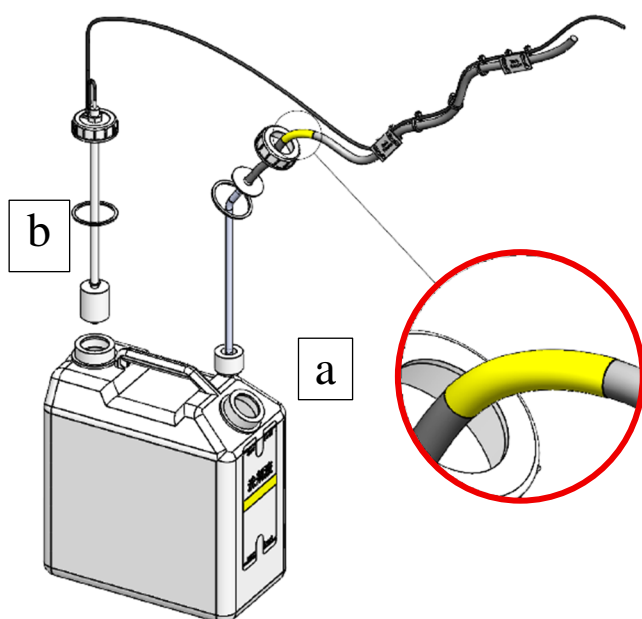
- After setting the wash solution tank, be sure to perform priming.
 "2.6.6. Priming (normal priming/activate priming)"
- Use only the accessories provided for the wash solution tank.



- (1) Remove the hose from the tank and refill the wash solution.



Check that it is the wash solution tank before refilling.



- (2) Attach the hose (a) and the zero-level sensor (b) to the two openings of the wash solution tank.



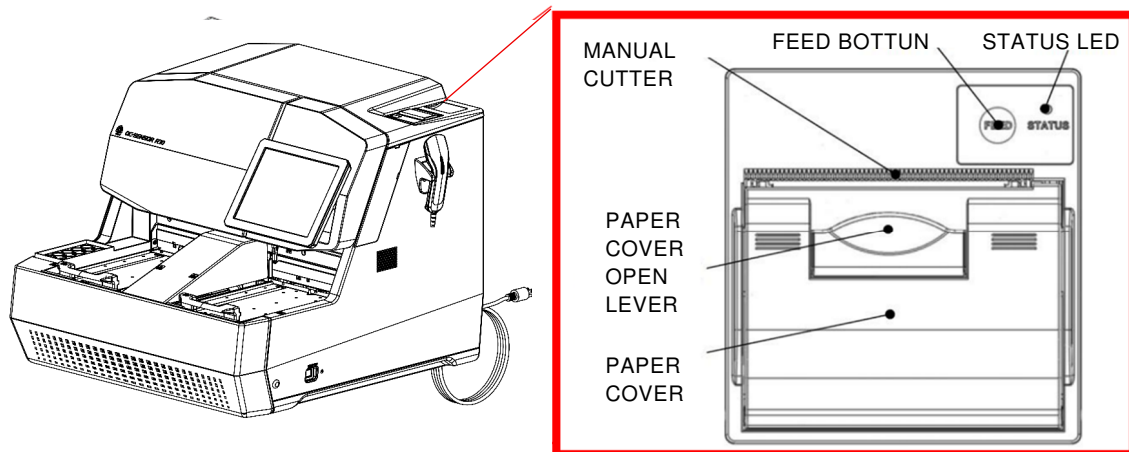
Do not install the hose and the zero-level sensor in reverse.



Ensure that the label affixed to the piping is **yellow**.
(See the figure to the left)

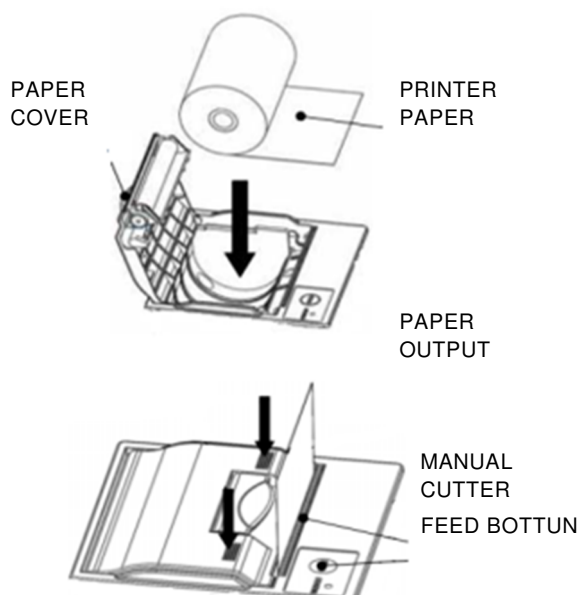
2.6.4. Load printer paper

Load the printer paper in the printer.



Caution

- Be careful of the blade of the manual cutter. Failure to observe this precaution may lead to injury.



- (1) Lift the paper cover and open the cover.
- (2) Set the paper in the orientation shown in the left figure.
- (3) Insert the leading edge of the paper forward from the paper ejection slot.
- (4) Push down the paper cover open lever.
- (5) Press both ends of the paper cover to close the cover. At this time, check that the cover is locked.
- (6) Press the FEED button.
- (7) Cut the paper with the manual cutter.

2.6.5. Execute initialization

Initialize each system component (moves them to the standby position).
The following components are initialized.

- Sample nozzle
- R1 nozzle
- R2 nozzle
- Cell wash nozzle
- Mixer
- Reaction table
- Reagent table
- Puncture system
- Squeeze system
- Supply bar
- Conveyance bar
- Discharge bar

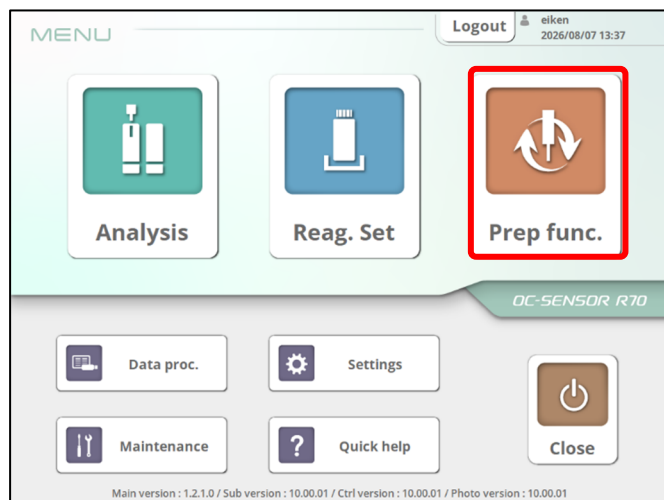


Caution

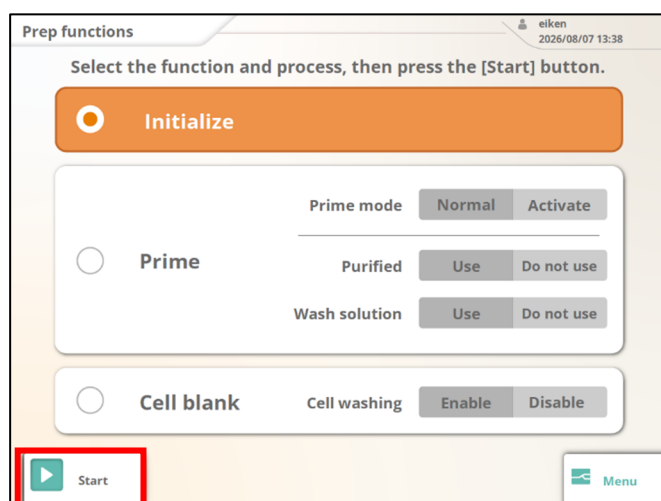


Pinching hazard

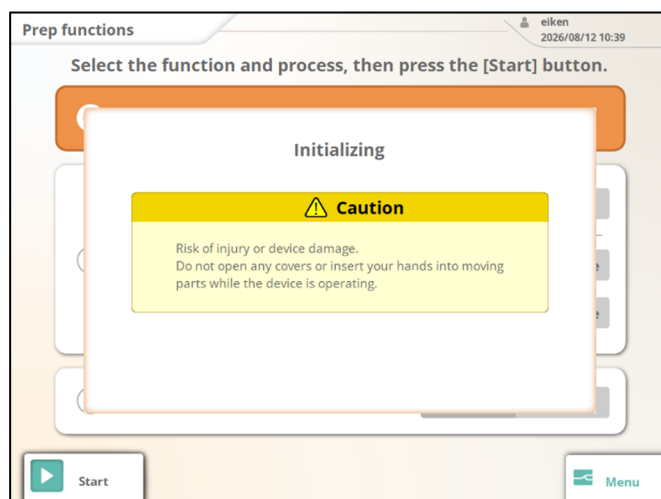
- The protective cover is locked during system operation. Do not forcibly open the protective cover while locked.
- Keep out of the operational range of the System during operation.
Failure to observe this precaution may lead to injury or damage.



- (1) From the menu screen, touch the {Aux func.} button.



- (2) Select {Initialize}.
- (3) Touch the {Start} button.



- (4) Initialization is executed.
- {Abort}: Cancel initialization.
- (5) After initialization is completed, the completion screen is displayed.

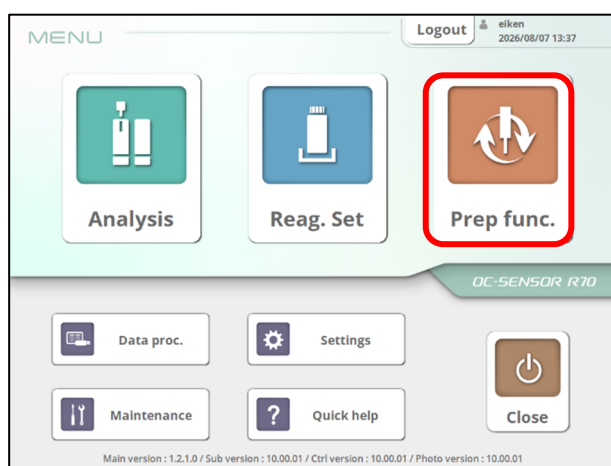
2.6.6. Priming (normal priming/activate priming)

There are two kinds of priming. “Normal priming” removes air bubbles in the piping, while “activate priming” introduces purified water and wash solution to the piping.

■ Normal priming

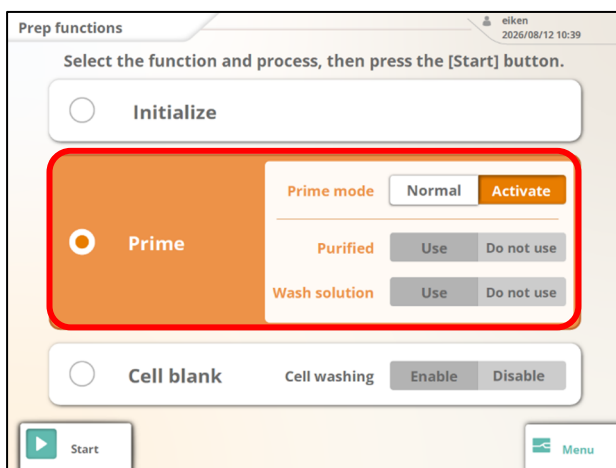
It is used to remove air bubbles in the piping.

“Normal prime” is also used when the System has been left off for some time.



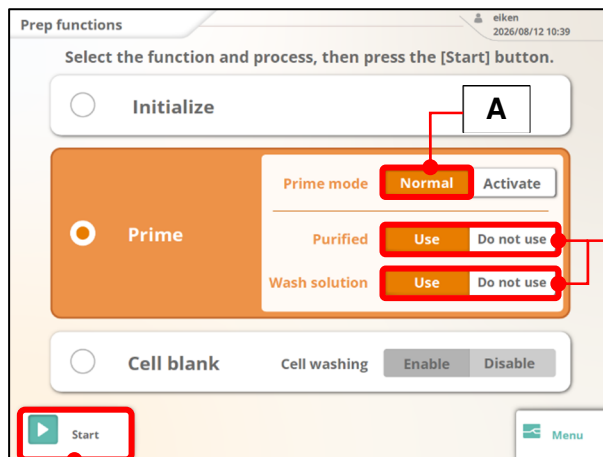
[MENU] screen

(1) Touch the {Auxiliary func.} button.



[Auxiliary functions screen]

(2) Select {Prime}.



(3) Select prime mode.

(A) Select {Normal}.

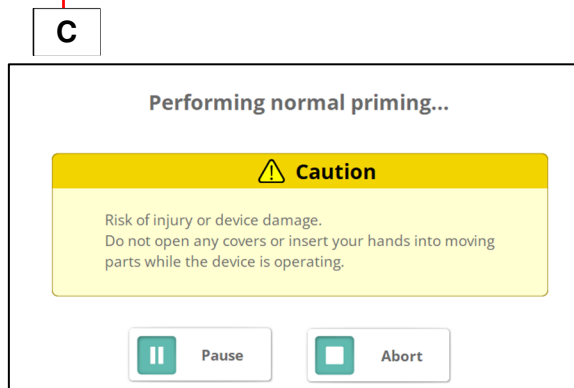
(B) Select items to prime.

■ Use: Prime

■ Do not use: Do not prime.

* The button is a toggle switch.

(C) Touch the {Start} button.



[Normal priming screen]

(4) During normal priming, a dialog box is displayed on the screen.

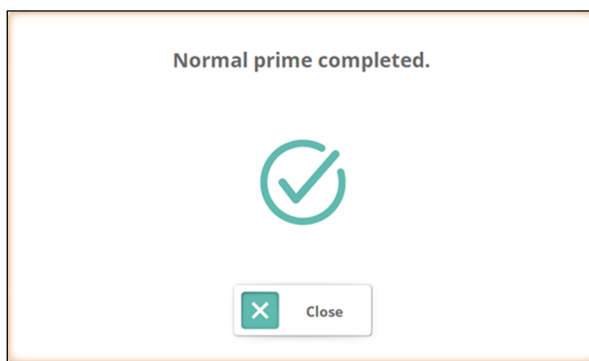
* When priming is complete, the dialog box closes.

{Pause}: Processing pauses.

{Start}: Resume processing.

If the {Pause} button is touched, it will change to the {Start} button.

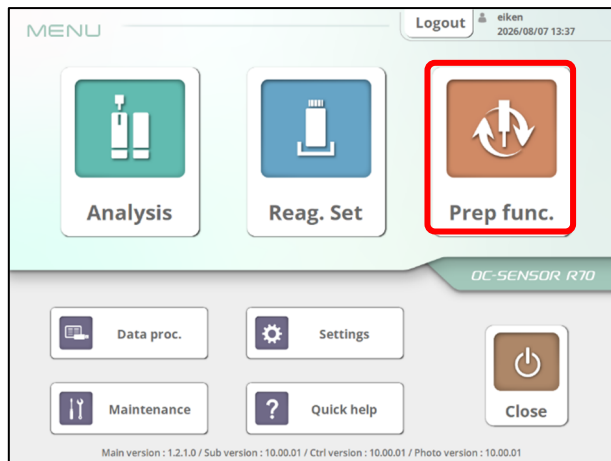
{Abort}: Abort processing.



(5) After priming is completed, the completion screen is displayed.

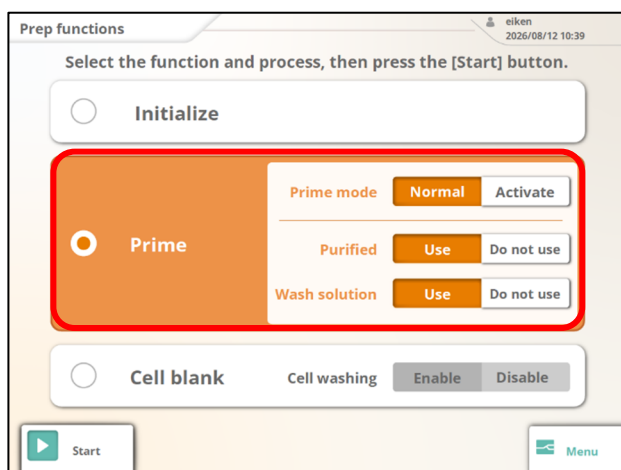
■ Activate priming

It is used to introduce purified water and wash solution for the first time into the piping.



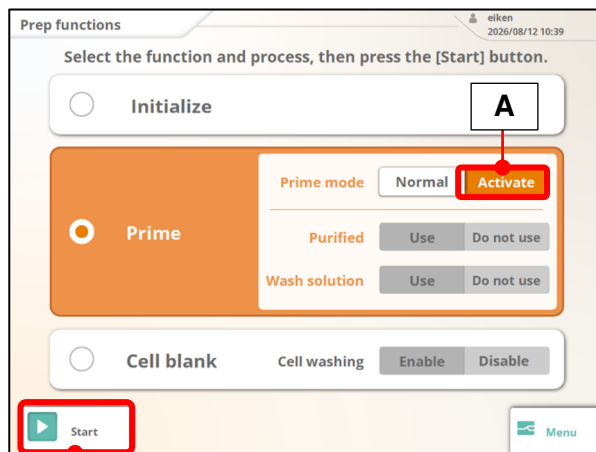
[MENU screen]

(1) Touch the {Aux func.} button.

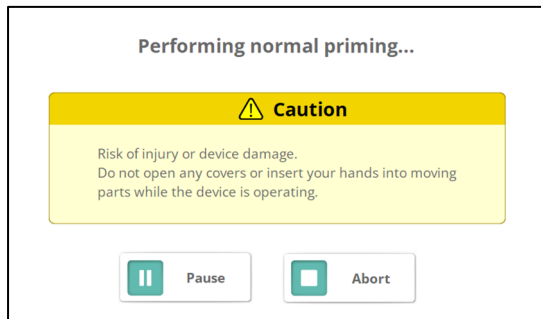


[Auxiliary functions screen]

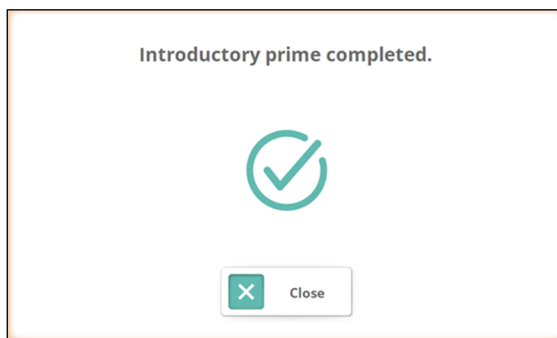
(2) Select {Prime}.



B



[Activate priming screen]



(3) Select prime mode.

(A) Select {Activate}.

* The button is a toggle switch.

(B) Touch the {Start} button.

(4) During activate priming, a dialog box is displayed on the screen.

* When priming is complete, the dialog box closes.

{Pause}: Processing pauses.

{Start}: Resume processing.

If the {Pause} button is touched, it will change to the {Start} button.

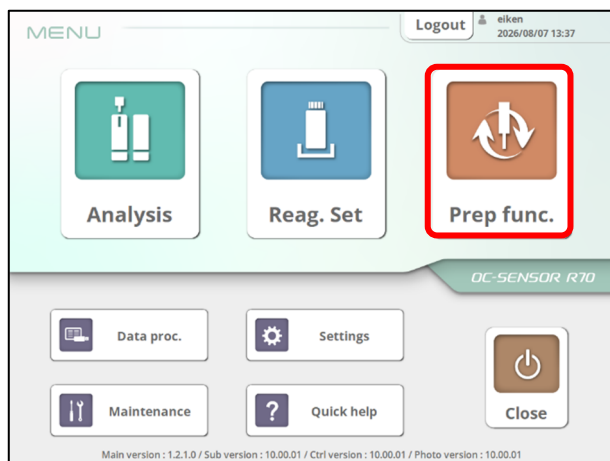
{Abort}: Abort processing.

(5) After priming is completed, the completion screen is displayed.

2.6.7. Measure cell blanks

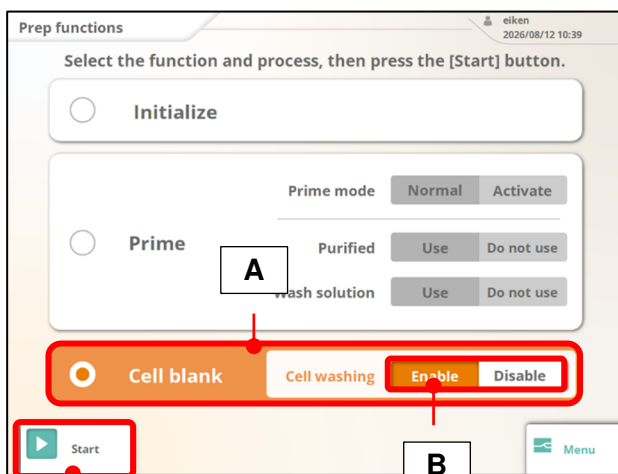
Run cell blanking to wash cells and evaluate them on a pass/fail basis.

If cell blank measurement is set to “ON” during the shutdown process, cell blank measurement is automatically run when the System starts.



[MENU screen]

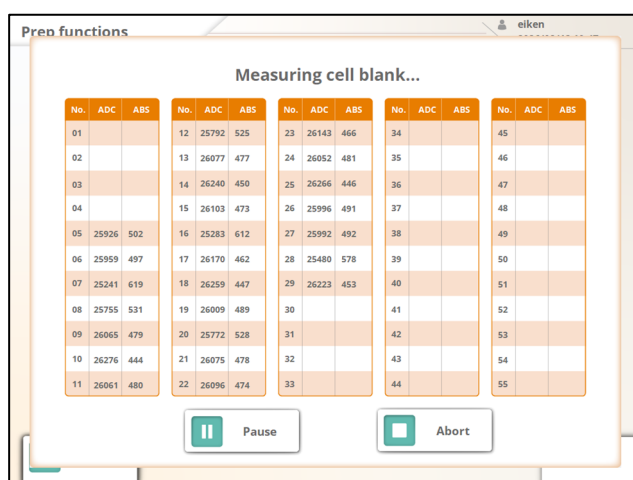
(1) Touch the {Aux func.} button.



[Auxiliary functions screen]

(2) Measure cell blanks.

- (A) Select {Cell blank}.
- (B) Select [Cell washing] to {Enable}.
* The button is a toggle switch.
- (C) Touch {Start} to begin the cell blank measurement.



(3) Measuring cell blank

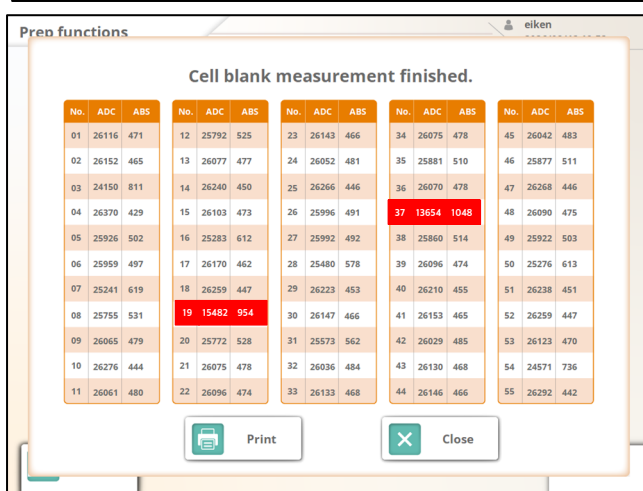
<Functions of each button>

{Pause}: Cell blank measurement pauses.

{Start} : Resumes cell blank measurement.

If the {Pause} button is touched, it changes to the {Start} button.

{Abort}: Aborts cell blank measurement.



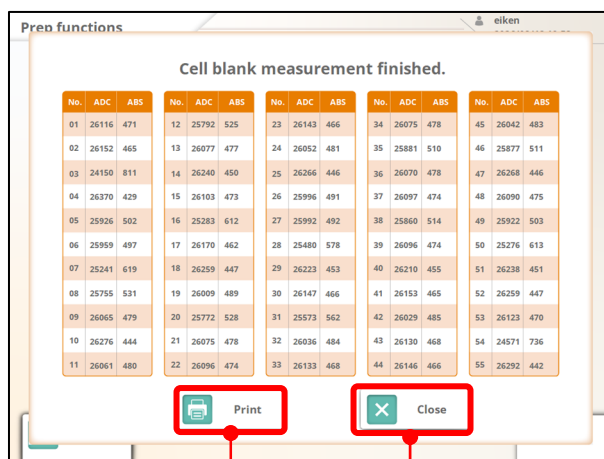
Cells that cannot be used are displayed in red.



When 10 or more cells can no longer be used, the following message is displayed: "There are more than 10 unclean measurement cells. This could reduce processing performance. Replace the measurement cells."

Replace the measurement cells

See Section 5.3



(4)

(5)

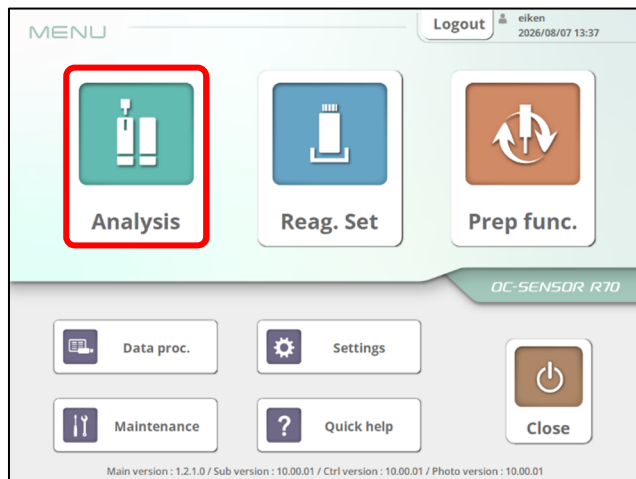
(4) Touch the {Print} button to print the measurement results.

(5) Touch the {Close} button.

* Return to the [Auxiliary functions] screen.

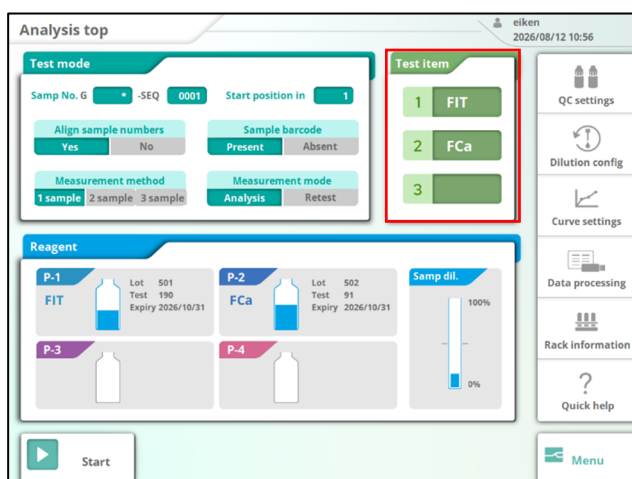
2.6.8. Register analysis items

Register the analysis items to be measured.



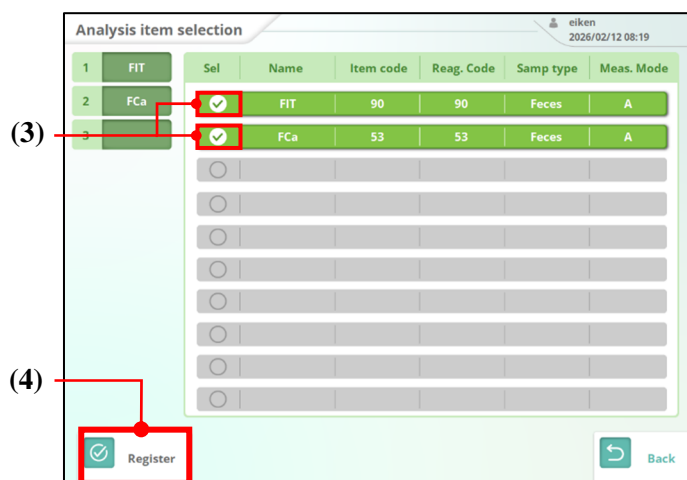
[MENU] screen

- (1) From the [MENU] screen, touch {Analysis}, and display the [Analysis top] screen.



[Analysis top] screen

- (2) Touch the {Test item} area.



[Test item] screen

- (3) Check the analysis items to be measured.
- (4) Touch the {Register} button.

- The item names and test items of the analysis items that can be set are as follows.

Item name	Test item
FIT	Faecal haemoglobin
FCa	Faecal calprotectin

2.6.9. Configure rack No.

Configure the rack numbers to be used for measurement.

The names and intended uses of each rack are as follows.

For the procedure of setting the rack No., see **Section 6.1.4**.

<Rack name and use>

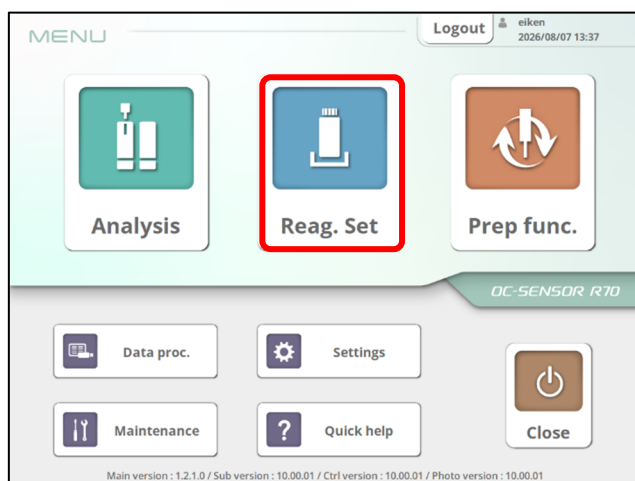
STD/QC	Use
STD/QC1, QC2, QC3	Use during STD/QC measurement. Can be set for each analysis item. QC1, QC2, and QC3 registered in QC settings are used.
STD/QC4, QC5, QC6	Use during STD/QC measurement. Can be set for each analysis item. QC4, QC5, and QC6 registered in QC settings are used.
QC	Use when performing QC measurement simultaneously for multiple analysis items. See Section 2.9.3 for the measurement procedure.
Dilution retest	Use when performing dilution retest. Up to 5 racks can be registered.
Retest	Use when performing retest. Up to 10 racks can be registered.



If a rack No. that is not registered is read, it is processed as a **“Sample”** rack.

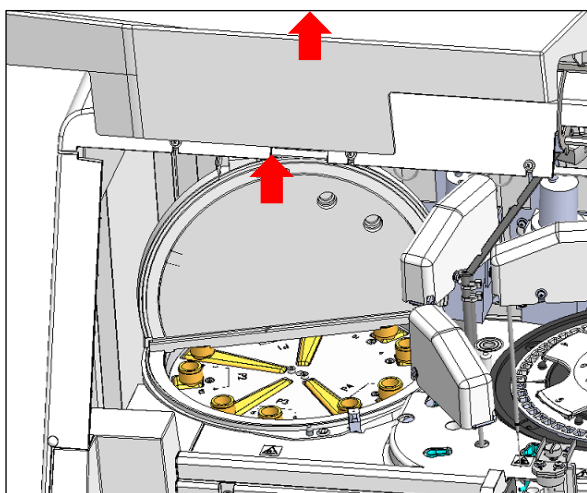
2.7. Installing Reagents

Install the R1 reagent, R2 reagent, and sample diluent in the reagent refrigerator in the System. The section describes the procedure for reagent installation.



[MENU] screen

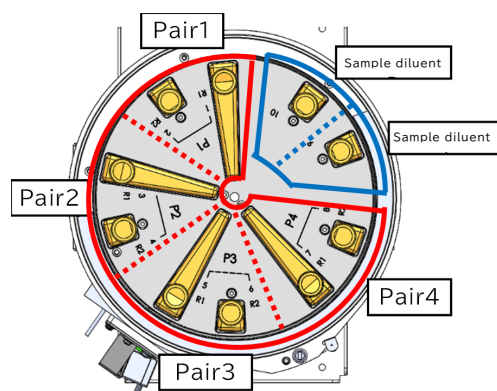
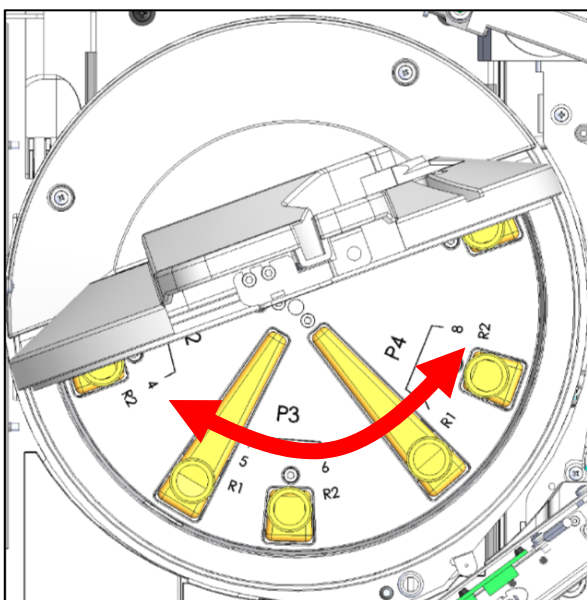
- (1) From the main menu screen, touch the {Reag. set} button.



- (2) Set the reagent bottle in the reagent refrigerator.

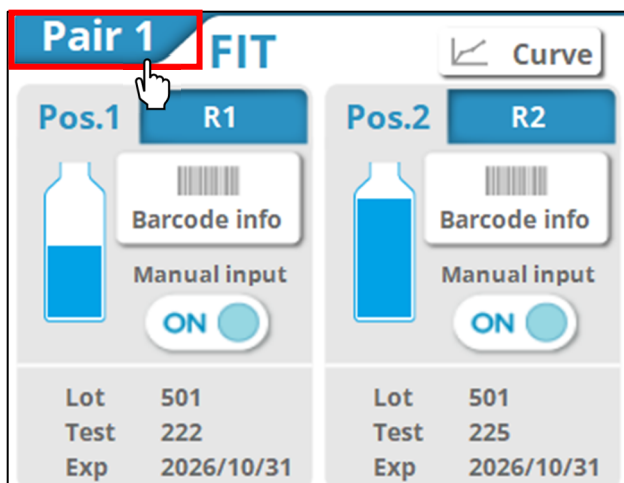
<Installation procedure>

- (A) Open the protective cover and the cover of the reagent refrigerator.
- (B) Remove the cap of the reagent bottle to be installed.
- (C) Rotate the reagent table, remove the currently installed reagent bottles, and install the reagent bottles to be installed at each position on the reagent table. The reagent table can be rotated manually or automatically.



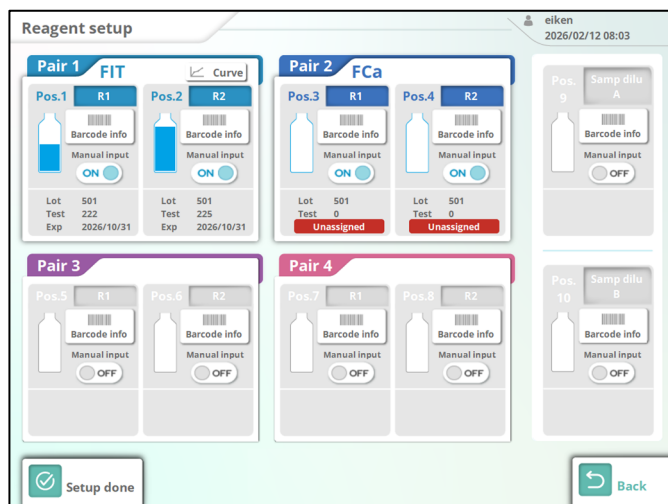
{For manual operation}

- Manually rotate the reagent table toward the front of the System. (See the figure to the left)



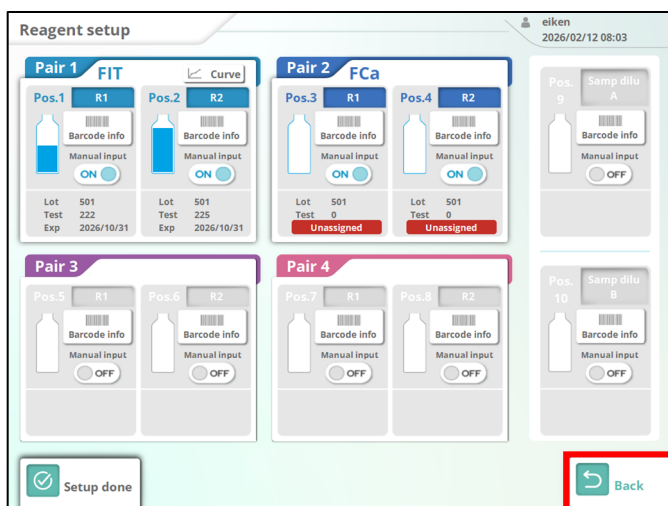
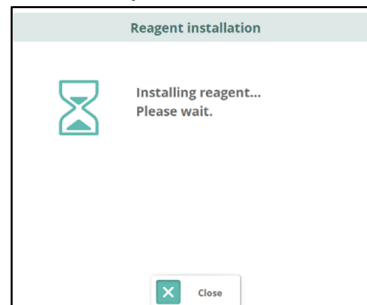
{For automatic operation}

- With the reagent cooler cover closed, touch the "Pair" area on the reagent setup screen.
- ☞ The reagent table automatically moves so that the touched Pair position is toward the front of the System.

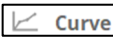


(3) Touch the {Setup done} button.

- The reagent barcode and reagent remaining volume are automatically read. During reading, the following dialog box is displayed, and it will close automatically when finished.



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

 ... Displays the registered calibration curve

- * Pairing refers to the state in which R1 reagent and R2 reagent of the same lot are installed as a set in each Pair.

(5) After confirmation, touch the {Back} button to return to the main menu screen.

 If there is no calibration curve for the installed reagent lots, **No curve** is displayed. Create a calibration curve.

 If there is an error in the installed reagent, an error is displayed in the expiry date field. (See next page)

 Reagent bottles display a 5-digit lot number, but the instrument displays only 3 of those digits (the 1st, 4th, and 5th digits).

Example: Bottle "5X001" → Instrument "501"

<Error messages>

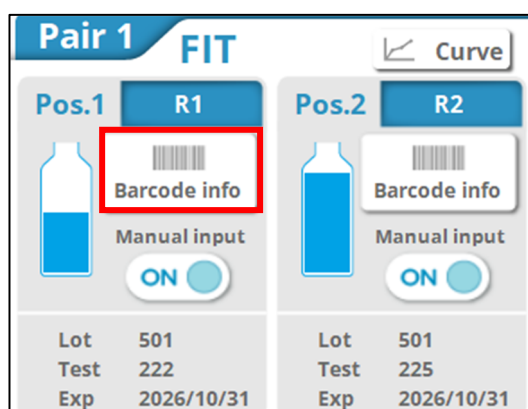
Message Name	Details
Barcode read error	Failed to read barcode
Unassigned reagent	A reagent that is not registered in the analysis items is installed.
Expired	The expiry date of the reagent has passed.
Empty	Reagent is empty
Bad setup	The installation position of R1/R2/sample diluent is inappropriate.
No pairing detected	The reagent lot information in the Pair does not match.
No calibration curve	There is no calibration curve for the reagent.
Low reagent	The remaining reagent volume is 10% or less.

* **How to manually edit reagent barcode information**

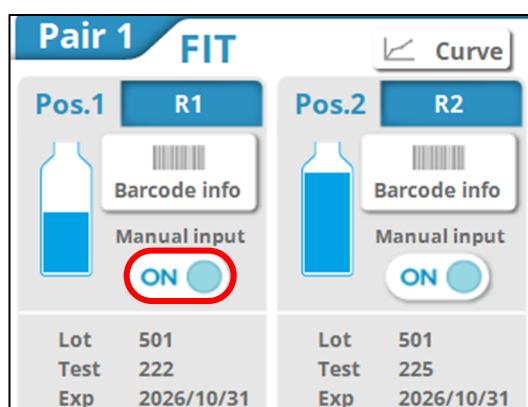
This section describes the procedure for manually editing registered reagent barcode information.



Editing of reagent barcode information can be performed only when the login account is "Admin."
If the login account is "User," editing is not possible.



- (1) Touch the {Barcode information} of the reagent Pos. you want to enter.
 - * The numeric keypad screen will open.
- (2) Enter the barcode information numbers (24 digits) using the numeric keypad.
 - * It is also possible to read with the optional Handy Barcode Reader.



After manual entry, confirm that "Manual Entry Priority" is set to "ON".

**Request****Reagent barcode information**

- The barcode affixed to the reagent bottle is a 24-digit ITF.
- When entering barcodes, follow the configuration below.

KKKAABBCRYMMDDXXXNNNNNM (barcode)

KKK : Manufacturer code, 3 digits (026)
 AA : Item code, 2 digits (numbers from 01 to 99)
 90: FIT 53: FCa 92: Sample Diluent
 BB : Product code, 2 digits (numbers 01 to 99)
 C : Bottle capacity, 1 digit (1: 20 mL, 2: 60 mL)
 R : Reagent type, 1 digit (1: R1, 2: R2, 3: sample diluent)
 YYMMDD : Expiry date, 6 digits (YYMMDD)
 XXX : Lot number, 3 digits (numbers 000 to 999)
 NNNNN : Bottle number, 5 digits (numbers 00001 to 99999)k
 M : Check digit

Switching of reagent and sample diluent bottles is as follows.

◎ **Reagent**

For each sample, compare the number of reagent tests and the number of sample replicates before the first dispensing. If the number of tests remaining in the reagent in use is low, it is determined to be insufficient, and the bottle to be used is automatically switched. The conditions for switching differ depending on the reagent lot number and the measurement mode.

Measurement mode	If same lot	If different lots
Sample (Retest)	The bottle is switched.	
QC	The bottle is switched.	The bottle is not switched.
Calibration curve generation	The bottle is not switched.	

Switching does not occur to reagent lots for which a calibration curve has not been created. Install reagent bottles of lots for which a calibration curve has been created.

If the reagent test count becomes "0" and there is no bottle available to switch to, analysis of subsequent samples is not performed.

Measurement results are output only for samples for which dispensing has been completed.

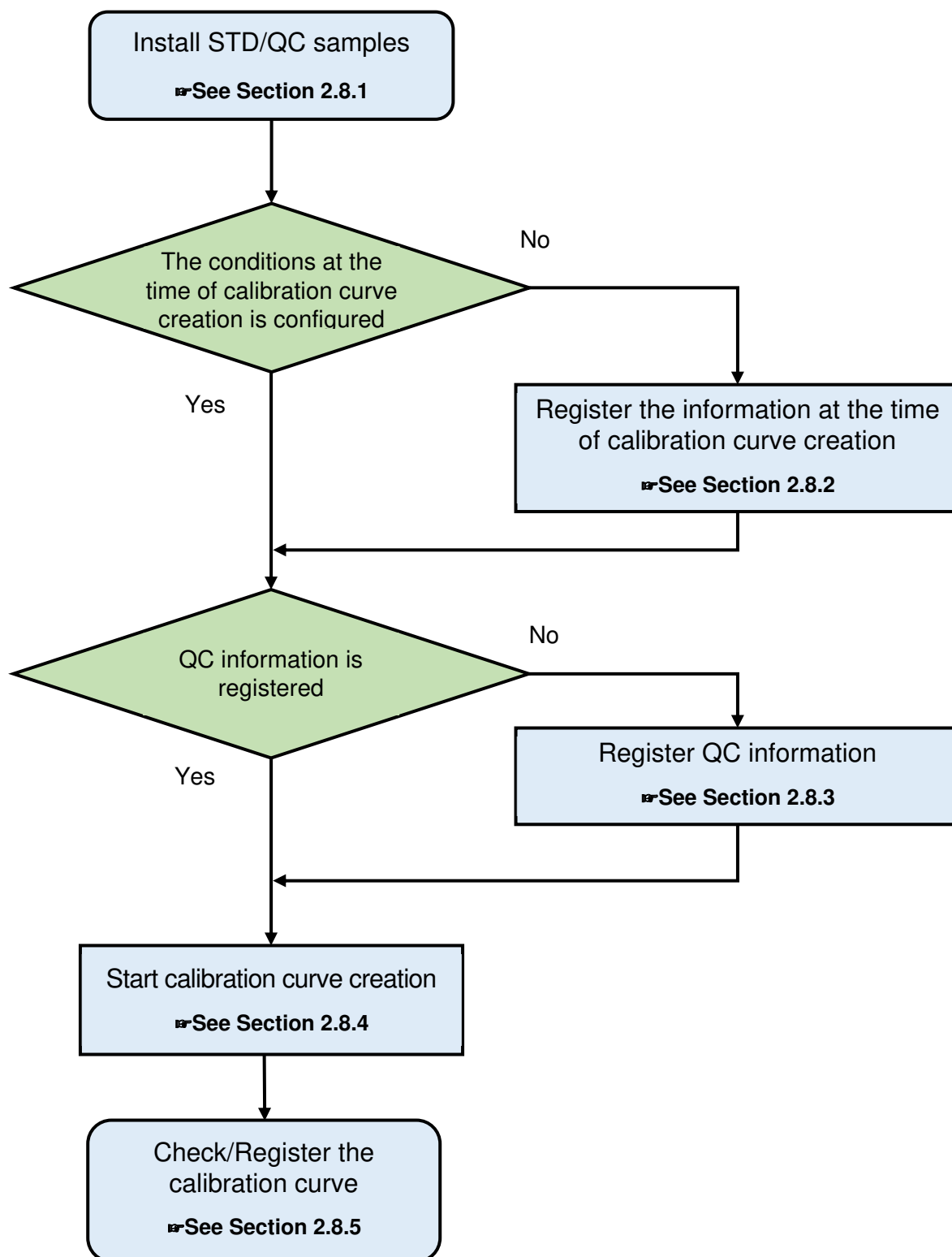
◎ **Sample diluent**

When one of the two bottles becomes empty, it automatically switches to the other bottle. However, the conditions for switching differ depending on the lot number of the sample diluent.

If same lot	If different lots
The bottle is switched.	The bottle is not switched.

2.8. Create a Calibration Curve

If a calibration curve is not registered for the installed reagent, create a calibration curve.
Perform according to the following operation flow.



2.8.1. Install STD/QC samples

Install the STD/QC samples on the STD/QC rack and install it into the System.

Request

- Install the STD samples (calibrator) and QC samples at the designated positions.
- When placing STD samples or QC samples into the sample cups, confirm that no bubbles are introduced.

Failure to do so may lead to accurate values not being obtained.

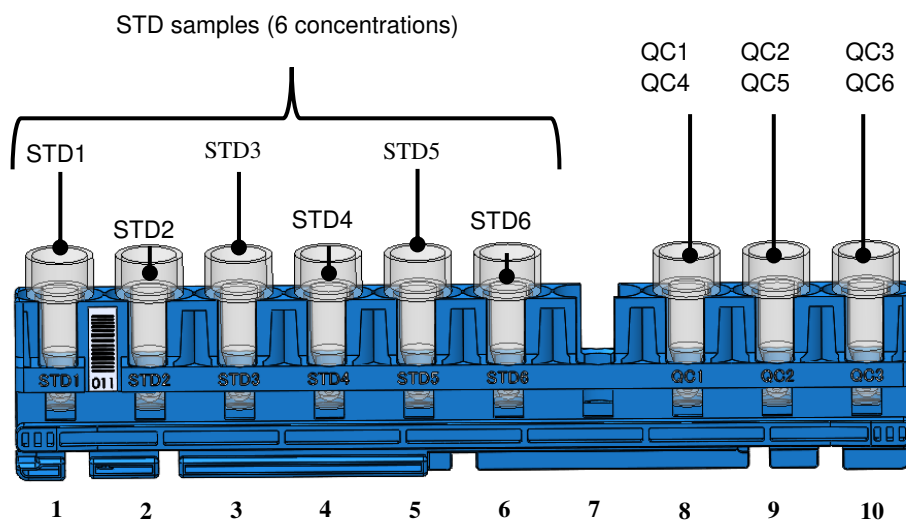


When measuring STD/QC samples, use the "**STD/QC rack**". Install the STD samples and QC samples on the rack.

(The number of QC samples is optional.)

After installation of STD/QC samples, confirm that the rack barcode No. is registered in the System.

- (1) Install the STD samples in rack positions 1-6 of the STD/QC rack.
When performing QC measurement simultaneously, install the QC samples in positions 8-10 in the rack.



The numbers in the diagram indicate the rack position number. Position 1 starts from the left.

- (2) Install the rack on the tray, and set it in the supply unit.

➡ See Section 2.9.1.1

2.8.2. Register the information at the time of calibration curve creation

Register the reagent information (calibrator, reagent lot) for calibration curve creation in the System.

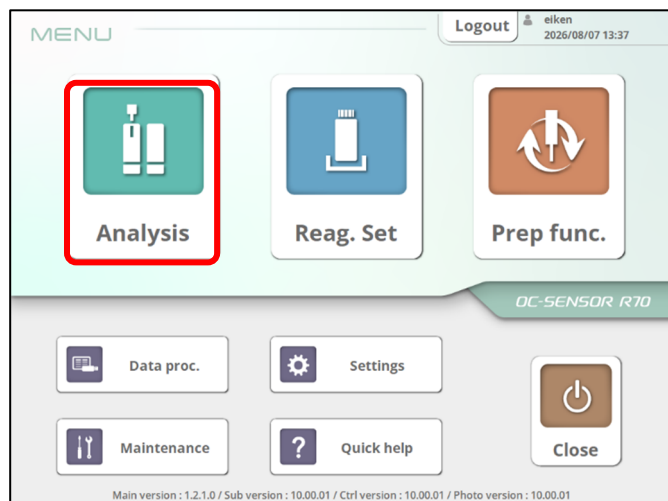


Warning



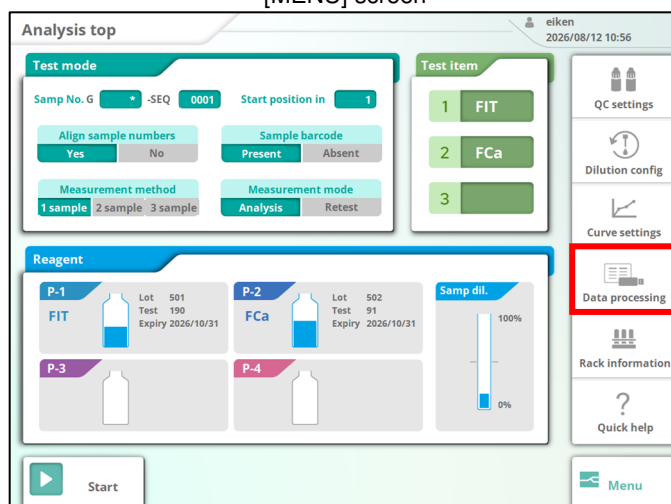
Must be executed

• When creating a calibration curve, please register the barcode information of the calibrator. If the barcode information is not registered, the calibration curve cannot be created.



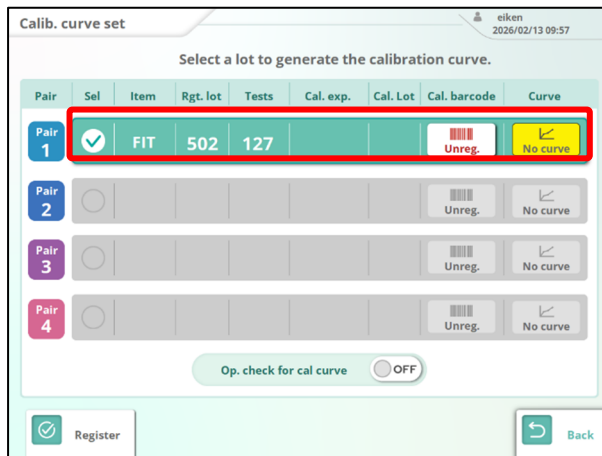
[MENU] screen

- (1) From the [MENU] screen, touch {Analysis}, and display the [Analysis top] screen.



[Analysis top] screen

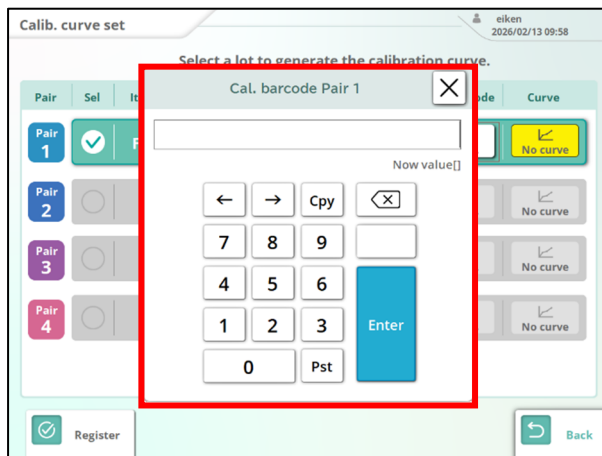
- (2) Touch the [Curve settings] button.



[Curve settings] screen

- (3) Select the reagent lot/Pair to create the calibration curve.

- * One pair of reagent lot/Pair can be selected for each item.
- * Pair 1 to 4 are the same positions as shown on the reagent set screen.
- * A calibration curve is created using the reagent bottles of the selected Pair.



Cal barcode input Screen

- (4) Register the calibrator barcode.



Touch .

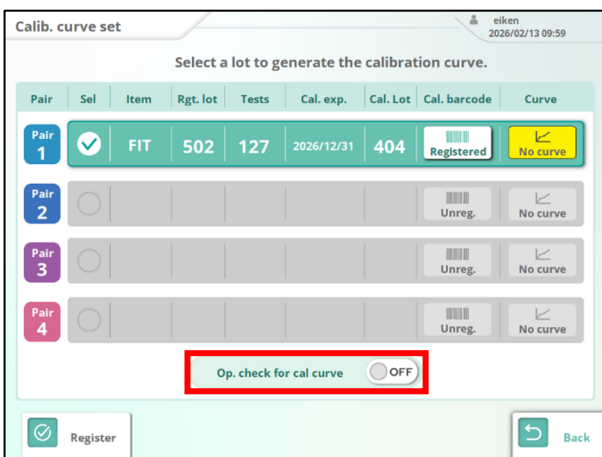
- (5) Enter the calibrator barcode.

Input the data manually using the numeric keypad or scan the "Calibrator Information" with the handy barcode reader (optional).
Touch [Enter].

*The numeric keypad screen will close.

*The lot number and expiration date will be displayed.

⚠ Calibrators that have passed their expiry date must not be used.



- (6) Select whether to perform operator check for calibration curve registration.

ON: A confirmation screen is displayed when creating the calibration curve.

OFF: A confirmation screen is not displayed when creating the calibration curve, and it is automatically registered to the System.

⚠ If the fitted value deviates from the specified upper or lower limits, the calibration curve confirmation screen is displayed.



Request

Calibrator barcode information

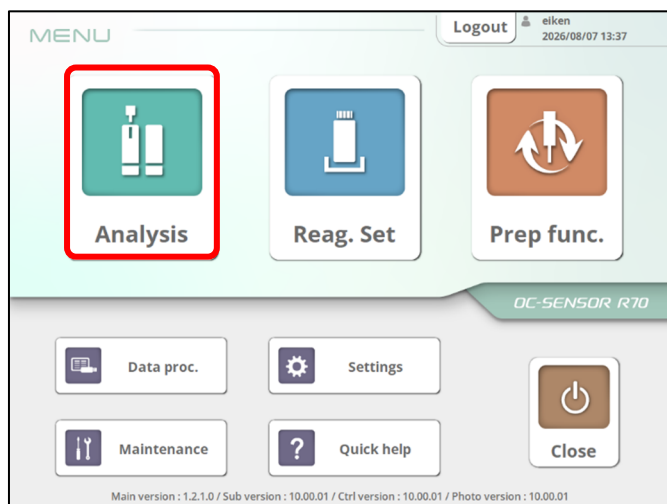
- The barcode affixed to the outer box is a 17-digit ITF.
- When entering barcodes, follow the configuration below.

KKKAABBYMMDDXXXNM (barcode)

KKK	: Manufacturer code, 3 digits (026)
AA	: Item code, 2 digits (numbers from 01 to 99)
	90: FIT 53: FCa
BB	: Product code, 2 digits (numbers 01 to 99)
YYMMDD	: Expiry date, 6 digits (YYMMDD)
XXX	: Lot number, 3 digits (numbers 000 to 999)
N	: Spare (0)
M	: Check digit

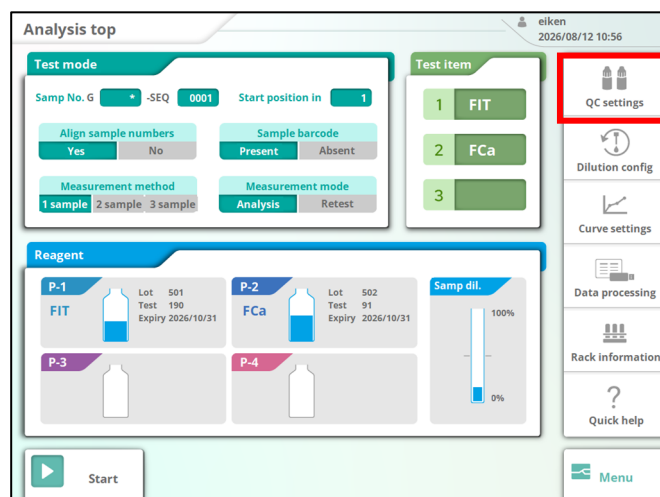
2.8.3. Register QC information

Register the QC information in the System.

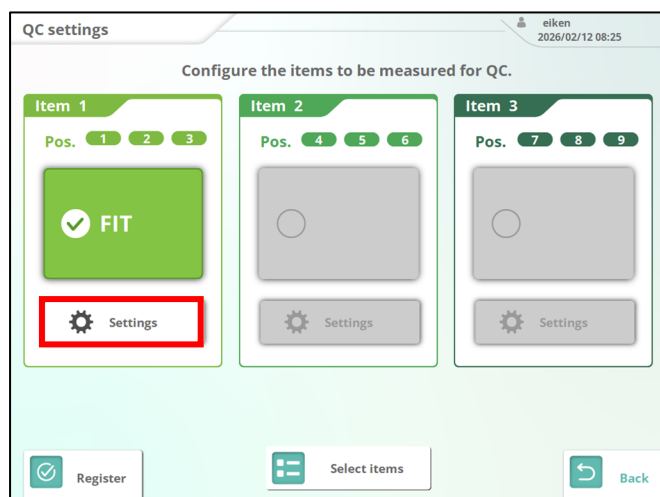


[MENU] screen

- (1) From the [MENU] screen, touch {Analysis}, and display the [Analysis top] screen.



- (2) Touch {QC settings}.



- (3) Touch {Settings} for the analysis item you wish to register.
QC advanced settings can be configured only for analysis items that are registered through item selection.

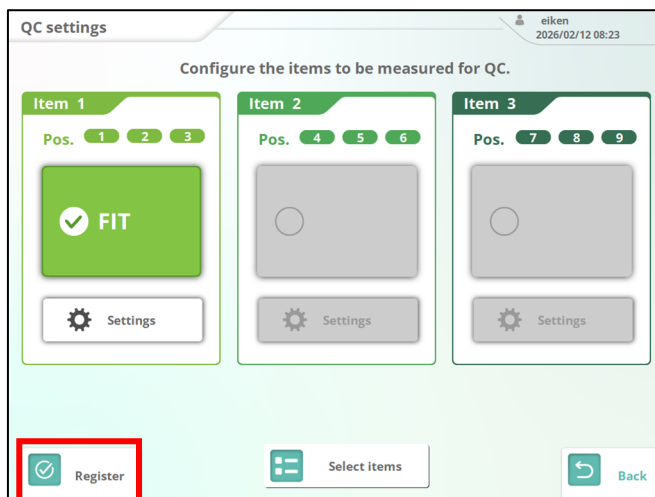
{QC advance settings screen}

<QC advanced setting procedure>

- (A) If there is a QC barcode, touch Barcode info and enter the barcode information.
(The numeric keypad screen will open.)
☞ Barcodes can also be read using the handy barcode reader (sold separately).
- (B) When barcode information is entered, the following items linked to the barcode information are automatically entered.
- QC lot
 - Lo. limit/Up. limit
 - Expiry date
- ☞ If there is no QC barcode, touch each input field (the numeric keypad screen will open) and input manually.
- (C) Touch the QCID and QC sequence No. input fields and enter them manually.

Item	Details
QCID	The QC ID can be output as the ID of the measured QC1 to QC6 to external media, printouts, and the host computer. Up to 50 half-width alphanumeric characters and symbols can be entered. Input can be omitted.
QC sequence No.	When performing QC measurement, set the sample No. start number on the [Analysis status] screen. Example (When "1" is entered in QC sequence No.) 00001(C1) └─ Sample No. starts from "0001". The entry range is 1 to 99,999.

- (D) Touch {Complete}.



(4) Touch {Register} to register QC information.

Request

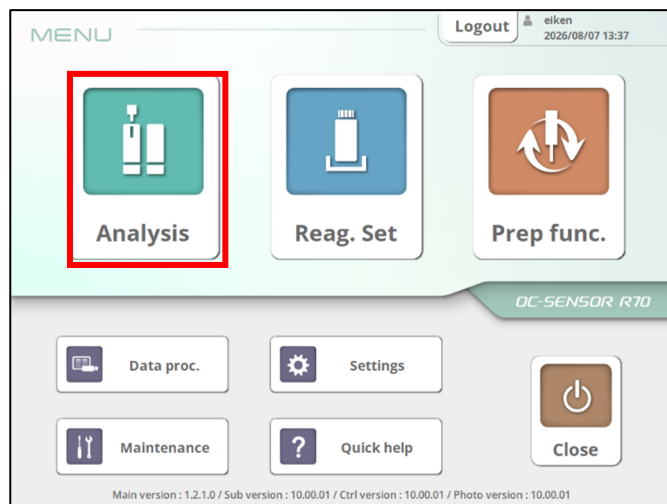
QC barcode information

- QC barcode is a 27-digit ITF.
- When entering barcodes, follow the configuration below.

KKKAABBCYYMMDDXXXYYYYZZZZM (barcode)

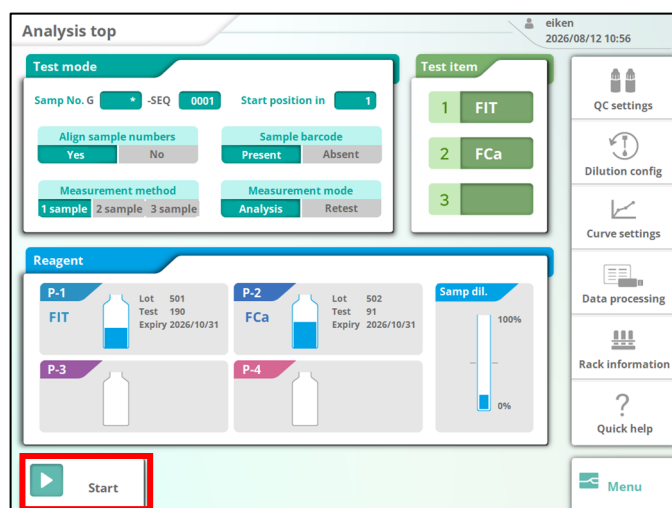
KKK	: Manufacturer code, 3 digits (026)
AA	: Item code, 2 digits (numbers from 01 to 99) 90: FIT 53: FCa
BB	: Product code, 2 digits (numbers 01 to 99)
YYMMDD	: Expiry date, 6 digits (YYMMDD)
XXX	: Lot number, 3 digits (numbers 000 to 999)
YYYYY	: Reference range lower limit (numbers 00001 to 99999)
ZZZZZ	: Reference range upper limit (numbers 00001 to 99999)
M	: Check digit

2.8.4. Start calibration curve creation



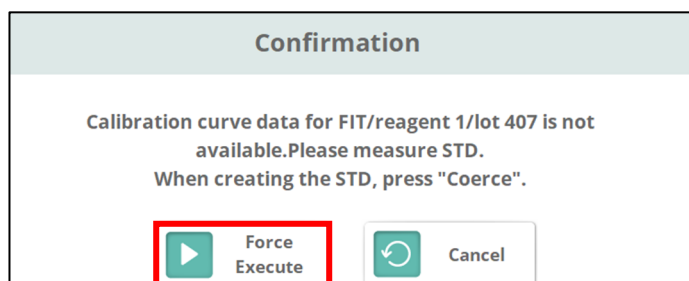
{MENU screen}

- (1) From the [MENU] screen, touch {Analysis}, and display the [Analysis top] screen.



[Analysis] top screen

- (2) Touch the {Start} button.

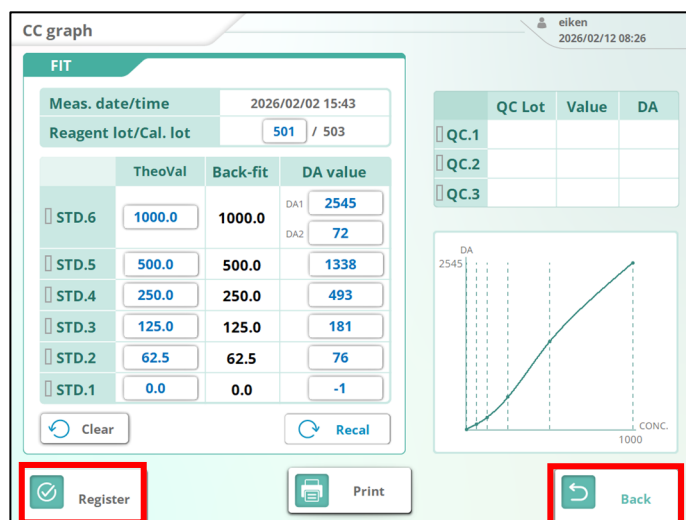


- (3) If a calibration curve is not registered in the reagent information that has been set, the [Confirmation screen] shown on the left is displayed.
To create a calibration curve, press {Coerce}.

⇨ During calibration curve creation, the [Analysis status] screen is displayed.

2.8.5. Check/Register the calibration curve

Check and register the calibration curve that has been created.



A [Calibration curve graph] screen

B

(1) When the calibration curve creation is completed, the [Calibration curve graph] screen is displayed.

(2) Check the calibration curve and set the registration status.

(A) **To registering a calibration curve**

Touch the {Register} button.

The calibration curve is registered in the System, and the screen returns to the [Analysis status] screen.

Upon registration, it is automatically set as the calibration curve to be used for analysis.

(B) **To not register a calibration curve**

Touch the {Back} button to return to the [Analysis status] screen. Create a calibration curve again.

(3) When continuing to analyze samples using the registered calibration curve, add racks to the supply tray.



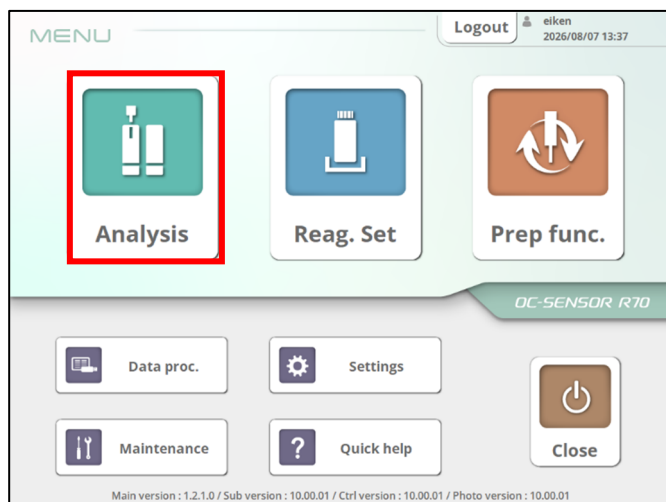
If "Op. Check for cal curve" is set to "OFF" in the calibration curve settings, when the created calibration curve is normal, it is automatically registered to the System, and the [Calibration curve graph] screen is not displayed.

* If there is an abnormality in the calibration curve, the [Calibration curve graph] screen is displayed.

2.8.6. Displaying the curve list

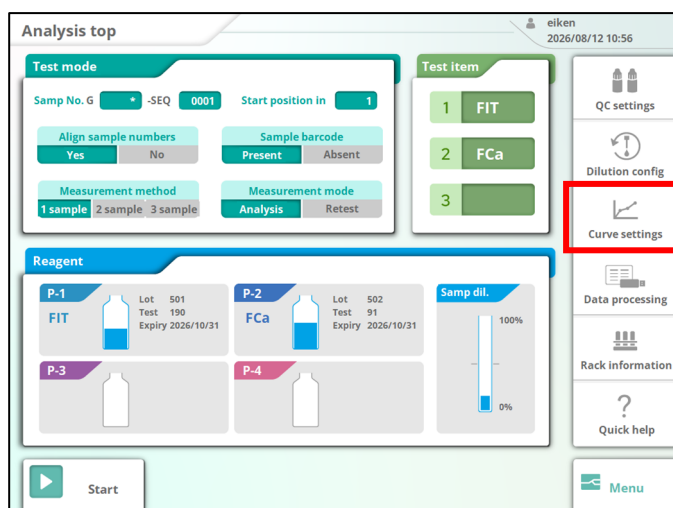
Calibration curves created in the past can be viewed on the [Curve settings] screen.

- !** The maximum number of calibration curves that can be registered for each lot is 10. If there are more than 10, the calibration curves created oldest will be deleted.



[MENU] screen

- (1) From the [MENU] screen, touch {Analysis}, and display the [Analysis] top screen.



[Analysis] top screen

- (2) Touch {Curve settings}.

Calib. curve set

Select a lot to generate the calibration curve.

Pair	Sel	Item	Rgt. lot	Tests	Cal. exp.	Cal. Lot	Cal. barcode	Curve
Pair 1	☒	FIT	501	222	2026/10/31	503	Registered	
Pair 2	☐						Unreg.	No curve
Pair 3	☐						Unreg.	No curve
Pair 4	☐						Unreg.	No curve

Op. check for cal curve ☐ OFF

 Register  Back

(3) Touch {Curve list}.

Curve list

Select a calibration curve to view details.

Current item **FIT**

Sel	Lot	Creation date	
☒	501	2026/02/02 15:43	In use
☐			
☐			
☐			
☐			

 Graph  Replicate  Back

(4) A list of calibration curves for the selected reagent lot is displayed.

◎ **To check the calibration curve information**

Select the calibration curve you want to check and touch {Graph}.

- * The calibration curve currently in use displays **In use** next to the creation date.

CC graph

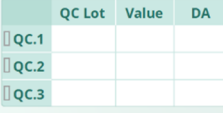
FIT

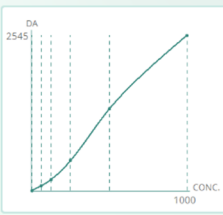
Meas. date/time 2026/02/02 15:43

Reagent lot/Cal. lot 501 / 503

	TheoVal	Back-fit	DA value
STD.6	1000.0	1000.0	DA1 2545
STD.5	500.0	500.0	DA2 72
STD.4	250.0	250.0	493
STD.3	125.0	125.0	181
STD.2	62.5	62.5	76
STD.1	0.0	0.0	-1

 Clear  Recal





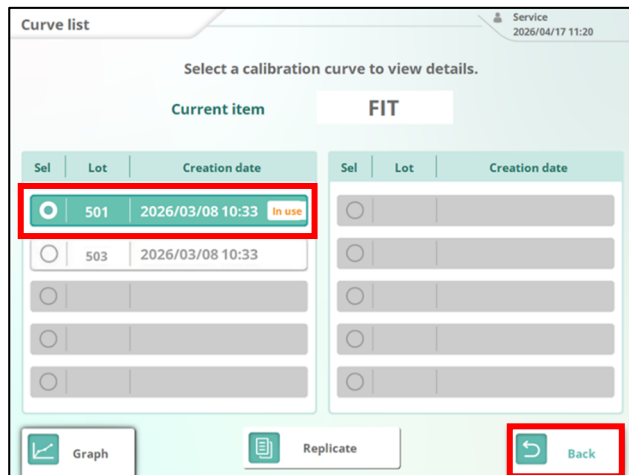
 Register  Print  Back

(5) The selected calibration curve is displayed. To change to the displayed calibration curve, touch {Register}. If no change is going to be made, touch {Back}.

- * Returns to the [Curve list] screen.

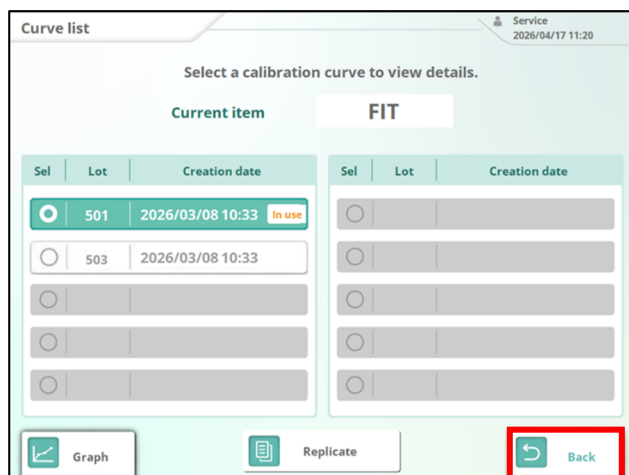
2.8.6.1 Setting up the calibration curve to be used in the analysis

From the calibration curve list, set the calibration curve to be used in the analysis.



1) A list of calibration curves is displayed.

2) Select the calibration curve you want to use for analysis.

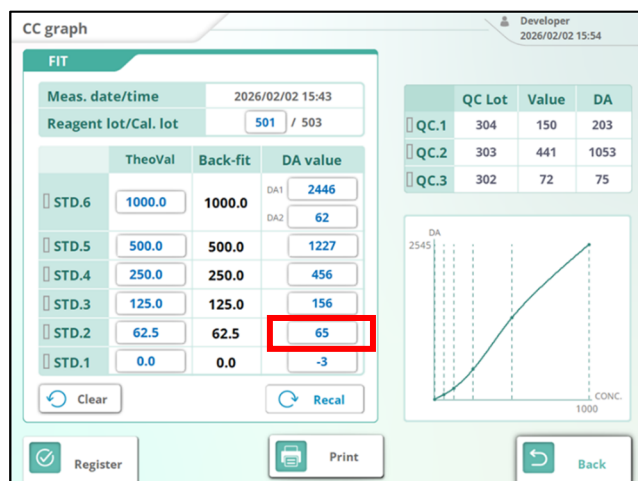


3) Touch the [Back] button.

2.8.6.2 Editing and recalculating an existing calibration curve

This section explains how to edit and recalculate the theoretical/DA1 values of a calibration curve that has already been created.

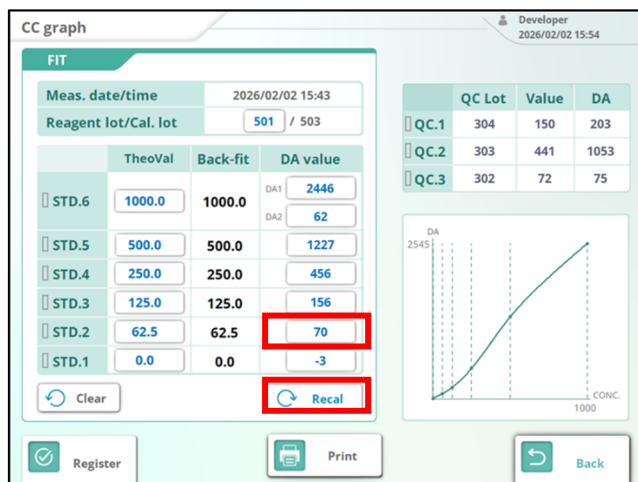
! Editing and recalculating calibration curves is only possible if your login privileges are "Administrator." This cannot be performed if your login privileges are "General."



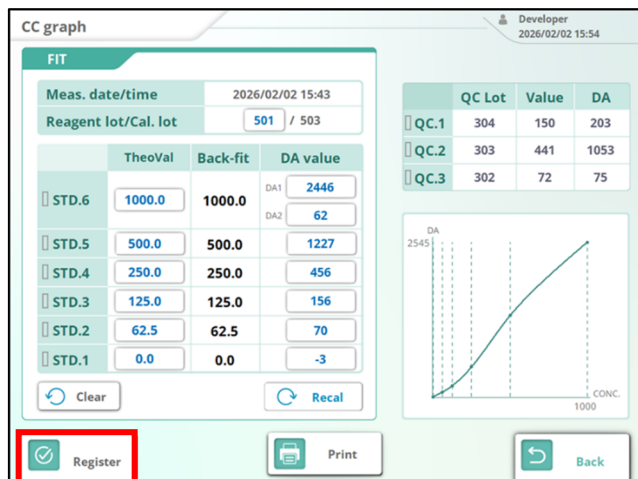
1) Display the "Calibration Curve Graph" for the calibration curve you want to edit. See section 2.8.6

2) Touch the item you want to edit and enter a value using the numeric keypad.

*In this manual, as an example, we will change the DA value of STD2 from 65 to 70.



3) Touch [Recal].

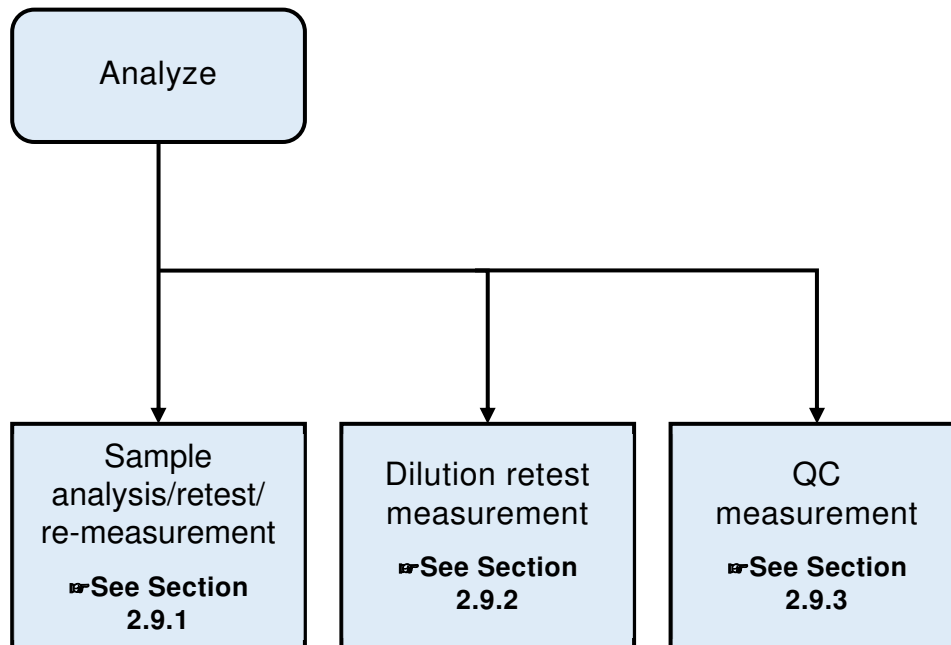


4) The recalculated fitted values, calibration curve graph, and QC measurement data are displayed.

5) To update to the recalculated calibration curve data, touch the [Register] button.

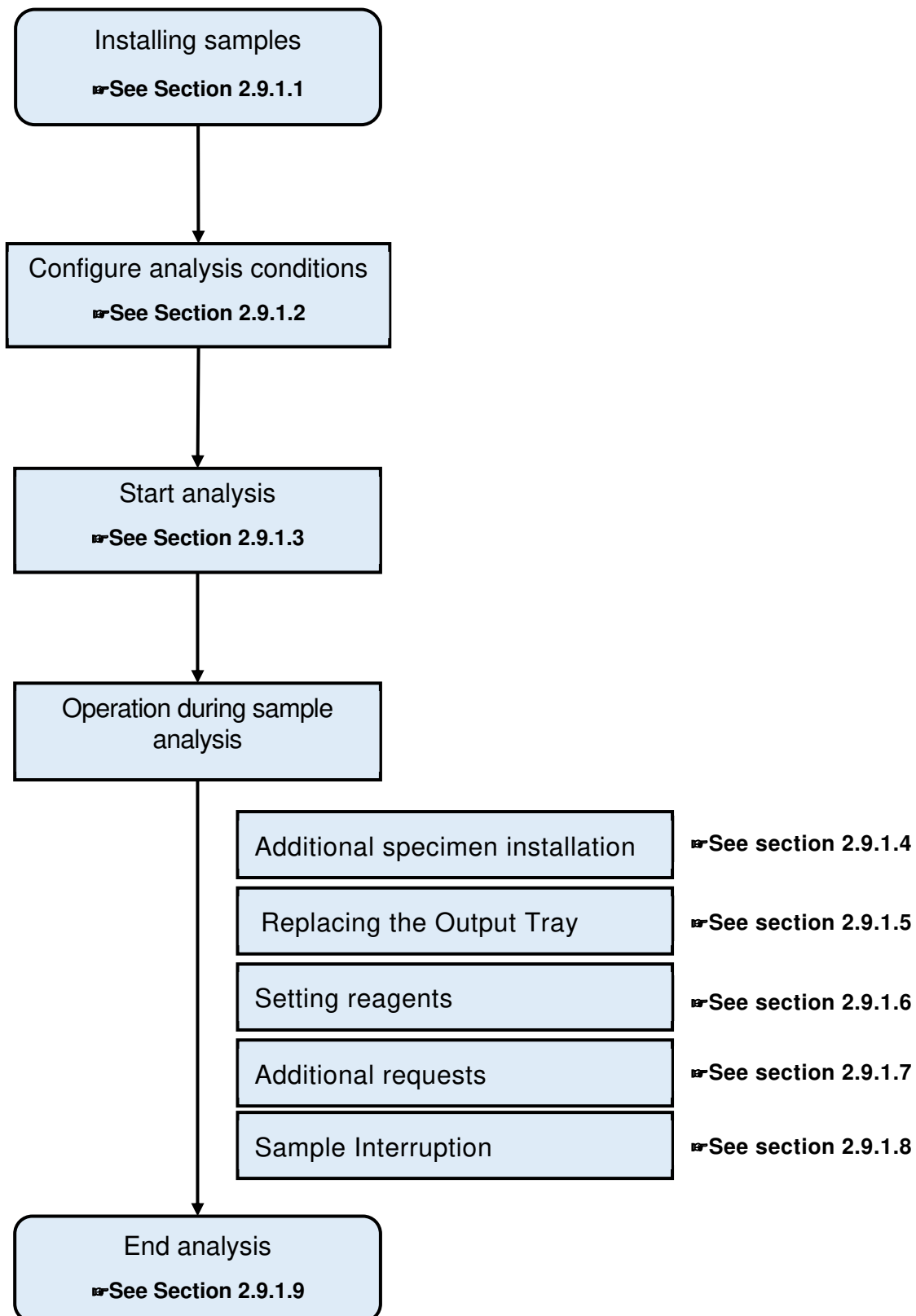
2.9. Analyze

Perform the analysis according to the following operation flow. The operation procedure differs depending on the analysis application.



2.9.1. Sample analysis/retest/re-measurement

This section describes the procedure for sample analysis and retest/re-measurement. Perform according to the following operation flow.



2.9.1.1. Installing samples

Place the rack to which samples have been set in the rack supply unit.

1. INSTALL THE SAMPLE BOTTLES TO THE RACK

Use a measurement mode and rack that suit the samples to be measured.

- When measuring samples, set the measurement mode to "**Analysis**" and use the "**Sample rack**".
- When re-measuring samples, set the measurement mode to "**Retest**" and use the "**Sample rack**".
- When retesting samples, use the "**Retest rack**".
(There is no need to specify the mode.)

- * Install the sample bottle vertically.



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

- * Install the sample bottle in the rack with the aluminum foil facing up.
- * There is no difference in operation between "re-measurement" and "re-test."
It is called a "re-test" when a re-test rack is used, and a "re-measurement" when the re-measurement mode is selected from the screen. However, unlike re-test data, results from a "re-measurement" are handled the same as routine analysis results.

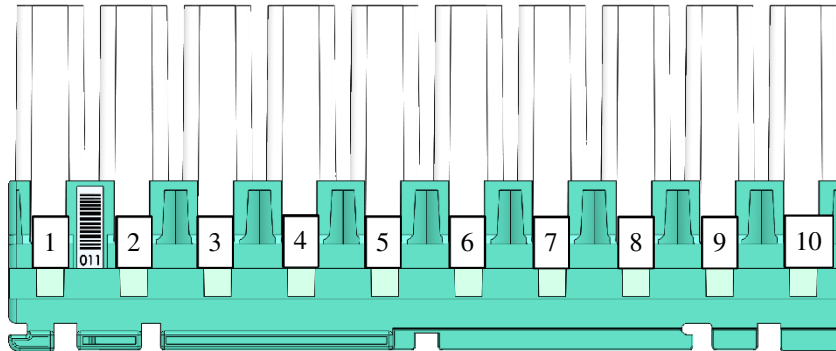
○ Setting samples using measurement method (1 sample/2 sample/3 sample)

Sample arrangement on racks varies according to the measurement method (1 sample/2 sample/3 sample).

Samples are arranged on the rack as follows.

<1-sample>

- Sample bottles for up to 10 people can be set to a single rack.



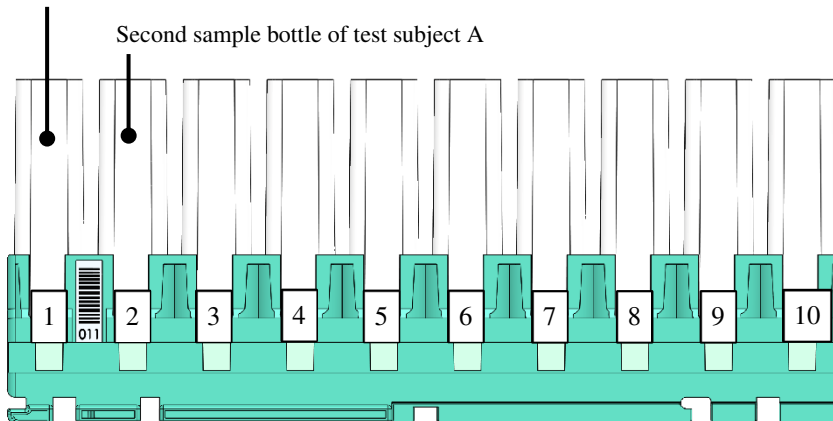
 Set the sample bottle to the rack, so that the barcode is facing to the front.

 The numbers in the diagram indicate the rack position number. Position 1 starts from the left.

<2-sample>

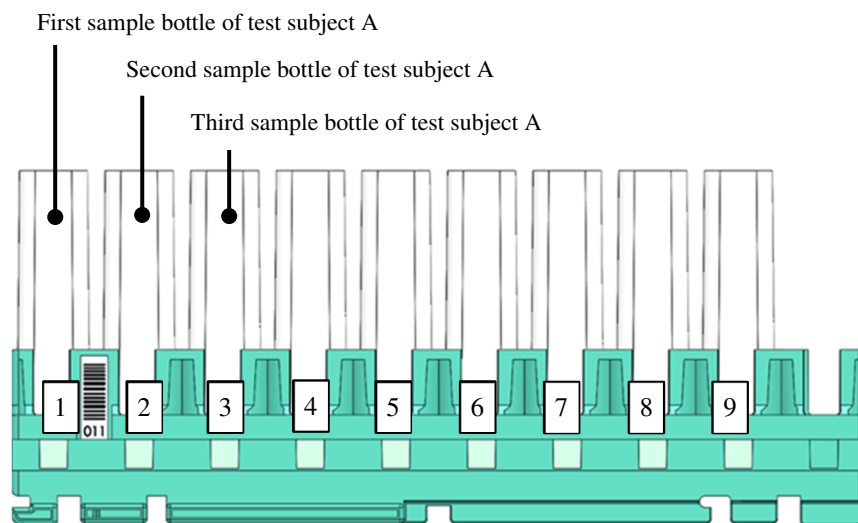
First sample bottle of test subject A

Second sample bottle of test subject A



- Arrange two sample bottles for a single person.
- Sample bottles for up to five people can be set on a single rack.

<3-sample>



- Arrange three sample bottles for a single person.
- Sample bottles for up to three people can be set on a single rack.



For 3 sample method, a bottle is not tested even if the sample is set to rack position No. 10 (right edge).



For 2 sample/3 sample method, if samples for all samples are not available, leave the positions with no samples empty. (Do not set the samples all together).

2. INSTALL THE RACK ON THE TRAY

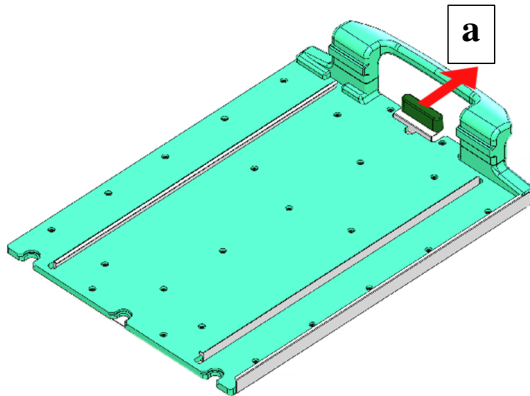


Caution

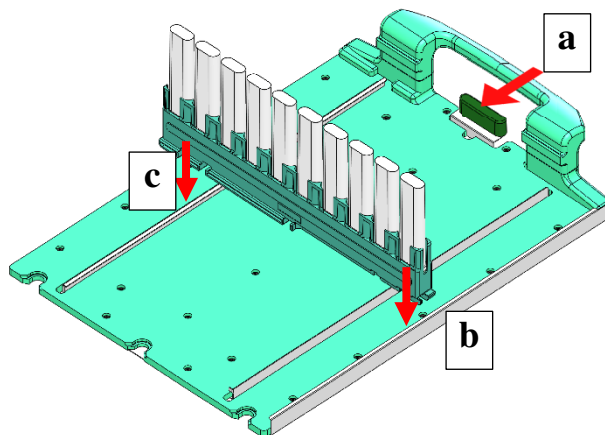


Required

- Set the rack in the tray so that the rack barcode faces toward the front of the System. If installed backward, the rack may tip over.

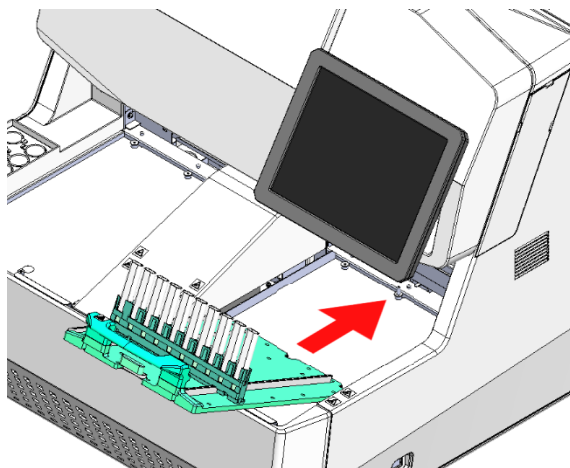


- (1) Pull the rack tray lever (a) forward.



- (2) Set the rack on the tray.
 - (a) Insert the leftmost groove of the rack into guide (b).
 - (b) Align the groove of the rack with the rail section (c) and set it.
- (3) Push lever (a) inward to lock the rack.

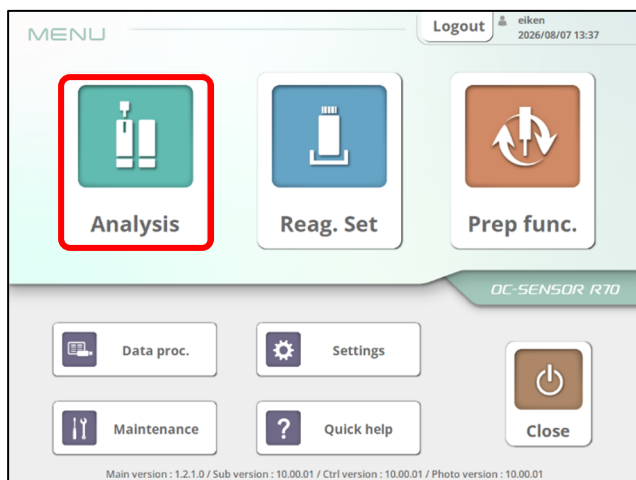
3. INSTALL THE TRAY ON THE SUPPLY UNIT



- Push the tray in from the front of the rack supply unit and install. The tray can be replaced during analysis as well.

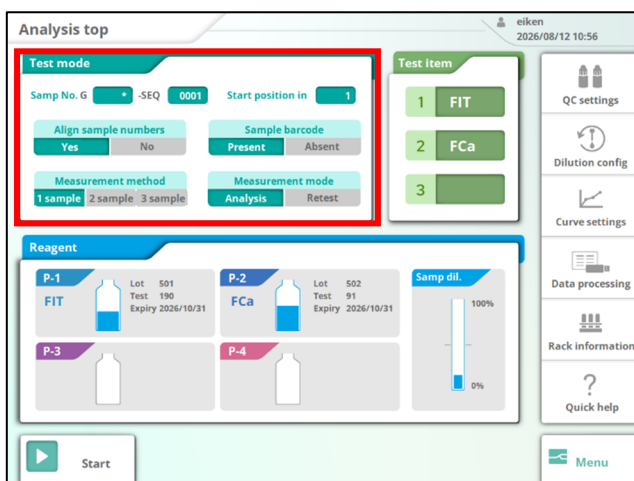
2.9.1.2. Test mode

Configure the conditions for analysis.



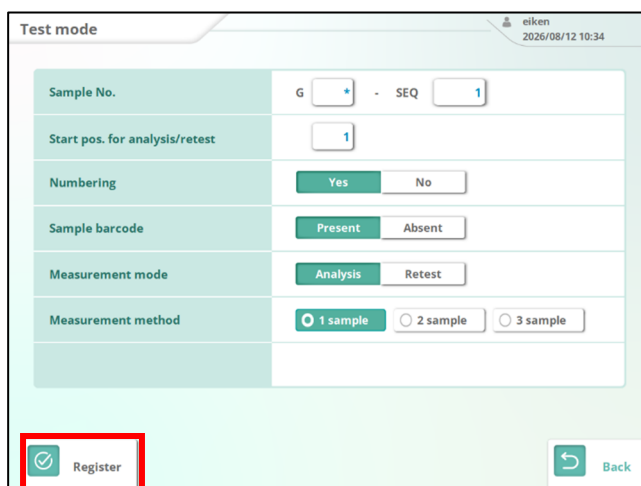
[MENU screen]

- (1) From the {MENU} screen, touch {Analysis}, and display the [Analysis top] screen.



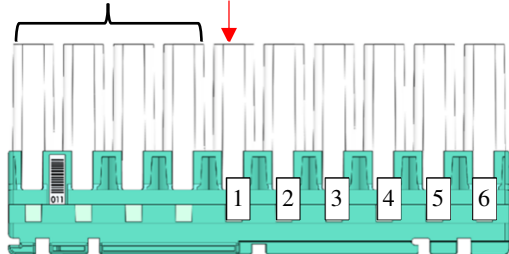
[Analysis top screen]

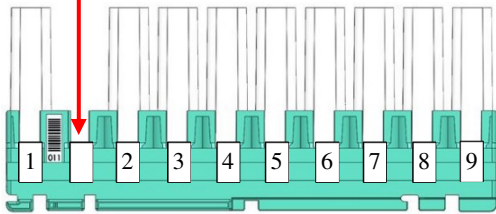
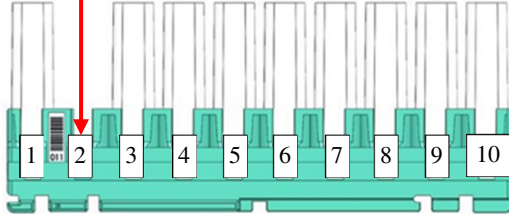
- (2) Touch the {Test mode} area.



[Test mode screen]

- (3) Set each item and touch {Register}.
For details, refer to the following page.
* "Rack No." and "Analysis item for retest" are configurable only for additional requests.

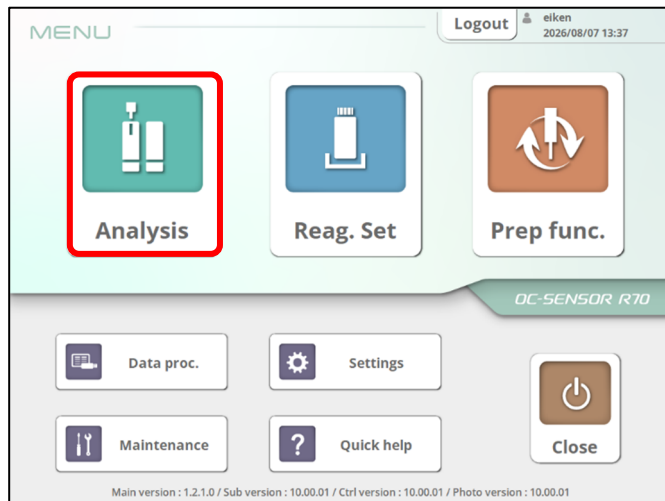
Setting item	Input range selection	Details
Sample No. Set the sample No. of the first sample. If the group No. will not be configured, enter "00". When the group No. is configured, the positive rate variation can be calculated by group. *Sequential numbers will be assigned to samples starting from the set sequence number. *When the power of the System is turned off, the setting is reset. G ☐ - SEQ ☐ G : Group No. SEQ : Sequence No.	*, 1-9 1-99999	<Example of input> When the group No. is configured to "1" and the sequence No. is configured to "3" Display of the first sample No. 1 — 00003 [Group No] [Sequence No.]
Start position in the rack during analysis and re-measurement Configure the analysis start position of the first rack. ☞ The sample No. is assigned from the analysis start position configured here. ☞ This setting does not apply to the retest rack and the dilution retest rack. * After analysis is completed, the settings is reset.	1-10	<Example of input> When the start position is set to "5" The first four are not analyzed Analysis starts from the fifth sample  <Example of start rack installation>

Setting Item	Input Range Selection	Details
Numbering The note explained how sample numbers are assigned when there are positions in the rack where no samples are installed. * The setting is retained even when the System power is turned off.	Yes	A sample No. is assigned only to samples that are installed. Sample No. is not assigned to locations where samples are not installed  <Example of sample installation>
	No	A sample number is also assigned to samples that are not installed. Sample No. is also assigned to locations where samples are not installed  <Example of sample installation> * If there is a location in the rack where a sample is not installed, a "Sample unset" error will occur.
Sample barcode use Set the use of sample barcode * The selected setting is also reflected in "Sample barcode settings." ➡ See Section 6.1.2 * The setting is retained even when the System power is turned off.	Present	Sample barcode is used.
	Absent	Sample barcode is not used.

Setting Item	Input Range Selection	Details
Measurement Mode Select the measurement mode.  Measurement values when retesting samples in Retest/Retest mode are reflected in the positive rate.  Measurement values when using a retest rack or dilution retest rack are not reflected in the positive rate. * This setting is retained even if the instrument's system power is turned off.	analysis: Re-measurement /re-examination:	Select this when measuring for the first time. Select this when re-measuring or re-running a sample.
Measurement method Select the measurement method * The setting is retained even when the System power is turned off.	1 sample: 2 sample: 3 sample:	Measurement is performed using the 1 sample method. Measurement is performed using the 2 sample method. Measurement is performed using the 3 sample method.

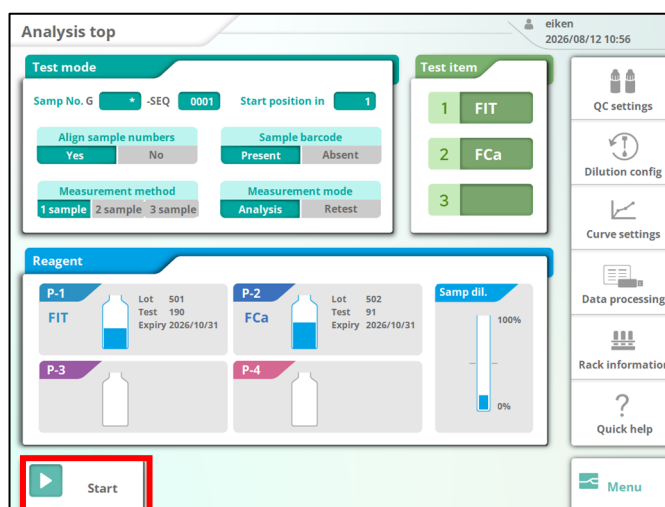
2.9.1.3. Start analysis

Start the analysis.

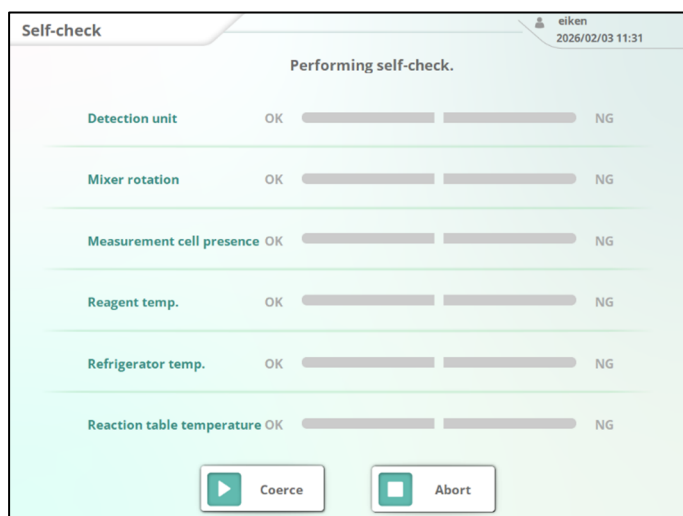


[MENU] screen

- (1) From the [MENU] screen, touch {Analysis}, and display the [Analysis top] screen.



- (2) Touch the {Start} button.



- (3) Self-check starts, and analysis begins after all items are judged as [OK].

<Self-check items>

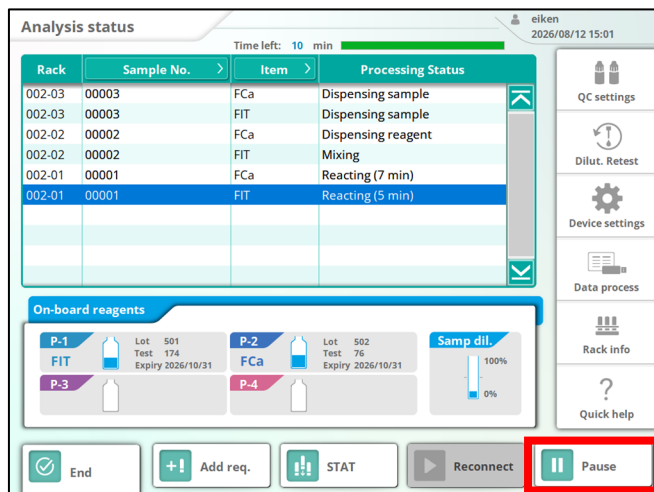
- Detection unit
- Mixer rotation
- Measurement cell presence
- Reagent temp.
- Refrigerator temp.
- Reaction table temperature

If {NG} appears in self-check

Check Item	Cause/Corrective Action of NG
Detection unit	{Cause} An abnormality was detected in the detection unit. {Action} Turn off the power and contact the manufacturer.
Mixer rotation	{Cause} An abnormality was detected in the mixer rotation. {Action} Turn off the power and contact the manufacturer.
Measurement cell presence	{Cause} The measurement cell is not set. {Action} Set the measurement cell on the reaction table.
Reagent temp.	{Cause} The temperature of the reagent refrigerator increased after the previous power OFF. {Action} Reagents that were in place before the power was turned on may not have been stored at the proper temperature. To avoid the possibility of a misdiagnosis, discard the reagent that was installed and perform reagent setup again. Alternatively, you can start the analysis by selecting "Coerce." If you use "Coerce," it may affect the measurement results.
Refrigerator temp.	{Cause} The set temperature has not been reached. {Action} Wait until the set temperature is reached. Alternatively, you can start the analysis by selecting "Coerce." If you use "Coerce," it may affect the measurement results.
Reaction table temperature	

2.9.1.4. Additional specimen installation

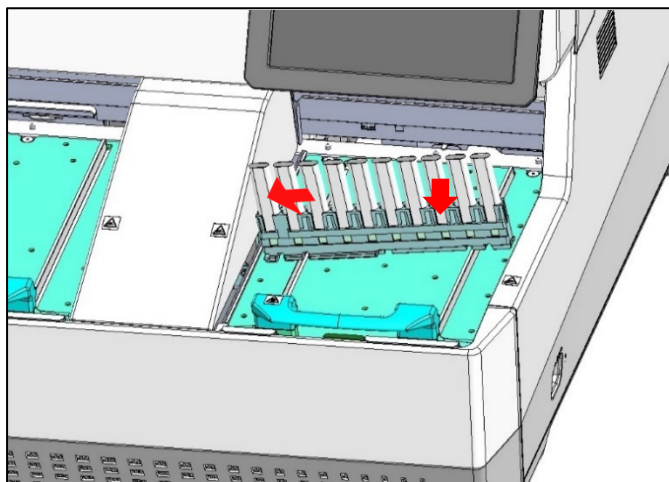
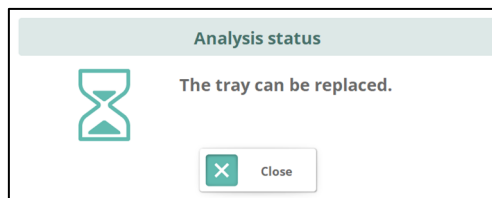
This section describes the procedure for adding a rack/tray to add samples during testing.



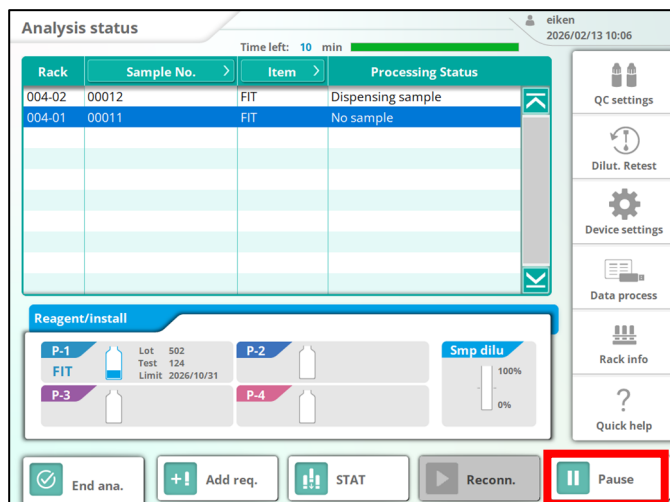
◎ When adding only the rack

- (1) Please check that the feed bar has returned to its original position and that the message "The tray can be replaced." appears on the screen. However, if you wish to add an item whilst the supply bar has not yet returned to its starting position, you can display the same screen by tapping the "Pause" button.

* The same screen is displayed even when all racks in the supply tray have been completely supplied.



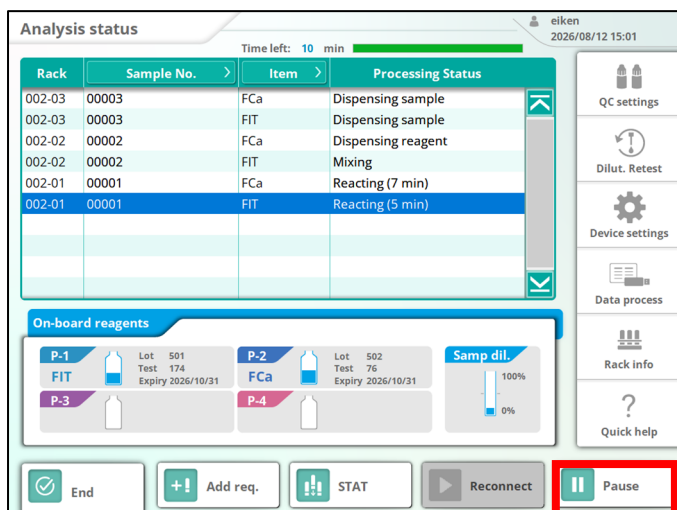
- (2) Place the rack with the samples installed on the supply tray.
 - (a) Insert the leftmost groove of the rack into guide.
 - (b) Align the groove of the rack with the rail section and set it.



(3) Touch "Start"

- * After the rack becomes available for supply, the rack is automatically supplied once the supply waiting time set in "Environment settings" has elapsed.

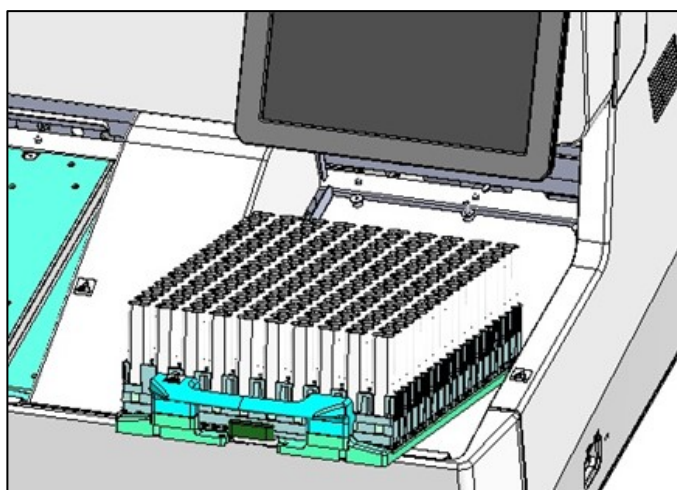
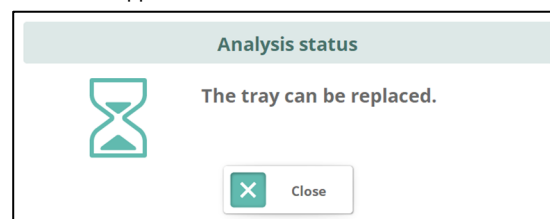
➡ See Section 6.2.1



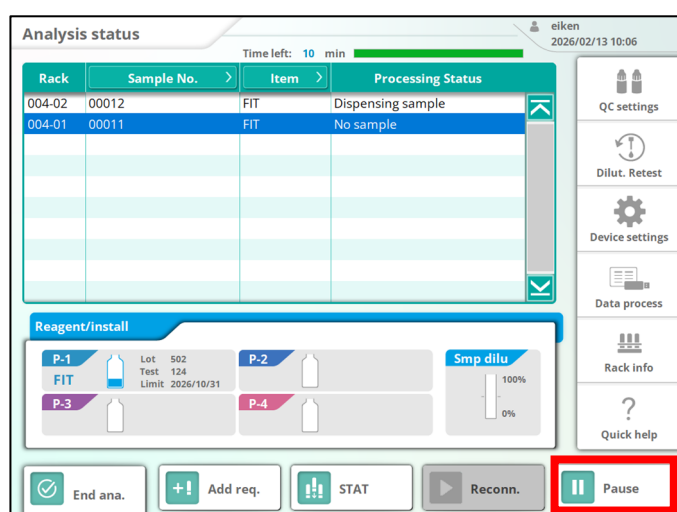
©When replacing the tray

- (1) On the [Analysis status] screen, touch "Pause."
The supply bar returns to the front, and "Tray can be replaced." message is displayed on the screen.

* The same screen is displayed even when all racks in the supply tray have been completely supplied.



- (2) Replace the supply tray.
- Remove the tray.
 - Insert the tray installed with samples from the front of the rack supply unit to install it.



- (3) Touch "Start"

* After the rack becomes available for supply, the rack is automatically supplied once the supply waiting time set in "Environment settings" has elapsed.

▣ See Section 6.2.1

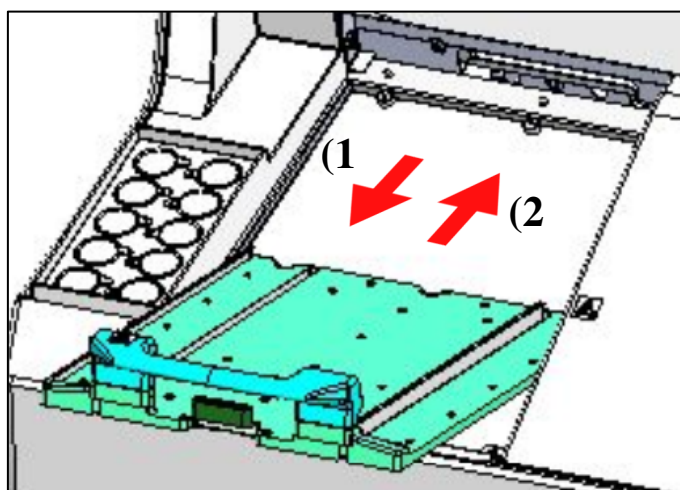
2.9.1.5. Replace the discharge tray

The discharge tray can be replaced at any time during analysis.



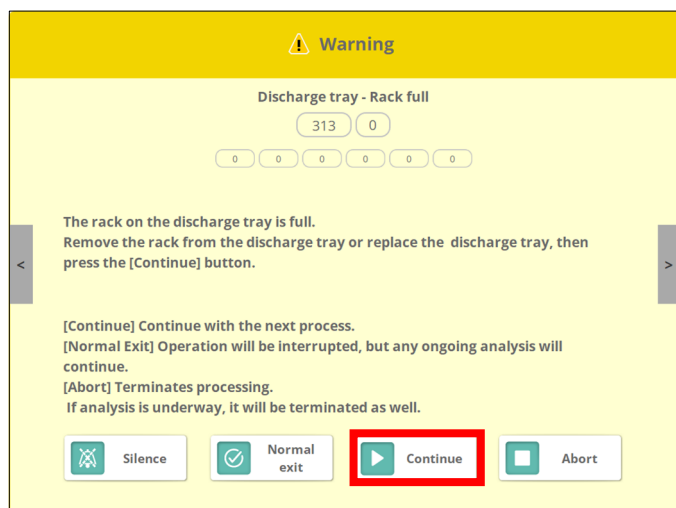
If the tray is not set when the rack is discharged, a "No discharge tray" error is issued.

Please stop the analysis by pressing the Pause button or confirm that there are no more racks to be discharged before replacing the discharge tray.



<How to replace>

- (1) Remove the tray.
- (2) Remove the rack from the tray, then insert it from the front of the rack discharge unit to load it.



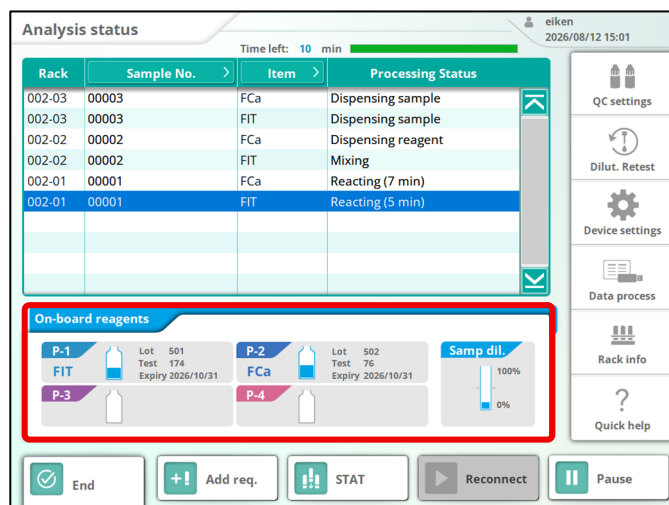
[Error - discharge tray full] screen

When the tray is full

- (1) When the discharge tray becomes full with racks, the "Error - discharge tray full" screen is displayed on the screen.
- (2) Replace the discharge tray. (See the preceding section.)
- (3) Touch "Continue".
Rack discharge operation resumes.

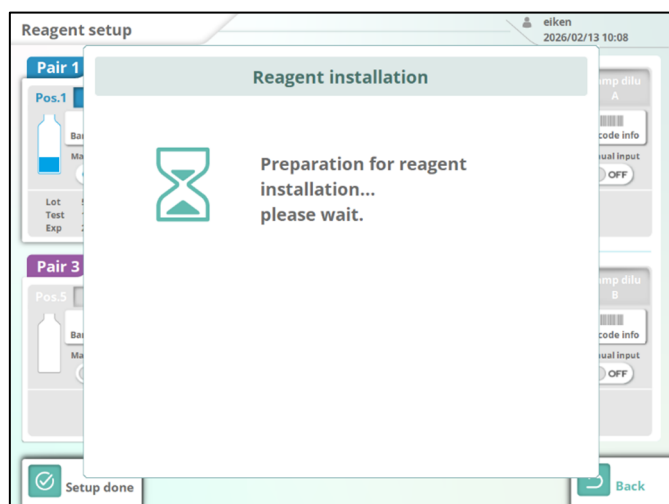
2.9.1.6. Install a reagent during analysis

This section describes the procedure for installing reagents during analysis.



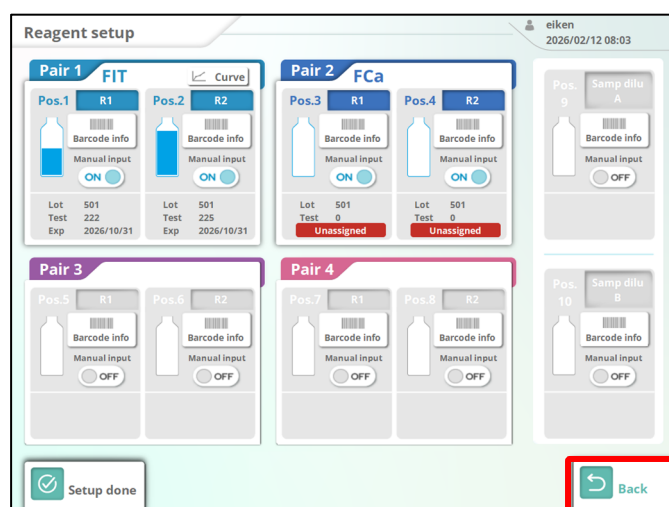
- (1) From the [Analysis status] screen, touch {Reagent} area.

[Analysis status] screen



- (2) Wait until the System is ready to start reagent installation.

A dialog box is displayed during operation. When the System becomes ready for reagent installation, the dialog box closes and the protective cover can be opened.



- (3) Install the reagent following the same procedure as described in “2.7. Installing reagents,” and after completing reagent loading, touch {Back}.

The screen returns to the [Analysis status] screen, and the analysis resumes.

2.9.1.7. Additional request



This section describes the procedure for changing the test mode during analysis.
Manual entry worksheet settings cannot be configured for an additional request.

[Analysis status] screen

[Add. req] screen

How to set up additional requests

- (1) From the [Analysis status] screen, touch {Add. req}.

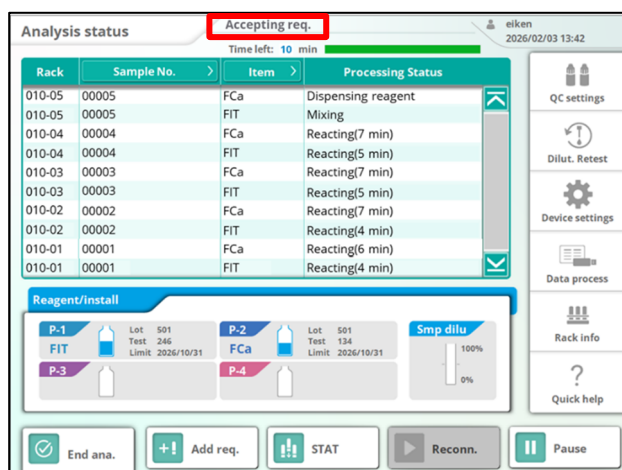
The additional request screen opens.

*The {Add. req.} button can only be pressed when all measurements have been completed.

- (2) Configure each item and touch {Register}.
For details, refer to the following page.

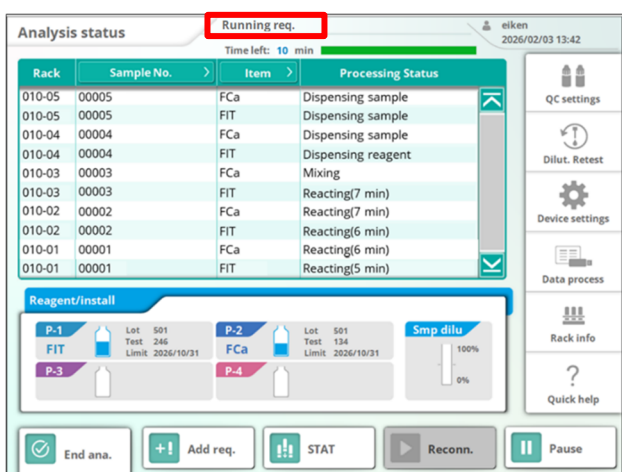
* In addition to the items configured in "Test mode" in the additional request, configure "Rack" and "Retest analysis item."

Additional setting	Input range/selection	Details
Rack No. No. ☐ - Number of racks ☐ No. : Rack No. Number of racks : Number of racks	No. : 1-99 Nonber of racks*, 1-99	Set the rack number where the changed analysis conditions will start to be applied, and the number of racks to which they will be applied. Once analysis of the number of racks to which you want to apply them has finished, the conditions will revert to those before the addition request. ☞ If you enter an "*" for the number of racks, the changed analysis conditions will be applied to all racks from the specified rack number onwards.
Retest analysis items	Analysis items selected in "Analysis item settings"	* Select the analysis items for retest. ☞ The settings are applied only when the order request is set to "None."



Executing an Addition Request

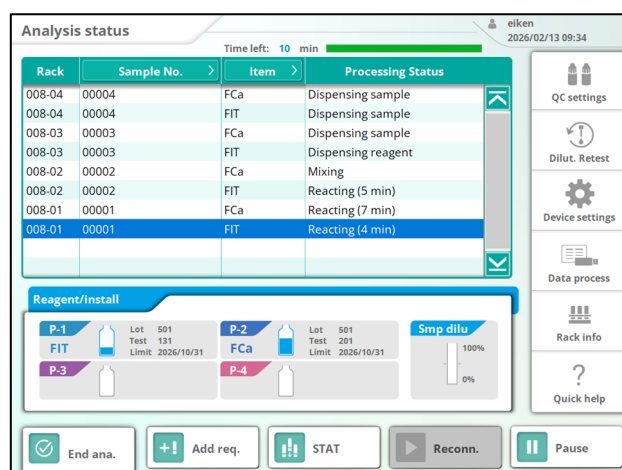
1) When you register an addition request, the [Analysis Status] screen displays "Accepting req."



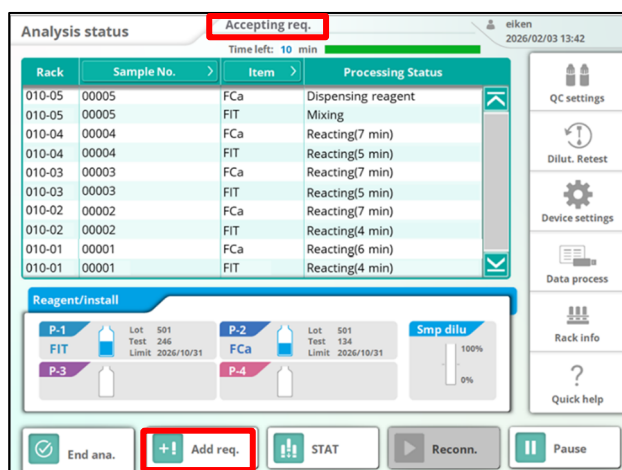
2) When the addition request is executed, the [Analysis Status] screen displays "Running req."

* You cannot change the addition request while "Running req." is displayed.

* If you set the number of racks to "*", the message will remain "Accepting req."



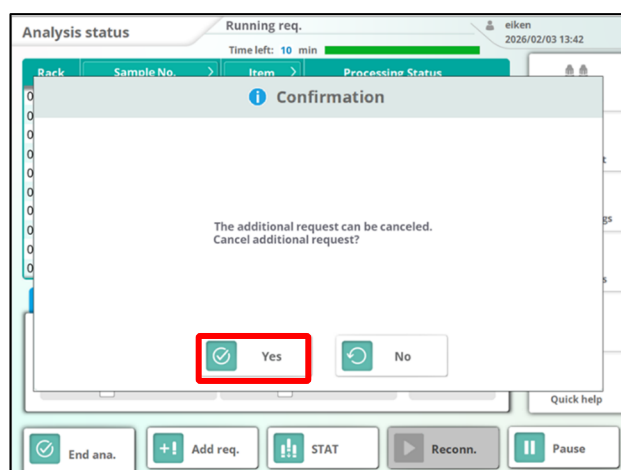
3) Once processing for the specified number of racks is complete, the "Running req." message will disappear.



Canceling an Add-on Request

1) When "Accepting req." is displayed, Touch the [Add-on Request] button.

* You cannot cancel an add-on request while "Running req." is displayed.



2). A confirmation message will appear; Touch the [Yes] button.

2.9.1.8. STAT analysis

This section describes the procedure for STAT analysis with a sample rack or STD/QC rack during analysis.

(STAT analysis)

- * In STAT analysis, the measurement mode is set to “Analysis mode”, and the measurement method is “1 sample.”
- * STAT analysis cannot be performed with retest racks or dilution retest rack.



Request



Required

After tapping {Add req.}, a message stating “Rack under analysis. Please wait.”. Please do not load any racks until the message has disappeared.

If a rack is installed whilst a message is being displayed, the system may incorrectly recognize that a rack is still on the conveyor line, and may be unable to start the interruption analysis.

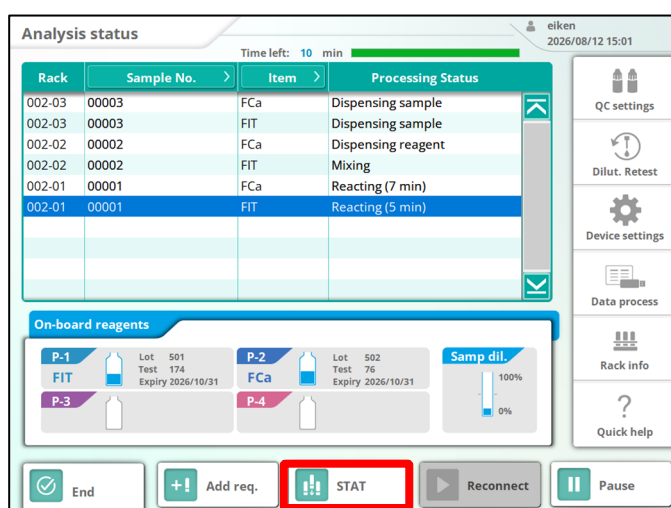


Request

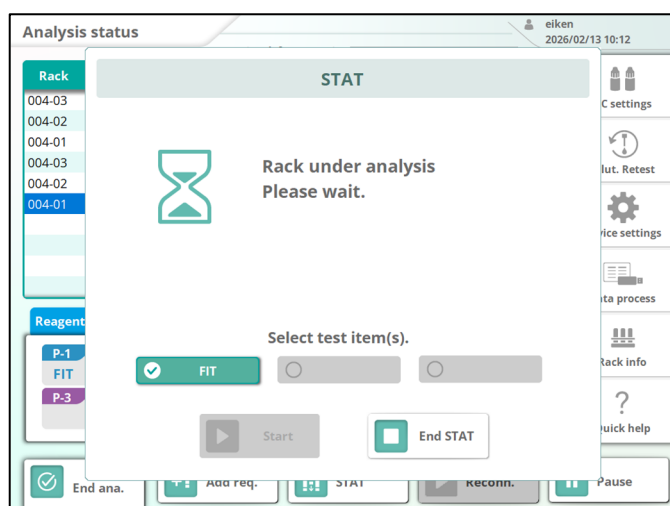


Prohibited

Do not interrupt STAT analysis while STAT analysis of STD samples is in progress. Interrupting the process will delete STD data that are in the middle of measurement.

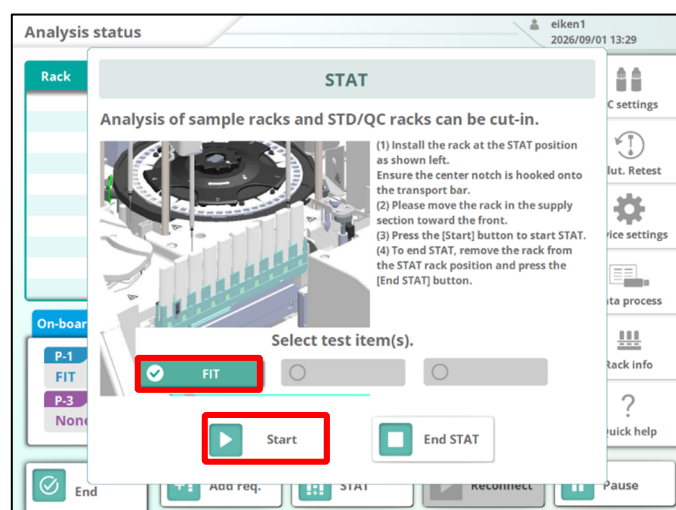


- (1) From the [Analysis status] screen, touch {STAT}.



- (2) Wait until the message “A rack is currently under analysis. Please wait.” disappears.

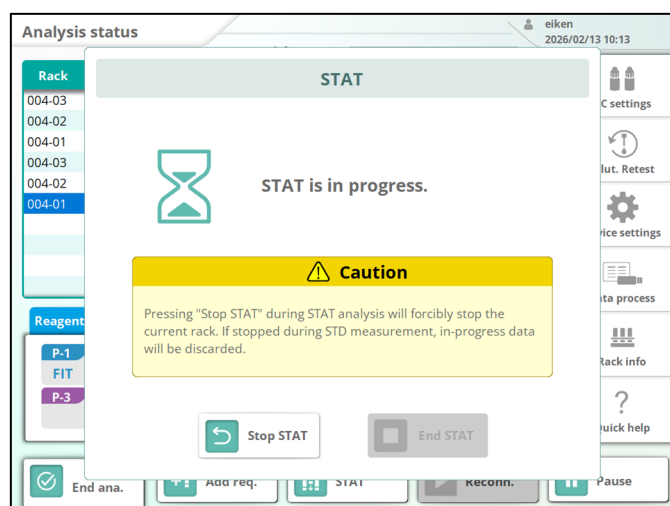
* When the rack under analysis is discharged, the {Start} button becomes available.



- (3) Install the rack into the STAT rack loading location, aligning it with the groove at the centre of the rack.

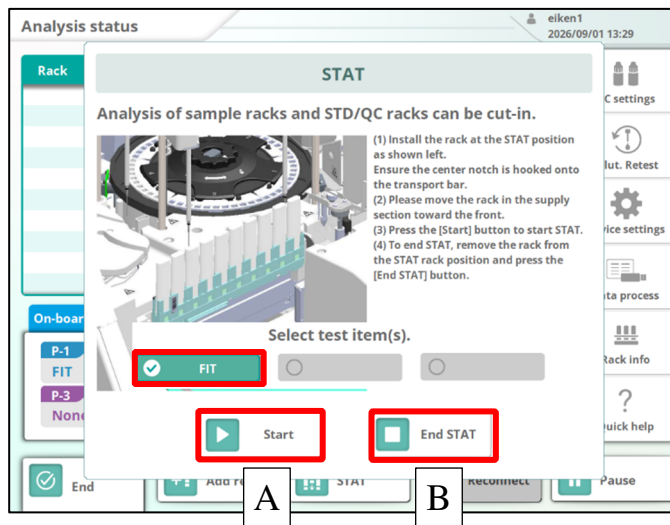
- (4) Please push the rack in the supply section back towards you.
There is a risk of interference with the STAT rack.

- (5) Select the analysis item and touch {Start }.



- (6) During STAT analysis, the screen “STAT is in progress” is displayed. To interrupt STAT analysis during operation, touch {Stop STAT}.

⚠ If STAT analysis is interrupted while STD samples are being analyzed, the STD measurement data is discarded. Use caution.



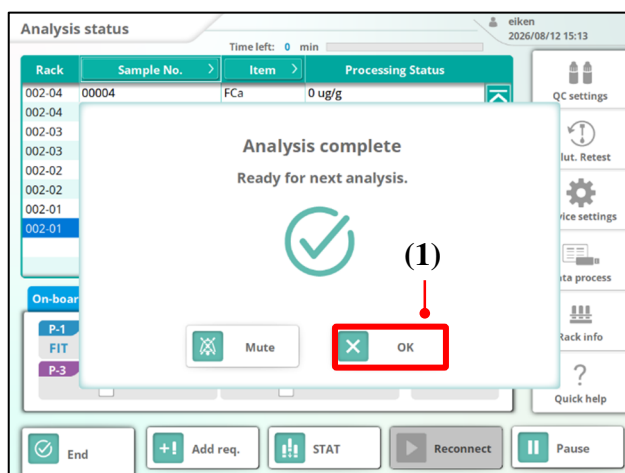
- (6) After STAT analysis is completed, the [STAT analysis] screen is displayed again.
- (A) To perform STAT analysis again, select the analysis item and touch {Start}.
- (B) To end STAT analysis, touch {End STAT}.

2.9.1.9. End analysis

There are two procedures for ending analysis. The section describes these procedures.

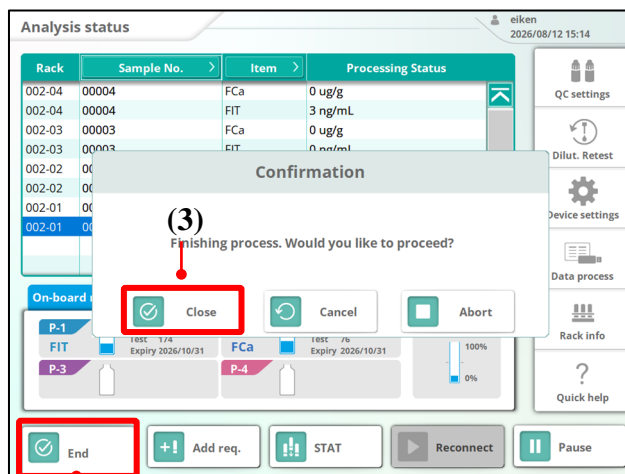
- **Normal end:** All samples currently in reaction are analyzed, and then analysis ends.
- **Forced end:** All operations are forcibly stopped and the display returns to the [MENU] screen.

■ At normal end



- (1) When analysis is completed, the screen on the left is displayed. Touch {OK}.

* The display returns to the [Analysis status] screen.



- (2) Touch the {End} button.

* The confirmation screen is displayed.

- (3) Touch the {Close} button.

* If "Output to external media" is enabled, measurement data are output to the external media.

* If the {Close} button is pressed during analysis, all samples currently in reaction are analyzed, and then the display returns to the [MENU] screen.

(2)

■ At force end



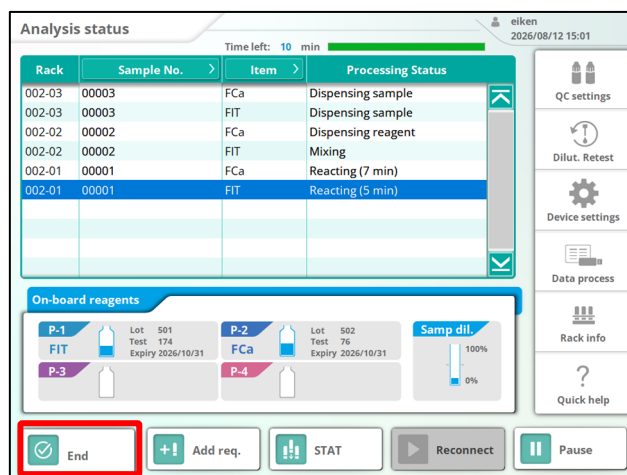
Caution



Required

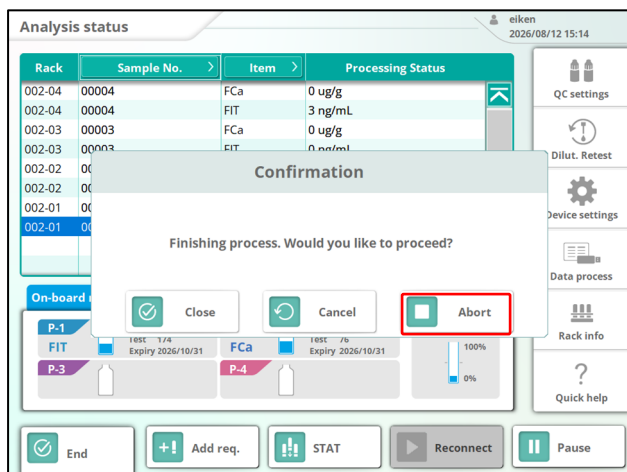
- If analysis is aborted, analysis results that are currently being measured are discarded.

Re-measure the samples currently under measurement and any samples that have not yet been analyzed.



(1) Touch the {End} button.

- * The confirmation screen is displayed.



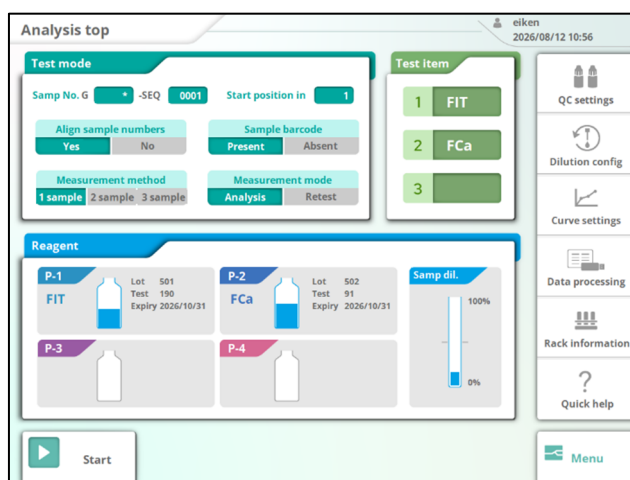
(2) Touch the {Abort} button.

- * Returns to the [MENU] screen.

2.9.2. Dilution retest measurement

This section describes the procedure for dilution retest measurement.

- ⚠ When performing dilution retest measurement, use the **"Dilution retest rack."**
- ⚠ When diluting and retesting, the number of replicates will be "1".
- ⚠ The number of selectable items is 2, and the number of samples that can be measured at once is 10.



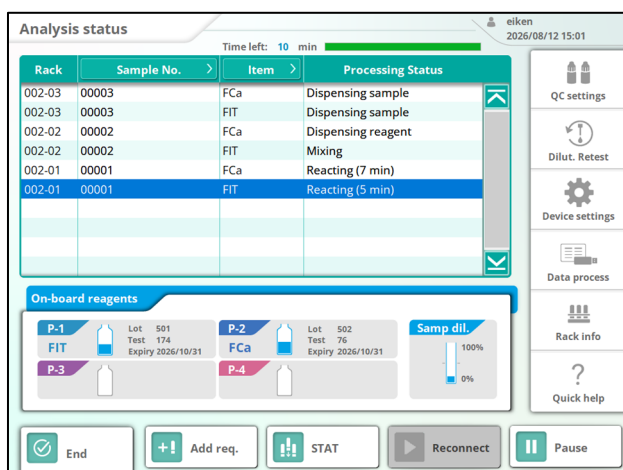
[Analysis top screen]

<How to Set Up Dilution Retest>

- 1) Open the Dilution Retest Settings

Before starting analysis

Touch [Dilution Retest Settings] on the [Analysis Main] screen.



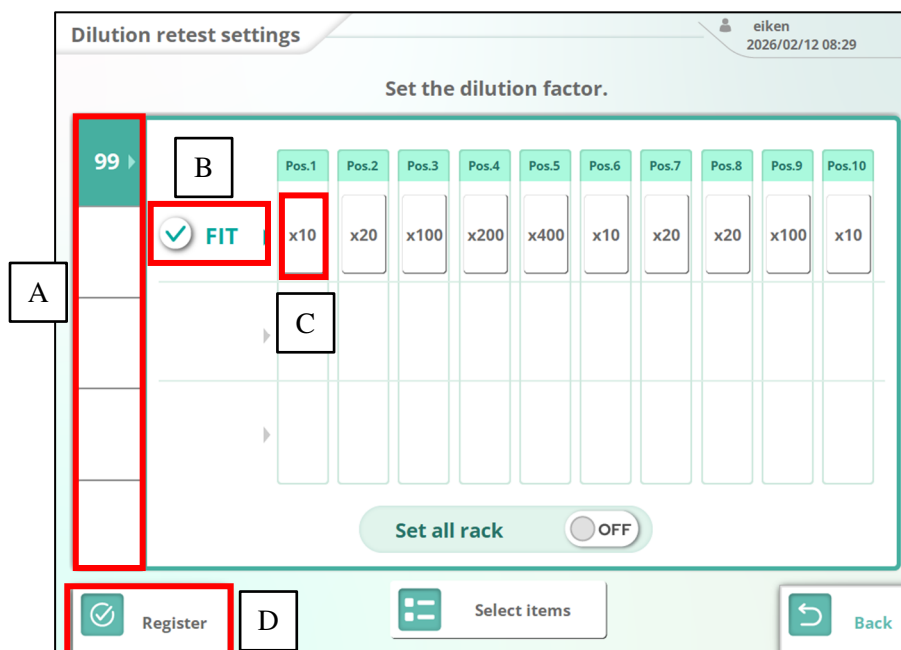
[Analysis Progress Screen]

During analysis

Touch [Dilution Retest Settings] on the [Analysis Status] screen.

Note: During analysis, the [Dilution Retest Settings] button can only be pressed once all measurement values for the sample being analyzed have been output.

2) Configure the dilution factor.



< Setting procedure >

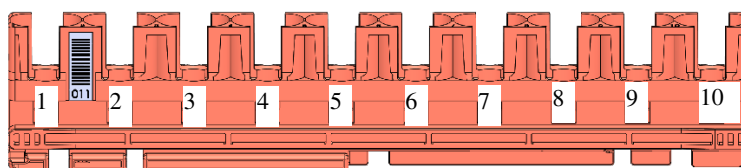
- (A) Select the rack number to configure.

The rack number set as a "diluted retest" rack in the rack No. settings is displayed.
To select all racks at once, set {Set all rack} to "ON".

- (B) Check the analysis items to be set.

- (C) Press the button for each position to set the dilution factor.

* "Pos.○○" on the screen corresponds to the position in the rack. (Refer to the following diagram.)



Each time the button is pressed, the dilution factor switches in the following order: (×10→20→100→200→400→ -)

Press repeatedly until the desired dilution factor is set.

When set to "-", it is excluded from analysis.

- (D) Touch {Register} to save the settings.

- (3) Install the rack on the supply tray and start the analysis. **See Section 2.9.1.4**

Racks are automatically supplied during analysis.

*If "Simultaneous First-Stage Analysis" is set to "Yes," when performing a 2-stage dilution (x100, x200, x400),
the first-stage diluted sample will also be analyzed simultaneously and its result will be output.

2.9.3. QC measurement

There are two QC measurement procedures, as described below.

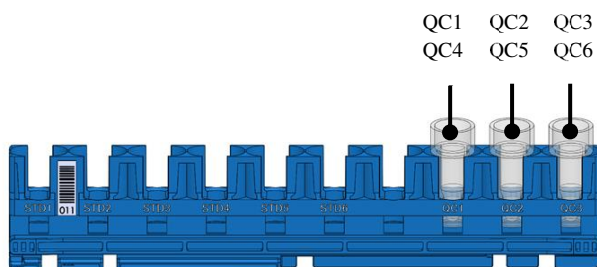
- Single-item QC measurement
- Multi-item QC measurement

 Note that the QC sample installation locations differ depending on the procedure.

2.9.3.1. Single-item QC measurement

This section describes how to perform QC measurement for one analysis item using one rack.

 When performing single-item QC measurement, use the **“STD/QC rack”**.



<Measurement procedure>

- (1) Install the QC samples into positions 8 to 10 in the STD/QC rack.
(See the figure to the left)

* Install the QC samples into the positions linked to the registered QC information.

➡ See Section 2.8.3

- (2) Install the rack on the supply tray and start the analysis. ➡ See Section 2.9.1.4
If analysis is in progress, the rack is supplied automatically.

2.9.3.2. Multi-item QC measurement

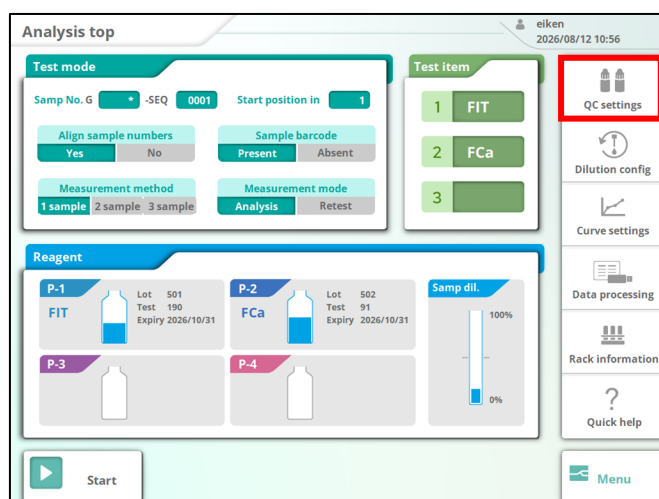
This section describes how to perform QC measurements for multiple analysis item using one rack.



When performing multi-item QC measurement, use the **“QC rack”**.



For multi-item QC measurement, only **“QC1, QC2, and QC3”** can be used as QC information. **“QC4, QC5, and QC6” cannot be used.** To use QC4, QC5, or QC6, perform single-item QC measurement.

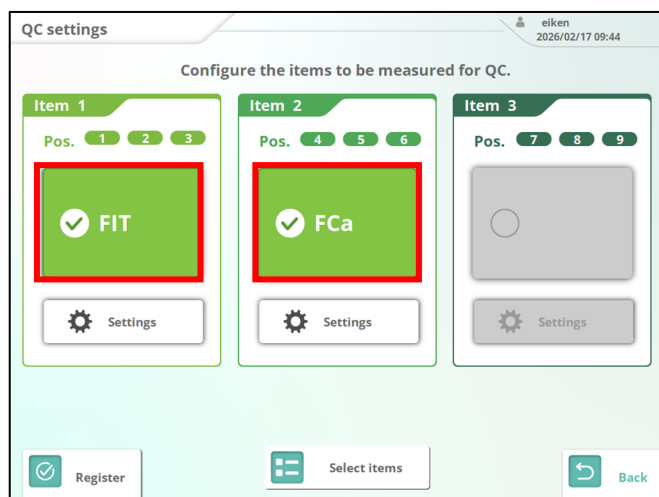


[Analysis top] screen

<Measurement procedure (when measuring FIT and FCa simultaneously)>

1) From the main analysis screen, touch [QC Settings].

* QC settings cannot be changed during analysis.

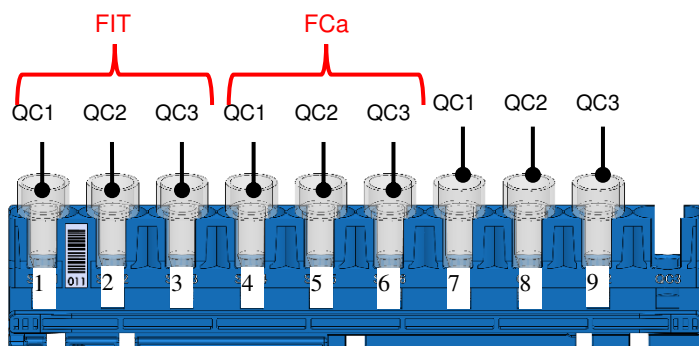


2) Check the analysis items for the QC samples you want to measure.

3) Place QC samples for each analysis item in positions 1-9 on the QC rack. (See the diagram on the left.)

* Place QC samples in the positions associated with the registered QC information.

☞ See Section 2.8.3



4) Place racks in the supply tray and begin analysis. ☞ See Section 2.9.1.3

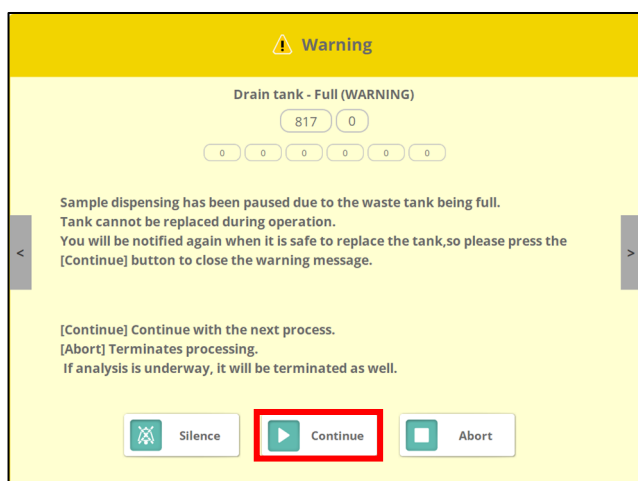
If analysis is in progress, racks will be supplied automatically.

2.9.4. Replacement of the drain tank and refill of purified water/wash solution during analysis

This section describes how to replace the drain tank and refill purified water or wash solution during analysis.

 Warning	
 Biohazard	- The device periodically drains condensed water. To prevent overflow, place the water in a separate container after removing the full tank sensor and hose. - Wear protective equipment when handling the drain tank. Failure to observe this precaution may lead to infection.

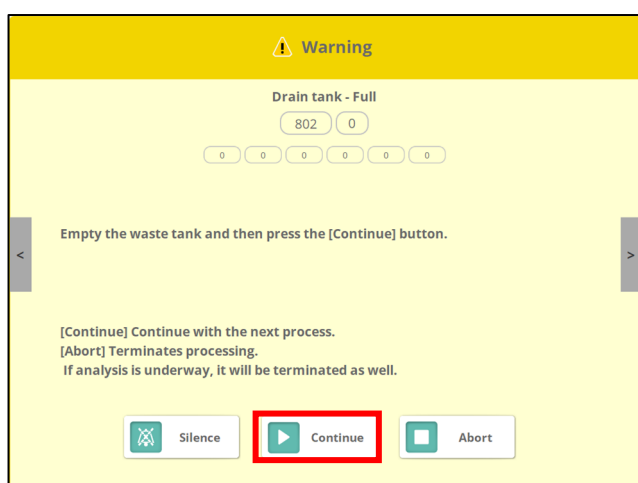
■ Replacing the drain tank



- (1) If the drain tank becomes full during analysis, the following error is displayed:

■ Drain tank full

- (2) Touch the {Continue} button.
- * Analysis continues until replacement becomes possible.

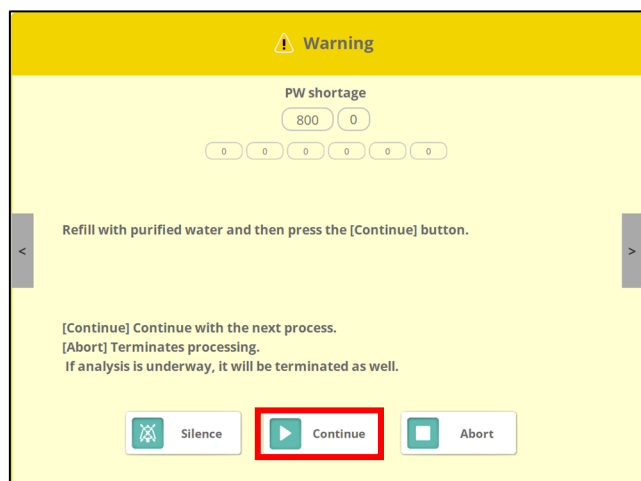


- (3) When replacement becomes possible, the following error is displayed:

■ Discard the drainage

- (4) Empty the drain tank.
- * See **Section 2.6.1**

- (5) Touch {Continue}.
- * Analysis resumes.



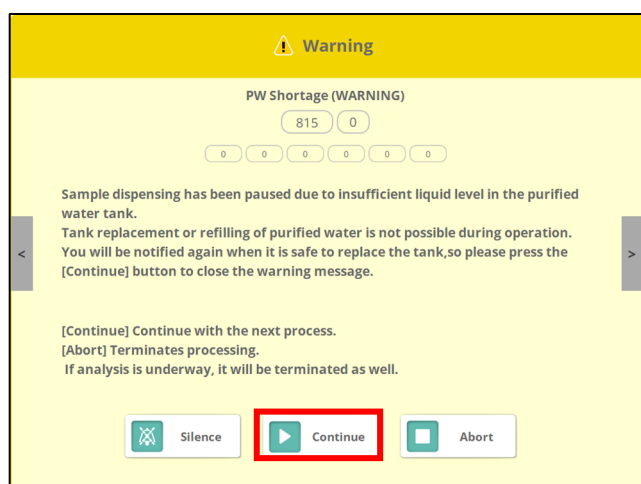
■ Refilling purified water/wash solution

- (1) If purified water or wash solution becomes insufficient during analysis, the following error is displayed:

- Purified water insufficient(for purified water)
- Wash solution insufficient (for wash solution)

- (2) Touch the {Continue} button.

* Analysis continues until refilling becomes possible.



- (3) When refilling becomes possible, the following error is displayed:

- Refill with purified water (for purified water)
- Refill with wash solution(for wash solution)

- (4) Refill purified water or wash solution.

☞ See **Sections 2.6.2 and 2.6.3**

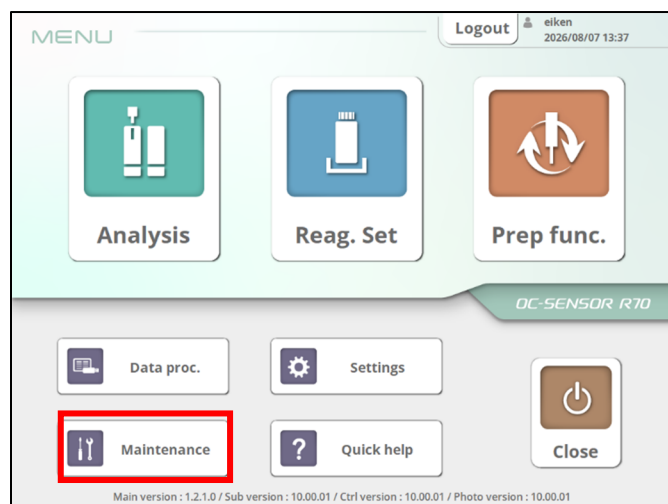
- (5) Touch {Continue}.

* Analysis resumes.

2.10. Care After Use

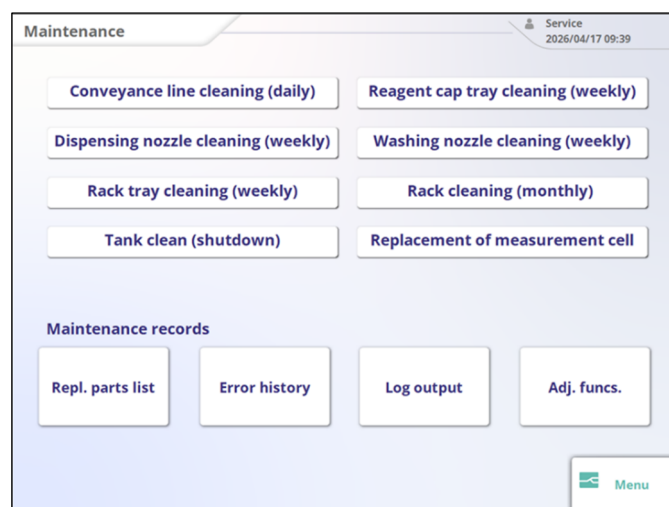
Clean the System before turning off the power of the System. This section explains how to read the cleaning procedures.

For details on the cleaning procedures, refer to **Section 5.2**.



[MENU screen]

1. From the [MENU] screen, touch the [Maintenance] button.



[MAINTENACE screen]

2. The Maintenance screen will appear. Touch a cleaning method to display the cleaning procedure. Follow the on-screen instructions to perform the cleaning.
For details on cleaning methods, see section 5.2.

2.11. System Shutdown

This section describes how to shut down the System. After the shutdown process is completed, the System automatically powers off.
(The main power switch cannot be turned off.)

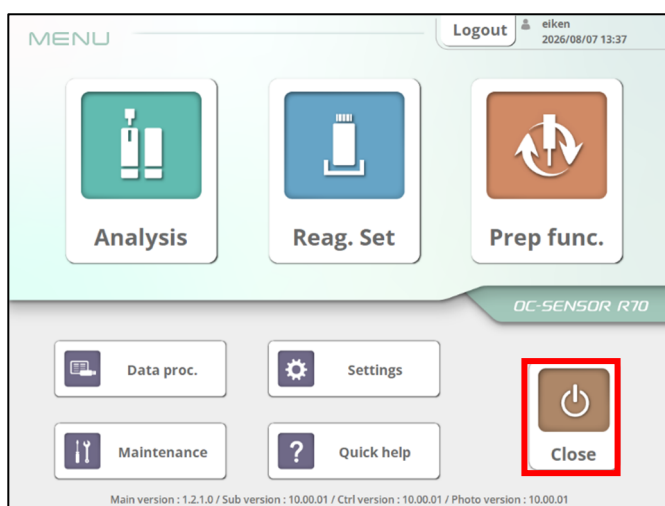


Caution



Required

- If the System will not be used for an extended period, set “LongShutdown” to “ON” during the shutdown process, and turn the main power switch “OFF”.

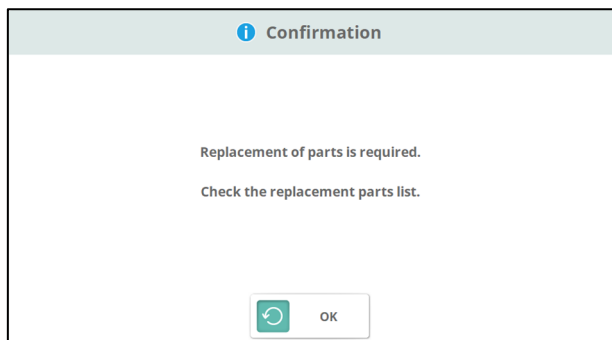


- (1) From the [MENU] screen, touch the {Shutdown} button.

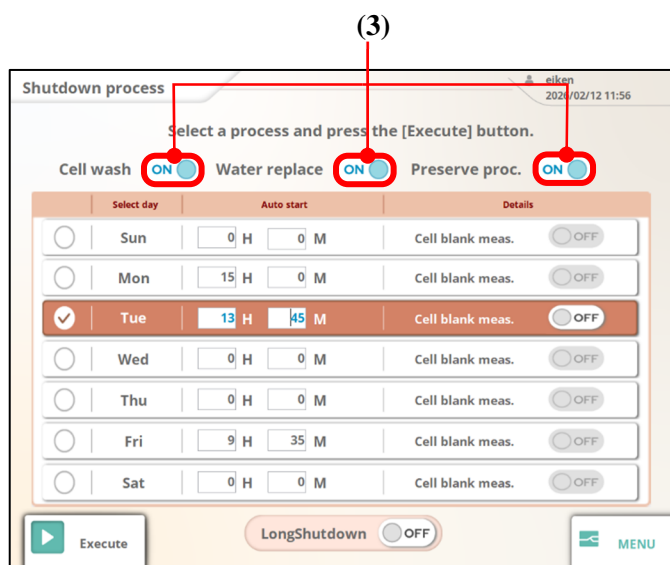


- (2) Initialization is executed.

- * A dialog box is displayed during operation. When initialization is complete, the dialog box closes.



If any parts have exceeded their replacement period, the following message is displayed: "Some parts require replacement. Please check the parts list." Contact the manufacturer.



(3) Select whether to execute "Cell wash," "Water replace," or "Preserve proc."

Details of processing

Item	Selection	Details
Cell wash	ON	Wash measurement cells when complete.
	OFF	Do not wash measurement cells when complete.
Water replace	ON	Replace wash solution piping inside the System with purified water.
	OFF	Do not replace wash solution piping inside the System with purified water.
Preserve proc.	ON	Soak the nozzle and cells in purified water.
	OFF	Do not soak the nozzle and cells in purified water.

Shutdown process eiken
2026/02/12 11:56

Select a process and press the [Execute] button.

Cell wash ☒ ON Water replace ☒ ON Preserve proc. ☒ ON

Select day	Auto start	Details
☐ Sun	0 H 0 M	Cell blank meas. ☐ OFF
☐ Mon	15 H 0 M	Cell blank meas. ☐ OFF
☒ Tue	13 H 45 M	Cell blank meas. ☒ OFF
☐ Wed	0 H 0 M	Cell blank meas. ☐ OFF
☐ Thu	0 H 0 M	Cell blank meas. ☐ OFF
☐ Fri	9 H 35 M	Cell blank meas. ☐ OFF
☐ Sat	0 H 0 M	Cell blank meas. ☐ OFF

A **B** **C**

LongShutdown ☐ OFF

(4) To enable auto-start, configure the following settings:

- (A) Select the day(s) of the week for auto-start.
- (B) Enter the auto-start time.
- (C) Select whether to perform cell blank measurement at startup.

Shutdown process eiken
2026/02/12 11:56

Select a process and press the [Execute] button.

Cell wash ☒ ON Water replace ☒ ON Preserve proc. ☒ ON

Select day	Auto start	Details
☐ Sun	0 H 0 M	Cell blank meas. ☐ OFF
☐ Mon	15 H 0 M	Cell blank meas. ☐ OFF
☒ Tue	13 H 45 M	Cell blank meas. ☐ OFF
☐ Wed	0 H 0 M	Cell blank meas. ☐ OFF
☐ Thu	0 H 0 M	Cell blank meas. ☐ OFF
☐ Fri	9 H 35 M	Cell blank meas. ☐ OFF
☐ Sat	0 H 0 M	Cell blank meas. ☐ OFF

LongShutdown ☐ OFF

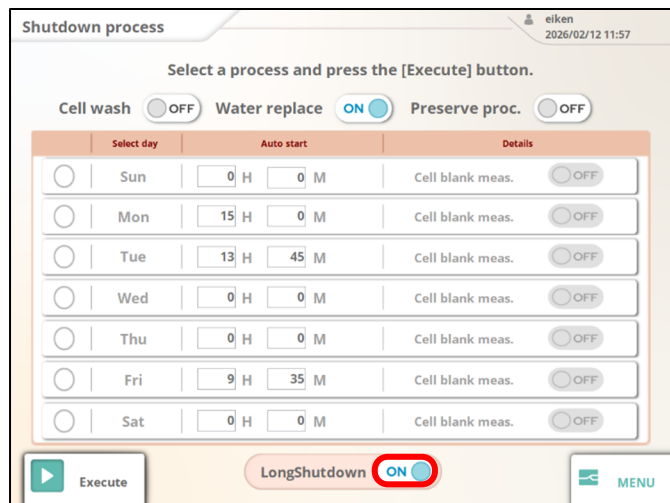
(5) Touch {Execute} to start the shutdown process.

- * When the selected processes are completed, the System automatically shuts down.

■ Long shutdown

If the System will not be used for a long period, execute the shutdown process with “LongShutdown” set to ON.

 When shutting down using LongShutdown, auto-start cannot be configured.



Shutdown process

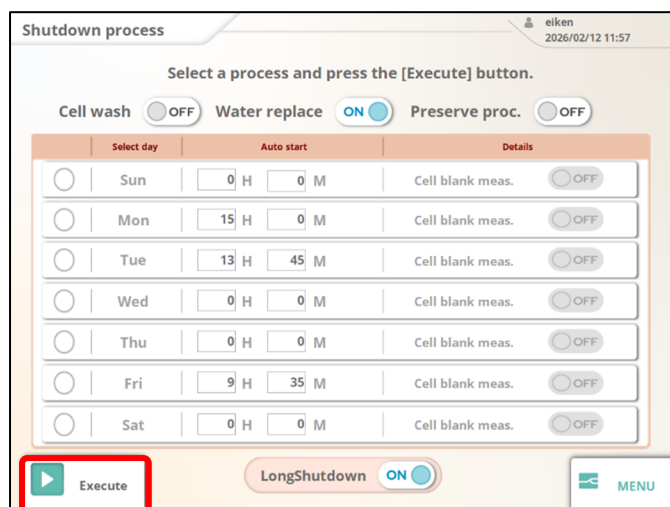
Select a process and press the [Execute] button.

Cell wash ☐ OFF Water replace ☒ ON Preserve proc. ☐ OFF

Select day	Auto start	Details
☐ Sun	0 H 0 M	Cell blank meas. ☐ OFF
☐ Mon	15 H 0 M	Cell blank meas. ☐ OFF
☐ Tue	13 H 45 M	Cell blank meas. ☐ OFF
☐ Wed	0 H 0 M	Cell blank meas. ☐ OFF
☐ Thu	0 H 0 M	Cell blank meas. ☐ OFF
☐ Fri	9 H 35 M	Cell blank meas. ☐ OFF
☐ Sat	0 H 0 M	Cell blank meas. ☐ OFF

LongShutdown ☒ ON

- (1) From the [Shutdown process] screen, set {LongShutdown} to ON.



Shutdown process

Select a process and press the [Execute] button.

Cell wash ☐ OFF Water replace ☒ ON Preserve proc. ☐ OFF

Select day	Auto start	Details
☐ Sun	0 H 0 M	Cell blank meas. ☐ OFF
☐ Mon	15 H 0 M	Cell blank meas. ☐ OFF
☐ Tue	13 H 45 M	Cell blank meas. ☐ OFF
☐ Wed	0 H 0 M	Cell blank meas. ☐ OFF
☐ Thu	0 H 0 M	Cell blank meas. ☐ OFF
☐ Fri	9 H 35 M	Cell blank meas. ☐ OFF
☐ Sat	0 H 0 M	Cell blank meas. ☐ OFF

LongShutdown ☒ ON

- (2) Touch the {Execute} button to start long shutdown.

* When long shutdown is completed, the System automatically shuts down.

2.12. Drain Tank Disposal

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



Warning



Biohazard

- The System periodically performs condensate drainage operations. There is a risk of overflow, so when you remove the full tank sensor and hose, place them in a separate container.
- Wear protective equipment (gloves and protective eyewear) when handling the drain tank.

Failure to observe this precaution may lead to infection.

3. Operation (Applied)

3.1. Measured Data Processing

From the [Data processing] screen, confirm, edit, and delete measurement data.



- Measurement data is saved for each analysis item.
- Up to 1,000,000 measurement records (including STD samples and QC samples) can be stored.



- When the logged-in account is set to “User ,” the available buttons are restricted.
* If the account is “Admin,” there are no button restrictions.

Button restrictions for measurement data processing (when the account is “User”)

Screen	Button functions								
	Delete	Output	Edit sample ID	Recalculate	Search	Cutoff calculation	Histogram	Calibration curve	Time course
Measurement data (Regular samples)	×	○	×	×	○	/	○	/	/
Measurement data (Positive samples)	×	○	/	×	○	×	/	/	/
Measurement data (QC samples)	×	○	/	/	○	/	/	/	/
Replicate	×		/	×	/	/	/	△	○

○ : Available

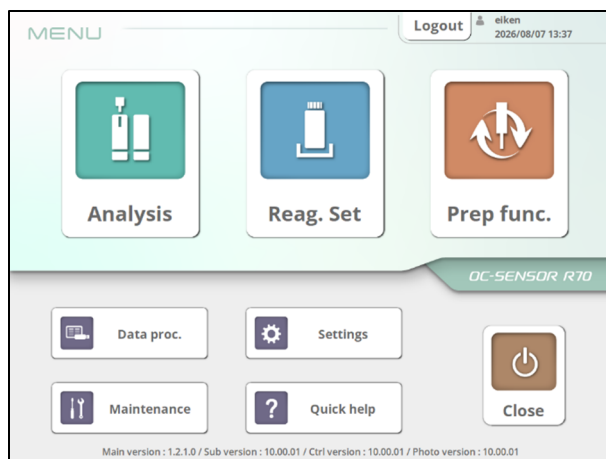
× : Not available

△ : View only (editing, etc. is not permitted)

3.1.1. Opening the [Process data] screen

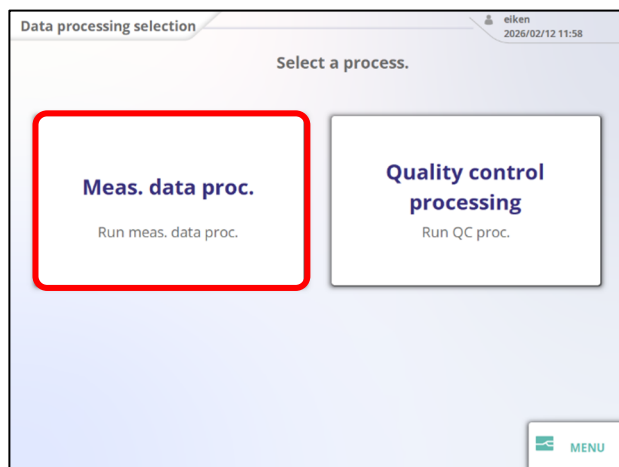
The [Process data] screen can be opened through the following two paths.

- Open from the [MENU] screen
- Open from the [Analysis top]/[Analysis status] screen



- Open from the [MENU] screen

(1) From the [MENU] screen, touch {Data proc.}.



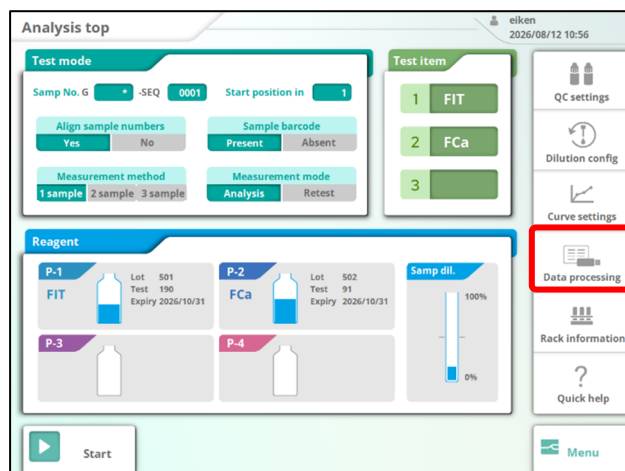
(2) Touch the {Meas. data proc.} button.
*The measurement data processing screen is displayed.

[Data processing selection] screen

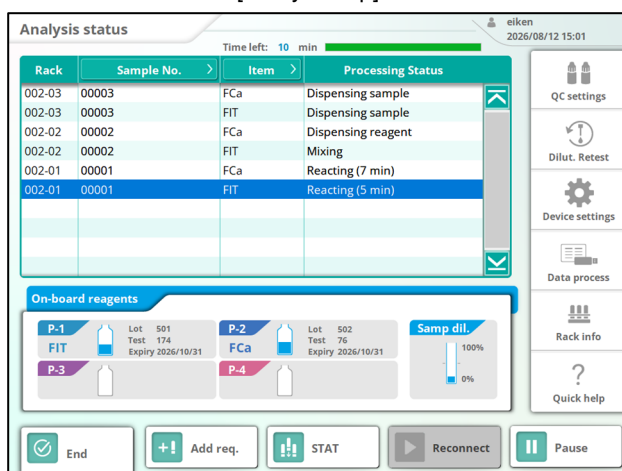
- Open from the [Analysis top]/[Analysis status] screen

From the [Analysis top]/[Analysis status] screen, touch {Data processing}.

*The measurement data processing screen is displayed.



[Analysis top] screen



[Analysis Progress Screen]

3.1.2. Display measurement data

Display the measurement data by specifying the following items on the [Data processing] screen.

<Specified items>

- Analysis samples (regular samples, positive samples, STAT samples, QC samples)
- Analysis items (FIT, FC)
- Measurement date range

(1) Select the analysis samples to be displayed.

- Regular samples (default)
- Positive samples
- STAT samples
- QC

Analysis sample	Information displayed
RegSamp	All measured samples are displayed.
PosSamp	Only positive samples are displayed.
STATSamp	Only samples measured by STAT analysis are displayed.
QC	Only QC samples are displayed.

(2) The measurement data of the selected analysis samples is displayed.

Date range specification

Specify the range. **B**

A 2026/02/02 ~ 2026/02/12 **C**

< 2026 Yr > < 2 Mo > ☒ Reg.

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

(3) Select the date range of the measurement data to be displayed.

(A) Select the range start date, and touch the date on the calendar.

(B) Select the range end date, and touch the date on the calendar.

(C) Touch {Register}.

Process data

[Select/Range selection] button: Clear selection

RegSamp FIT Date range 2026/02/02 ~ 2026/02/12 Select Srch

Date/Time	Rack	SEQ	SampleID	Value[ng/mL]	Flag	Comment	Lot.	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0 [-]			501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0 [-]			501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0 [-]			501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0 [-]			501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0 [-]			501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0 [-]			501	

Measurement data Replicate

Number of samples= 34

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

(4) The measurement data for the specified date range is displayed.

■ Content displayed on the [Measurement data] screen (Samples)

Display	Details	
Date/Time	The date and time sample was measured	
Rack	Rack No. – Position number in the rack	
SEQ	Sample sequence No.	
SampID	Barcode information affixed to the sample bottle	
Value (Unit)	Result (concentration value) *The unit of the measured value varies depending on the analysis item. FIT : ng/mL FCa : µg/g	
Flag	-, +, 1+, 2+, 3+	
Comment	Error information	
	UR	Below the lower measurement limit
	OR	Above the upper measurement limit
	PRC	Prozone detected by the PRC method
	RBC	Prozone detected by the RBC method
Lot.	Reagent lot used for measurement	
Dil	Sample dilution information	
	Space	No dilution (analysis, remeasurement)
	A	No dilution (retest)
	A10	10-times dilution (retest)
	A20	20-times dilution (retest)
	A100	100-times dilution (retest)
	A200	200-times dilution (retest)
	A400	400-times dilution (retest)

■ Content displayed on the [Measurement data] screen (QC)

Display	Information displayed	
Date/Time	The date and time sample was measured	
Rack	Rack No. – Position number in the rack	
QCNo.	QC No.1-6	
QC lot	QC lot	
Value (Unit)	Result (concentration value) *The unit of the measured value varies depending on the analysis item. FIT : ng/mL FCa : µg/g	
Comment	Error information	
	UR	Below the lower measurement limit
	OR	Above the upper measurement limit
	PRC	Prozone detected by the PRC method
	RBC	Prozone detected by the RBC method

3.1.3. Select measurement data (single row/range)

This section describes how to select measurement data by single-row selection or range selection.

◎Single-row selection

- (1) Confirm that the button in the upper right of the screen is set to “Select.”

If it is set to “Range sel.,” touch the button to switch it to “Select.”

The screenshot shows the 'Process data' screen with the 'Selection: Select data.' status. The 'Date range' is set to '2026/02/12'. The 'Select' button is highlighted with a red box. Below the table, the 'Measurement data' section shows a list of samples with columns: Date/Time, Rack, SEQ, SampleID, Value(ng/mL), Flag, Comment, Lot, and Dil. The 'Replicate' button is visible. At the bottom, there are buttons for 'Recal', 'Pos. rate', 'Histogram', 'Cutoff calc.', 'CalCurve', 'Register', 'Delete', 'Output', and 'Back'.

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0	[-]		501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	

- (2) Touch the row of the measurement data you want to select.

The screenshot shows the 'Process data' screen with the 'Selection: [Select/Range selection] button: Clear selection' status. The 'Date range' is set to '2026/02/12'. The first row of the measurement data table is highlighted in blue. The 'Replicate' button is visible. At the bottom, there are buttons for 'Recal', 'Pos. rate', 'Histogram', 'Cutoff calc.', 'CalCurve', 'Register', 'Delete', 'Output', and 'Back'.

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0	[-]		501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	

◎Range selection

- (1) Confirm that the button in the upper right of the screen is set to “Range sel.”

If it is set to “Select,” touch the button to switch it to “Range sel.”

The screenshot shows the 'Process data' screen with the 'Date range' set to '2026/02/12'. The 'Select' button is highlighted with a red box. The table below shows measurement data for various samples.

Date/Time	Rack	SEQ	SampleID	Value[ng/mL]	Flag	Comment	Lot	Dil
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	
26/02/03 12:16	010-07	0-00029	EUJCM8	0.0	[-]		501	
26/02/03 12:17	010-08	0-00030	KMAKP8	1.8	[-]		501	

- (2) Touch the first row of the measurement data to be selected.

The screenshot shows the 'Process data' screen with the first row of the measurement data table highlighted in red. The 'Select' button is still visible in the upper right.

Date/Time	Rack	SEQ	SampleID	Value[ng/mL]	Flag	Comment	Lot	Dil
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	
26/02/03 12:16	010-07	0-00029	EUJCM8	0.0	[-]		501	
26/02/03 12:17	010-08	0-00030	KMAKP8	1.8	[-]		501	

- (3) Touch the last row of the measurement data to be selected.

* The measurement data within the touched range are selected.

The screenshot shows the 'Process data' screen with the last row of the measurement data table highlighted in red. The 'Range sel.' button is now visible in the upper right, indicating that the range selection mode is active.

Date/Time	Rack	SEQ	SampleID	Value[ng/mL]	Flag	Comment	Lot	Dil
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0	[-]		501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	
26/02/03 12:16	010-07	0-00029	EUJCM8	0.0	[-]		501	

3.1.4. Search measurement data

Search for measurement data.

Process data

Selection: Select data.

RegSamp: FIT Date range: ~ 2026/02/12 Select **Srch**

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/03 12:13	010-01	0-00023	EUJCOF	0.0	[-]		501	
26/02/03 12:13	010-02	0-00024	EUJCOR	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJCOA	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCN5	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	
26/02/03 12:16	010-07	0-00029	EUJCM8	0.0	[-]		501	

Measurement data Replicate

Number of samples= 34

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

(1) Display measurement data.

■ See Section 3.1.2

(2) Touch {Srch}.

Search

Specify conditions.

☒ Sample ID **EX8DZE**

☐ Sample No. G: 1 -SEQ: 1

☐ Rack No. 1 - 1

A

B

Search Cancel

(3) Enter the search conditions.

- (A) Touch the input field next to the setting item, and enter the numerical values for the specified condition.
- * The numeric keypad screen is displayed.

<Conditions to specify (multiple selections allowed)>

- Sample No.
- Sample ID
- Rack No.

(B) Touch {Srch}.

Process data

Selection: Select data.

RegSamp: FIT Date range: ~ 2026/02/12 Select **Srch**

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/03 12:13	010-01	0-00023	EUJCOF	0.0	[-]		501	

Measurement data Replicate

Number of samples= 1

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

(4) Measurement data that match the specified conditions are displayed.

3.1.5. Sort measurement data

Display measurement data sorted by the most recent measurement date.

Process data eiken
2026/02/12 12:12

Selection: Select data.

RegSamp FIT Date range ~ 2026/02/12 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0	[-]		501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	
26/02/03 12:16	010-07	0-00029	EUJCMB	0.0	[-]		501	

Measurement data Replicate

Number of samples= 34

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

(1) Display measurement data.

See Section 3.1.2

Process data eiken
2026/02/12 12:13

Selection: Select data.

RegSamp FIT Date range ~ 2026/02/12 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0	[-]		501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	

Measurement data Replicate

Number of samples= 34

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

(2) Touch the "↑↓" next to "Date/Time."

(3) The displayed measurement data are sorted in descending order (newest first).

* Touch the "↑↓" again to sort the data in ascending order (oldest first).

3.1.6. Sort measurement data by sequence No.

Display measurement sorted by sequence No. in ascending order.

Process data eiken
2026/02/12 12:24

Selection: Select data.

RegSamp FIT Date range ~ 2026/02/12 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/06 13:12	001-08	0-00018	ETZ59B	1.4 [-]			501	
26/02/06 13:10	001-07	0-00017	EW267W	0.0 [-]			501	
26/02/06 13:08	001-06	0-00016	EW2DC5	0.2 [-]			501	
26/02/06 13:06	001-05	0-00015	KNCM1Y	0.2 [-]			501	
26/02/06 13:04	001-04	0-00014	KNC639	0.2 [-]			501	
26/02/06 13:02	001-03	0-00013	ETZ5DA	1.2 [-]			501	
26/02/06 13:01	001-02	0-00012	KNC60U	0.0 [-]			501	

Measurement data Replicate

Number of samples= 34

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

(1) Display measurement data.

See Section 3.1.2

Process data eiken
2026/02/12 12:24

Selection: Select data.

RegSamp FIT Date range ~ 2026/02/12 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/06 13:12	001-08	0-00018	ETZ59B	1.4 [-]			501	
26/02/06 13:10	001-07	0-00017	EW267W	0.0 [-]			501	
26/02/06 13:08	001-06	0-00016	EW2DC5	0.2 [-]			501	
26/02/06 13:06	001-05	0-00015	KNCM1Y	0.2 [-]			501	
26/02/06 13:04	001-04	0-00014	KNC639	0.2 [-]			501	
26/02/06 13:02	001-03	0-00013	ETZ5DA	1.2 [-]			501	
26/02/06 13:01	001-02	0-00012	KNC60U	0.0 [-]			501	

Measurement data Replicate

Number of samples= 34

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

(2) Touch the "↑↓" next to "SEQ".

(3) The displayed measurement data are sorted in ascending order of sequence No.

* Touch the "↑↓" again to sort the data in descending order.

3.1.7. Edit sample ID

Edit the sample ID of the data selected on the [Process data] screen.

Process data

Selection: Select data.

RegSamp - FOBT - Date range ~ 2026/02/13 Select Search

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
25/10/06 15:48	297-01	0-00001		156.0	[+]		402	
25/10/06 15:48	297-02	0-00002		152.4	[+]		402	
25/10/06 15:48	297-03	0-00003		465.6	[+]		402	
25/10/06 16:11	297-01	0-00001		1772.7	[+]		402	A10
25/10/06 16:11	297-02	0-00002		1844.8	[+]		402	A20
25/10/06 16:11	297-03	0-00003		35309.8	[+]		402	A100
25/10/06 16:11	297-04	0-00004		35492.5	[+]		402	A200

Measurement data Replicate

Number of samples= 594

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

- (1) Display measurement data.

➡ See Section 3.1.2

- (2) Select one row of the measurement data to be edited, and touch "Sample ID."
Touch "Sample ID".

* The keyboard screen opens.

SampID

Current value []

1	2	3	4	5	6	7	8	9	0	-	^	\	Del
q	w	e	r	t	y	u	i	o	p	@	[		Back Space
a	s	d	f	g	h	j	k	l	;	:	]		Enter
z	x	c	v	b	n	m	,	.	/	_		Clear	
a/A													

- (3) Edit the sample ID.

(A) Enter the sample ID using the keyboard.

(B) Touch [Enter].

3.1.8. Recalculate measurement data

Recalculated measurement data by changing the cutoff values and FACTOR A and B.

- The values used for judgment of the displayed measurement data are shown as Cutoff 1, Cutoff 2, and Cutoff 3.
- If you select multiple analysis results that were analyzed using different cut-off values, it is unclear which cut-off value to apply. Consequently, 0' will be displayed for Cut-off 1, Cut-off 2 and Cut-off 3.
- The values set during recalculation are not reflected in the protocol settings.
- Recalculation is not performed by fitting to the calibration curve.

Process data

[Select/Range selection] button: Clear selection

RegSamp FIT Date range ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/ml)	Flag	Comment	Lot.	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJCOF	0.0 [-]			501	
26/02/03 12:13	010-02	0-00024	EUJCOR	0.0 [-]			501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0 [-]			501	
26/02/03 12:13	010-04	0-00026	EUJCOA	0.0 [-]			501	
26/02/03 12:15	010-05	0-00027	EUJCN5	0.0 [-]			501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0 [-]			501	

Measurement data Replicate

Number of samples= 61

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

- (1) Display measurement data.
 ■ See Section 3.1.2
- (2) Select or range-select the measurement data to be recalculated, and touch {Recal}.

Recalculate

A Specify conditions.

Cutoff 1 100 FACTOR A 1.000

Cutoff 2 200 FACTOR B 0.00

Cutoff 3 300

B Recal Cancel

- (3) Enter the conditions for recalculation.
 (A) Touch the input field next to the item and enter the value.
 * The numeric keypad screen is displayed.

<Conditions to specify>

- Cutoff 1
- Cutoff 2
- Cutoff 3
- FACTOR A
- FACTOR B

Process data eiken
2026/02/13 11:29

[Select/Range selection] button: [Clear selection](#)

RegSamp: FIT Date range: ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value[ng/mL]	Flag	Comment	Lot.	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0 [-]			501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0 [-]			501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0 [-]			501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0 [-]			501	
26/02/03 12:15	010-05	0-00027	EUJCN5	0.0 [-]			501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0 [-]			501	

Measurement data Replicate

Number of samples= 61

Recal
Pos. rate
Histogram
Cutoff calc.
CalCurve

Register
Delete
Output
Back

- (4) The recalculated measurement data are displayed.
- (5) To update the measurement data with the recalculated results, touch {Register}.

3.1.9. Display positive rate variation

Display the positive rate variation of measurement data.

There are two display modes for the positive rate trend: by sample and by subject. The calculation formulas are as follows:

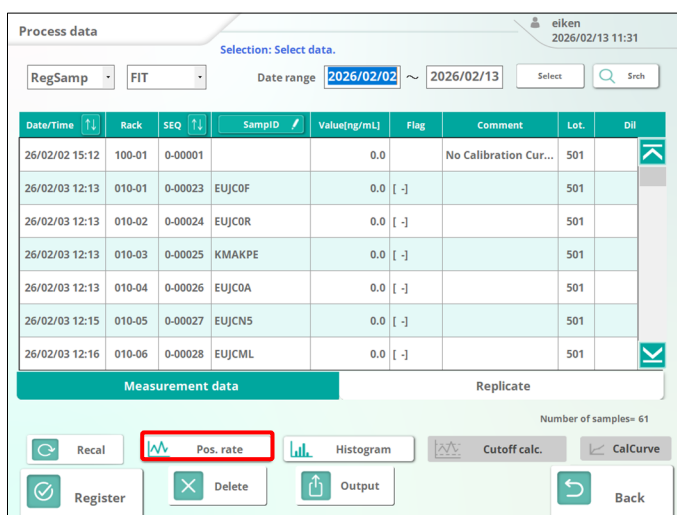
By sample mode : Positive rate (%) = Number of positive samples ÷ Total number of samples × 100
(Total number of samples = Number of samples in the range specified on the [Measurement data] screen)

By subject mode : Positive rate (%) = Number of positive subjects ÷ Total number of subjects × 100
(Total number of subjects = the number of subjects within the range specified on the [Measurement data] screen)

The positive rate variation can be displayed only when the sample type is set to “RegSamp.” It cannot be displayed when set to PosSamp, STATSamp, or QC.

This system can store up to 10 years of positive rate variation data.

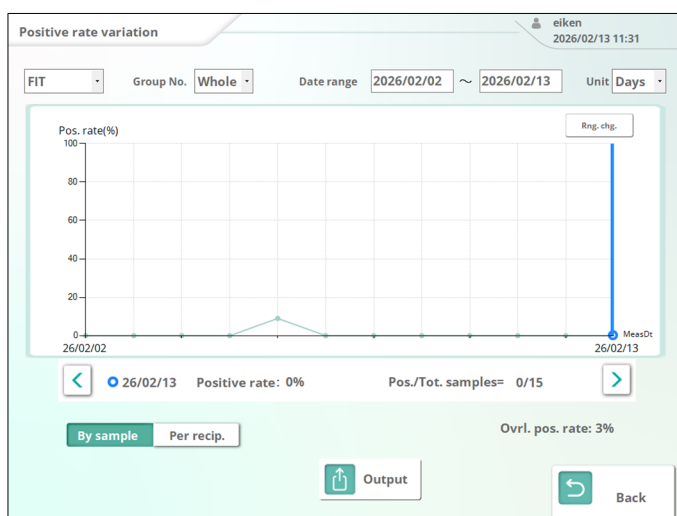
The maximum number of data points that can be displayed at one time is 5,000.



(1) Display measurement data.

See Section 3.1.2

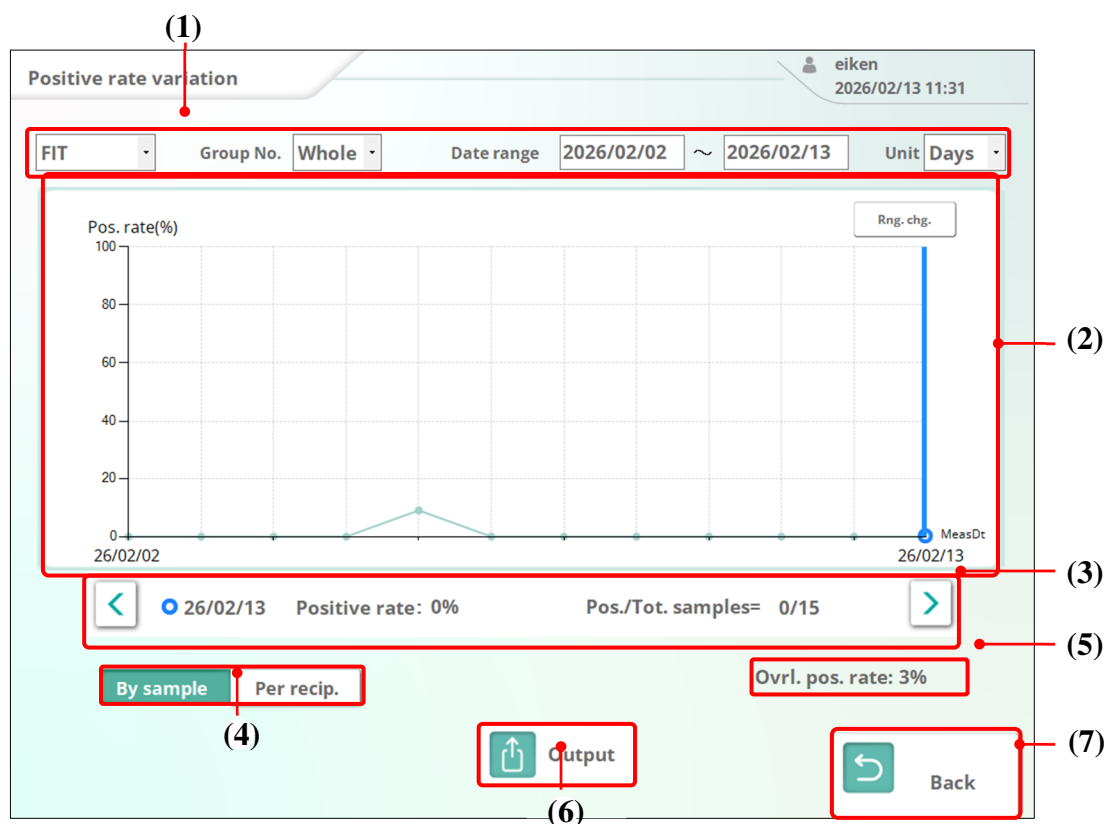
(2) Touch {Pos. rate}.



(3) The positive rate variation graph is displayed.

* By default, data for one year are displayed.

<Understanding the positive rate variation graph>

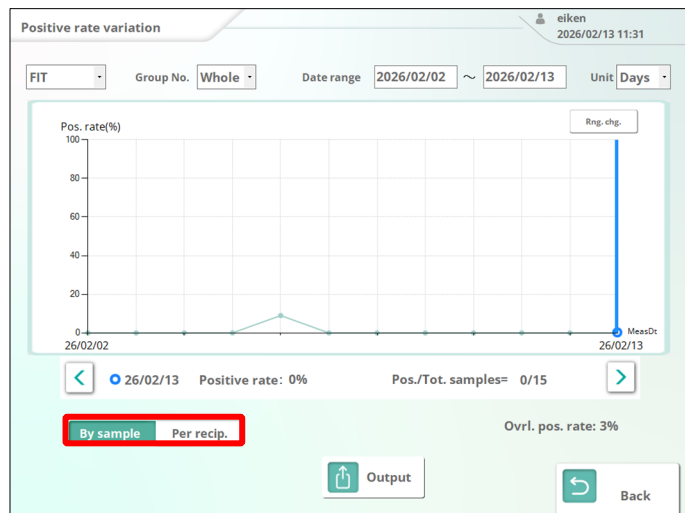


Name	Details
(1) Positive rate calculation conditions	Sets the conditions for positive rate calculation. ■See Section 3.1.9.1
(2) Positive rate graph	Displays a graph with the measurement date on the horizontal axis and the positive rate on the vertical axis.
(3) Cursor value information	Displays numerical information for the date indicated by the cursor. The cursor can be moved with button. The displayed information differs depending on the display mode. (See below) <By sample mode> • Measurement date • Positive rate • Number of positive <By subject mode> • Measurement date • Positive rate • Number of positive subjects /
(4) Display mode switching	Switches between by sample mode and by subject mode.
(5) Overall positive rate	Displays the positive rate of all displayed data
(6) Output	Outputs positive rate variation information. ■See Section 3.1.9.3
(7) Back	Returns to process data screen.

3.1.9.1. Configure positive rate calculation conditions

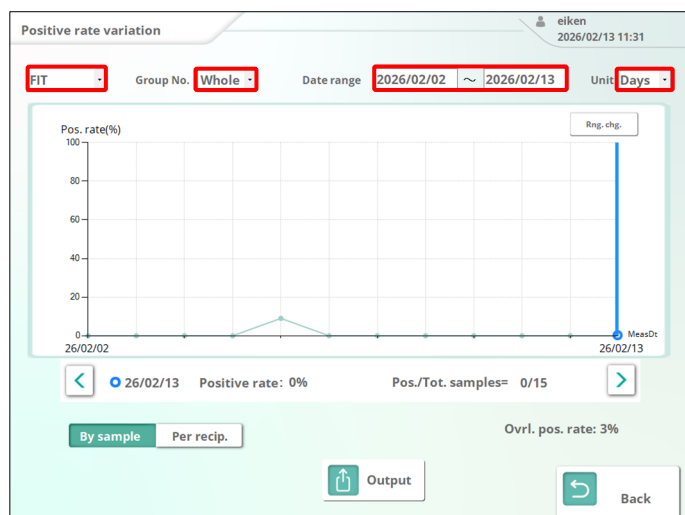
Configure each item to calculate the positive rate.

The maximum number of data points between the start date and end date is 5,000.



(1) Display the [Positive rate variation] screen.

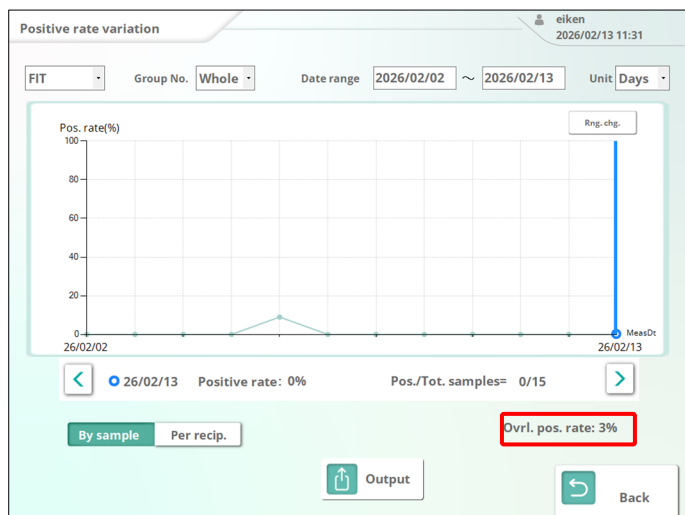
(2) Select the positive rate display mode.



(3) Select the calculation conditions.

<Selectable items>

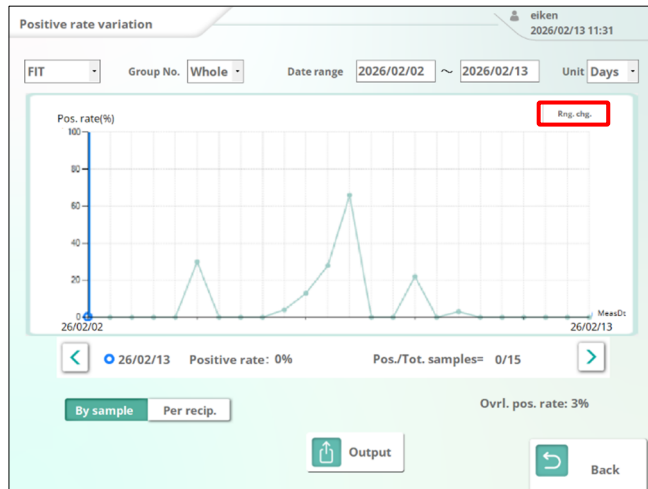
- Analysis items (FIT, FCa)
- Group No.
- Measurement date range
- Calculation unit for positive rate (day, week, month)



(4) The positive rate based on the selected calculation conditions is displayed.

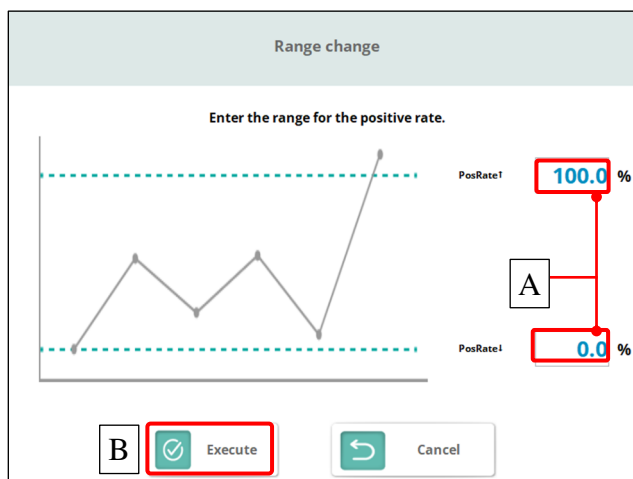
3.1.9.2. Change the range of positive rate variation

Set the “PosRate ↑” and “PosRate ↓” to change the vertical axis range of the positive rate trend graph.



(1) Display the [Positive rate variation] screen.

(2) Touch the {Rng. chg.} button.

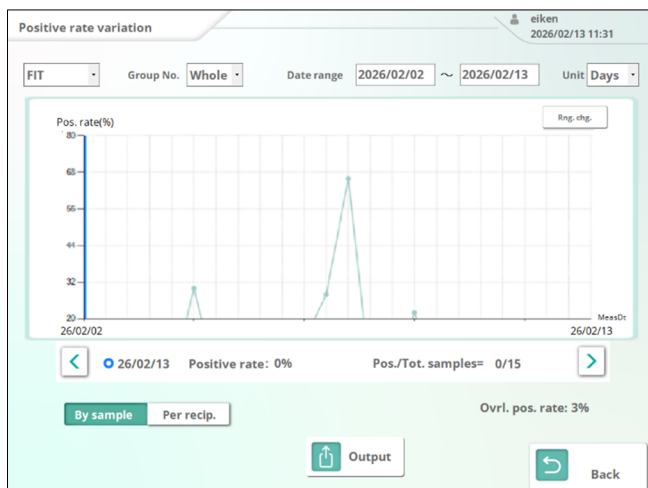


(3) Change the vertical axis range.

<Procedure>

(A) Touch the input fields for [PosRate ↑] and “PosRate ↓] and enter the values using the numeric keypad.

(B) Touch {Execute} button.

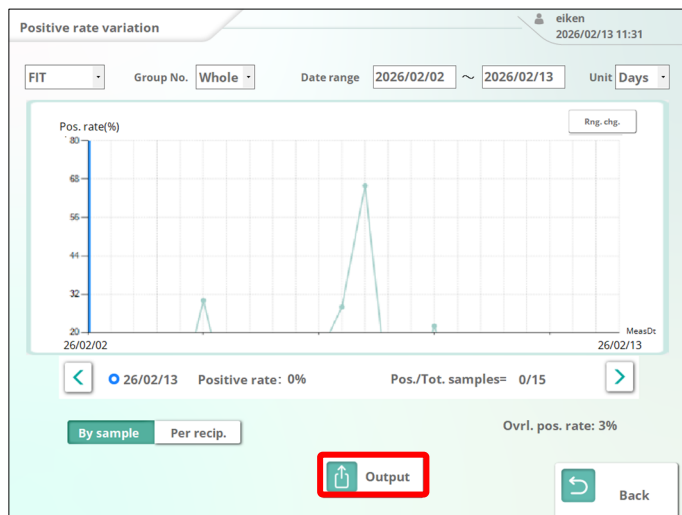


(4) The positive rate variation graph with the updated vertical axis range is displayed.

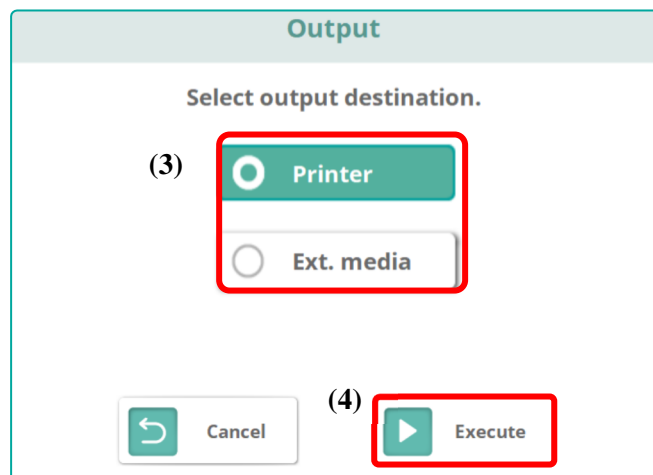
3.1.9.3. Output the positive rate variation

Output the positive rate variation to the selected output destination. There are the following two output methods:

- Print using the printer.
- Save to external media.



- (1) Display the [Positive rate variation] screen.
- (2) Touch {Output}.



- (3) Select the output destination.
 - Printer
 - Ext. media
- (4) Touch the {Execute} button.

3.1.10. Calculate cutoff values from the positive rate

Using the displayed measurement data of positive samples and the entered positive rate, calculate Cutoff 1 by reverse calculation.

The reverse-calculated Cutoff 1 value is reflected in Cutoff 1 when {Recal} is touched.

The method for calculating the cutoff value differs between by sample mode and by subject mode.

- Reverse calculation of cutoff values can be performed only when the displayed sample type is set to "PosSamp".
It cannot be performed when set to "RegSamp," "STATSamp," or "QC."

Process data

Selection: Select data.

PosSamp FIT Date range 2026/02/02 ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/06 13:28	100-01	0-00021		145.7	[+]		501	
26/02/06 13:29	100-02	0-00022		430.5	[+]		501	

Measurement data Replicate

By sample Per recip. Pos./Tot. samples= 2/61 Pos. rate= 3.3% Number of samples= 2

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

- (1) Select the display mode for positive samples.

➤ See Section 3.1.2

- (2) Select or range-select the measurement data for which the cutoff value is to be reverse-calculated.

➤ See Section 3.1.3

Process data

Selection: Select data.

PosSamp FIT Date range 2026/02/02 ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/06 13:28	100-01	0-00021		145.7	[+]		501	
26/02/06 13:29	100-02	0-00022		430.5	[+]		501	

Measurement data Replicate

By sample Per recip. Pos./Tot. samples= 2/61 Pos. rate= 3.3% Number of samples= 2

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

- (3) Touch {Cutoff calc.}.

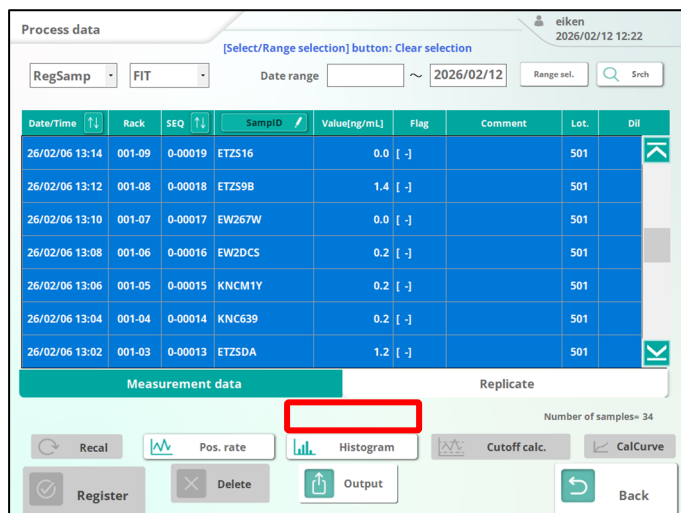
- (4) Enter the positive rate to reverse-calculate cutoff 1.

<Procedure>

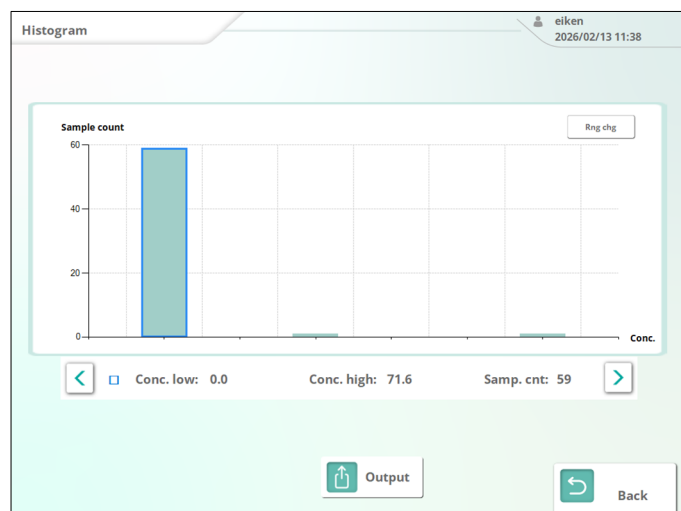
- (A) Touch the input field for the positive rate, and enter the value.
- (B) The calculated cutoff value is displayed in the {Cutoff} field.
- (C) Touch {Memory}.
- * The value is reflected as cutoff 1 for recalculation.

3.1.11. Displaying the histogram

Display a histogram of measurement data.



- (1) Select or range-select the samples for which the histogram is to be displayed, and touch {Histogram}.



- (2) A histogram of the selected range is displayed.

- Move the [☐] displayed on the histogram using the [< >] buttons to check information for each interval. The information for the selected interval is displayed at the bottom of the graph. (Refer to the following diagram.)



- Information displayed

☐	Conc. low: 0.0	Conc. high: 71.6	Samp. cnt: 59
--------------------------	----------------	------------------	---------------

(A)

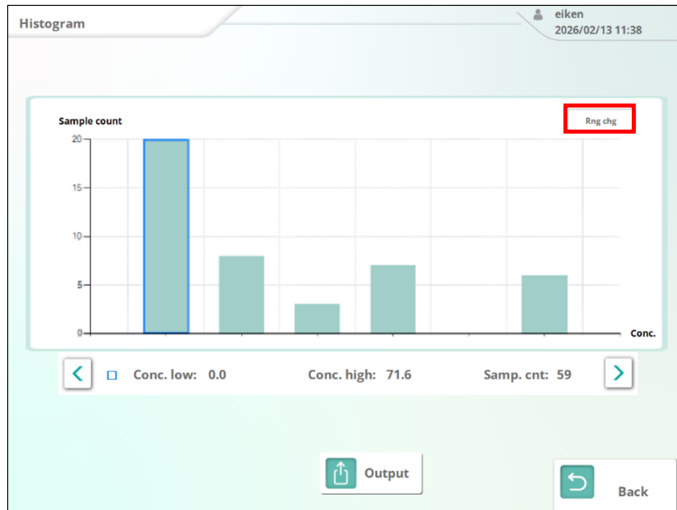
(B)

(C)

- (A) Conc. low: Lower concentration limit of the selected interval
- (B) Conc. high: Upper concentration limit of the selected interval

3.1.11.1. Change the histogram range

Change the histogram range by entering “Samp. Max,” “MinConc,” “MaxConc,” and “ClsCnt.”



■ Range change procedure

- (1) Display the [Histogram] screen.
- (2) Touch the {Rng chg.} button.

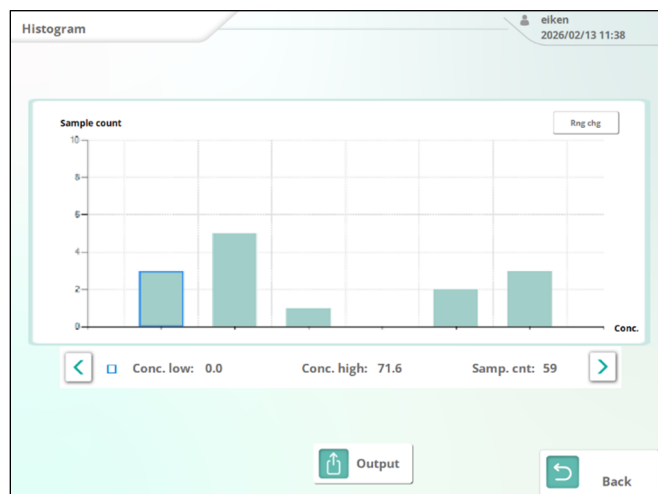
The screenshot shows the 'Range change' screen with the title 'Enter each range val.'. It contains four input fields: 'Samp. Max' with the value '10', 'MinConc' with the value '100.0', 'MaxConc' with the value '300.0', and 'ClsCnt' with the value '6'. The 'ClsW' value is '33.3'. There are 'Execute' and 'Cancel' buttons at the bottom. A red box highlights the 'Execute' button.

- (3) Change each range.

<Procedure>

- (A) Touch the input fields for “Samp. Max,” “MinConc,” “MaxConc,” and “ClsCnt,” and enter values using the numeric keypad.

- (B) Touch the {Execute} button.



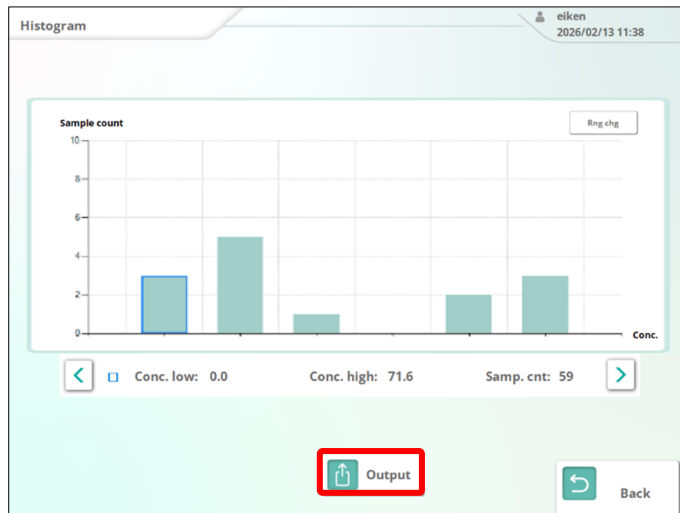
- (4) The histogram with the updated range displayed.

Setting item	Setting range	Description
Samp. Max	0-9999	Upper limit of the number of samples displayed in the histogram
MinConc	0-999999999.9	Minimum concentration displayed in the histogram
MaxConc	0-999999999.9	Maximum concentration displayed in the histogram
ClsCnt	1-99	Number of divisions used in the histogram

3.1.11.2. Output the histogram

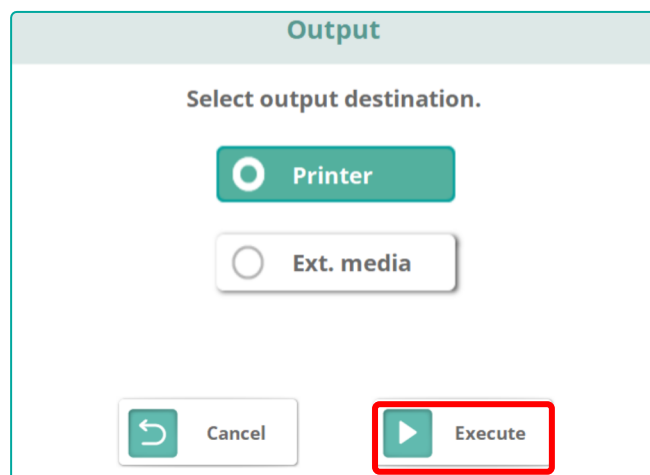
Output the histogram to the selected output destination. There are the following two output methods:

- Print using the printer.
- Save to external media.



(A) Display the [Histogram] screen.

(B) Touch {Output}.



(C) Select the output destination.

- Printer
- Ext. media

(D) Touch the {Execute} button.

3.1.12. Delete measurement data

Delete measurement data.



Measurement data can be deleted only when the logged-in account permission is set to “Admin.”
It cannot be performed when the account permission is set to “User.”

Process data eiken 2026/02/13 11:40

[Select/Range selection] button: Clear selection

RegSamp - FIT - Date range ~ 2026/02/13 Select Search

Date/Time	Rack	SEQ	SampleID	Value[ng/mL]	Flag	Comment	Lot	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0 [-]			501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0 [-]			501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0 [-]			501	
26/02/03 12:13	010-04	0-00026	EUJCOA	0.0 [-]			501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0 [-]			501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0 [-]			501	

Measurement data Replicate

Number of samples= 61

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register **Delete** Output Back

(1) Select or range-select the measurement data to be deleted.

➡ See Section 3.1.3

(2) Touch {Delete}.

Process data eiken 2026/02/13 11:40

[Select/Range selection] button: Clear selection

RegSamp - FIT - Date range ~ 2026/02/13 Select Search

Date/Time	Rack	SEQ	SampleID	Value[ng/mL]	Flag	Comment	Lot	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0 [-]			501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0 [-]			501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0 [-]			501	
26/02/03 12:13	010-04	0-00026	EUJCOA	0.0 [-]			501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0 [-]			501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0 [-]			501	

Measurement data Replicate

Number of samples= 61

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

(3) To apply the deletion to the measurement data, touch {Register}.

3.1.13. Output measurement data

Output measurement data to the selected destination. There are the following three output methods:

- Print using the printer.
- Save to external media.
- Output online to the host computer.

The 'Process data' screen displays a table of measurement data. The table has columns: Date/Time, Rack, SEQ, SampleID, Value(ng/mL), Flag, Comment, Lot, and Dil. The data is filtered by Date range (2026/02/02 ~ 2026/02/13). The 'Output' button is highlighted with a red box.

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJC0F	0.0	[-]		501	
26/02/03 12:13	010-02	0-00024	EUJC0R	0.0	[-]		501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0	[-]		501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0	[-]		501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0	[-]		501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0	[-]		501	

Measurement data

Replicate

Number of samples= 61

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete **Output** Back

(1) Display measurement data.

■ See Section 3.1.2

(2) Select or range-select the measurement data to be output.

■ See Section 3.1.3

(3) Touch {Output}.

The 'Output' dialog box shows the 'Select output destination' screen. It has two radio buttons: 'Printer' (selected) and 'Ext. media'. At the bottom, there are 'Cancel' and 'Execute' buttons. The 'Execute' button is highlighted with a red box.

(4) Select the output destination.

- Printer
- External media
- Online

(5) Touch the {Execute} button.

The 'Output Status' dialog box shows the 'Outputting...' screen. It has a green progress bar and a 'Cancel' button at the bottom.

(6) The measurement data are output.

- * The measurement data are output to the selected destination.
- * When the output is completed, the dialog box closes.

3.2. Replicate

Display the replicate data of the measurement data. On the [Replicate] screen, the time course and calibration curve can be checked.

3.2.1. Display replicate data

Display the replicate data of the specified measurement data.

Process data

[Select/Range selection] button: Clear selection

RegSamp - FIT - Date range ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot	Dil
26/02/02 15:12	100-01	0-00001		0.0		No Calibration Cur...	501	
26/02/03 12:13	010-01	0-00023	EUJCOF	0.0 [-]	(2)		501	
26/02/03 12:13	010-02	0-00024	EUJCOR	0.0 [-]			501	
26/02/03 12:13	010-03	0-00025	KMAKPE	0.0 [-]			501	
26/02/03 12:13	010-04	0-00026	EUJC0A	0.0 [-]			501	
26/02/03 12:15	010-05	0-00027	EUJCNS	0.0 [-]			501	
26/02/03 12:16	010-06	0-00028	EUJCML	0.0 [-]	(3)		501	

Measurement data Replicate

Number of samples= 61

Recal Pos. rate Histogram Cutoff calc. CalCurve

Register Delete Output Back

- (1) Display measurement data.
■ See Section 3.1.2
- (2) Select or range-select the measurement data for which replicate data are to be displayed.
■ See Section 3.1.3
- (3) Touch the {Replicate} tab.

Process data

Selection: Select data.

RegSamp - FIT - Date range ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot	Dil
26/02/03 12:15	010-04	0-00026	EUJC0A	0.0 [-]			501	

Measurement data Replicate

Number of samples= 1

Recal Pos. rate Time course Cutoff calc. CalCurve

Register Delete Output Back

- (4) The replicate data for the selected measurement data are displayed.

[Replicate] screen

3.2.2. Recalculate replicate data

Recalculate replicate data by changing the cutoff values and FACTOR A and B.

- The values used for judgment of the displayed measurement data are shown as Cutoff 1, Cutoff 2, and Cutoff 3.
- If you select multiple analysis results that were analyzed using different cut-off values, it is unclear which cut-off value to apply. Consequently, 0' will be displayed for Cut-off 1, Cut-off 2 and Cut-off 3.
- The values set during recalculation are not reflected in the protocol settings.
- Recalculation is not performed by fitting to the calibration curve.

Process data

Selection: Select data.

RegSamp: FIT Date range: ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/ml)	Flag	Comment	Lot	Dil
26/02/03 12:15	010-04	0-00026	EUJC0A	0.0 [-]			501	

(2)

Measurement data

(3)

Recal Pos. rate Time course Cutoff calc. CalCurve

Register Delete Output Back

Number of samples= 1

(1) Display the replicate data.

■ See Section 3.2.1

(2) Select or range-select the replicate data to be recalculated.

(3) Touch {Recal}.

* If no data are selected, all data within the measurement date range are recalculated.

Recalculate

Specify conditions.

Cutoff 1 0 FACTOR A 1.000

Cutoff 2 0 FACTOR B 0.00

Cutoff 3 0

Recal Cancel

(4) Enter the conditions for recalculation.

(A) Touch the input field next to the item and enter the value.

* The numeric keypad screen is displayed.

<Conditions to specify>

- Cutoff 1
- Cutoff 2
- Cutoff 3
- FACTOR A
- FACTOR B

(B) Touch {Recal}.

Process data

Selection: Select data.

RegSamp - FIT - Date range ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value[ng/mL]	Flag	Comment	Lot.	Dil
26/02/03 12:15	010-04	0-00026	EUJC0A	0.0	[-]		501	

Measurement data Replicate

Number of samples= 1

Recal Pos. rate Time course Cutoff calc. CalCurve

Register Delete Output Back

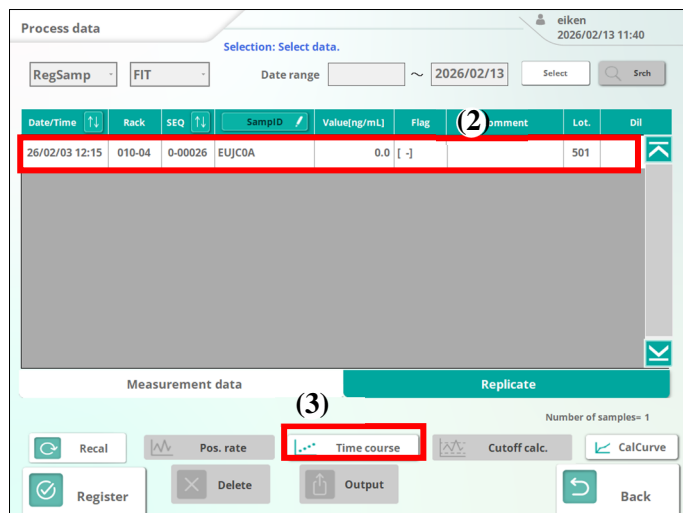
(5)

(5) The recalculated replicate data are displayed.

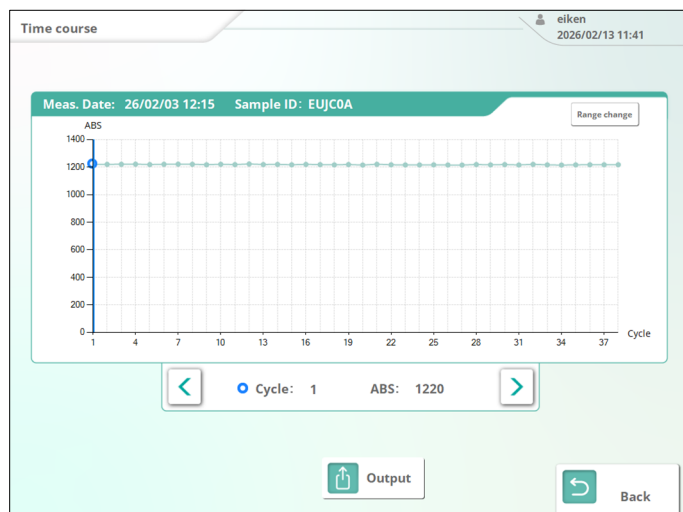
(6) To update the measurement data with the recalculated results, touch {Register}.

3.2.3. Display the time course of replicate data

Display the time course of replicate data.



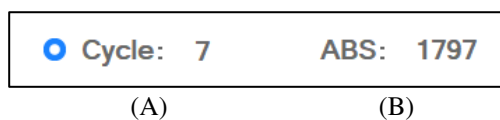
- (1) Display the replicate data.
- (2) Select one row of the replicate data for which the time course is to be displayed.
- (3) Touch {Time course}.



- (4) The time course of the selected replicate data is displayed.

Move the [●] displayed on the time course graph using the [< >] buttons. The cursor value information is displayed at the bottom of the graph. (See below)

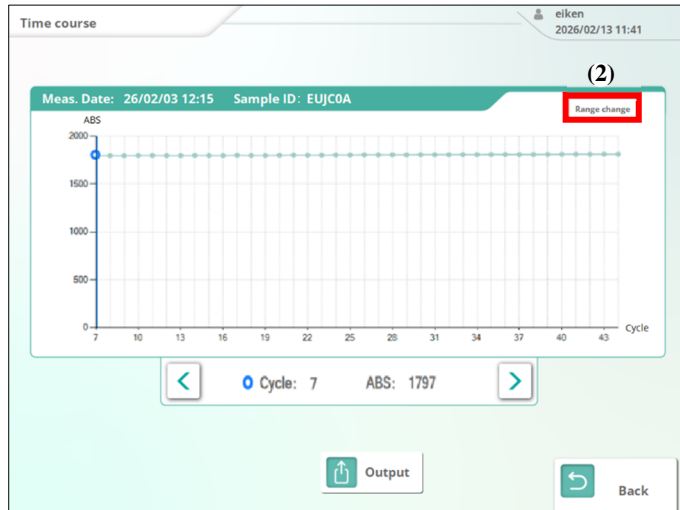
Information displayed



- (A) Cycle: Cycle number
- (B) ABS: Absorbance at the selected cycle

3.2.3.1. Change the range of the time course

Enter the "ABS max" and "ABS min" to change the vertical axis range of the time course.



(1) Display the [Time course] screen.

▀ See Section 3.2.3

(2) Touch the {Rng chg.} button.

Range change

Enter the ABS range.

ABS max value 1900

ABS min value 1600

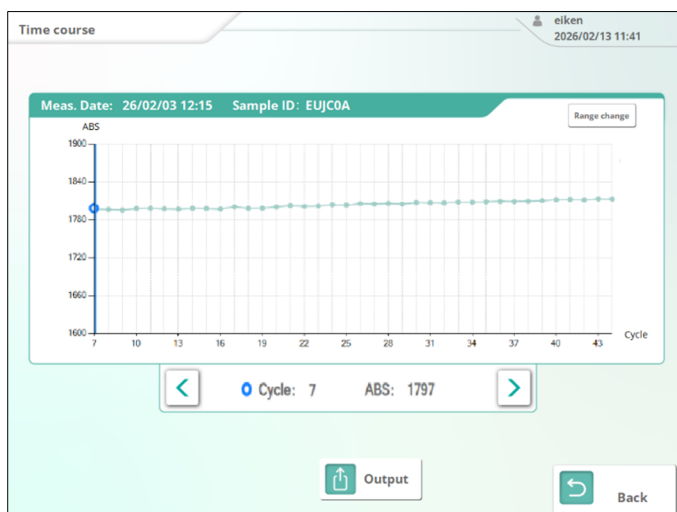
Execute Cancel

(3) Change the vertical axis range.

<Procedure>

(A) Touch the input fields for [ABS max] and [ABS min], and enter values using the numeric keypad.

(B) Touch the {Execute} button.

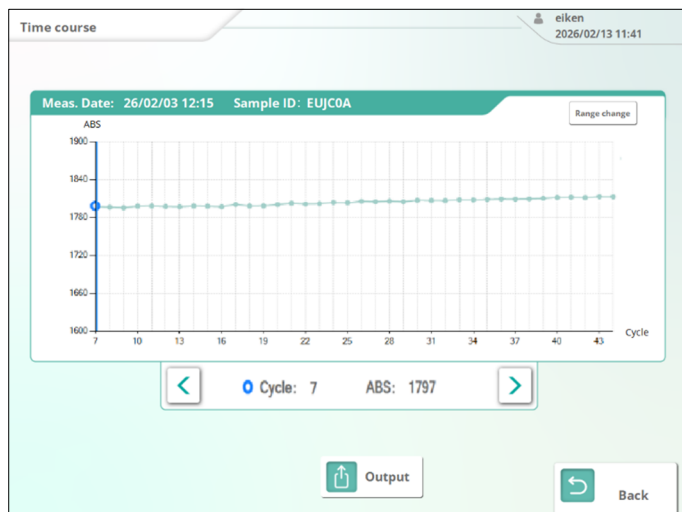


(4) The time course with the updated ranged is displayed.

3.2.3.2. Output the time course

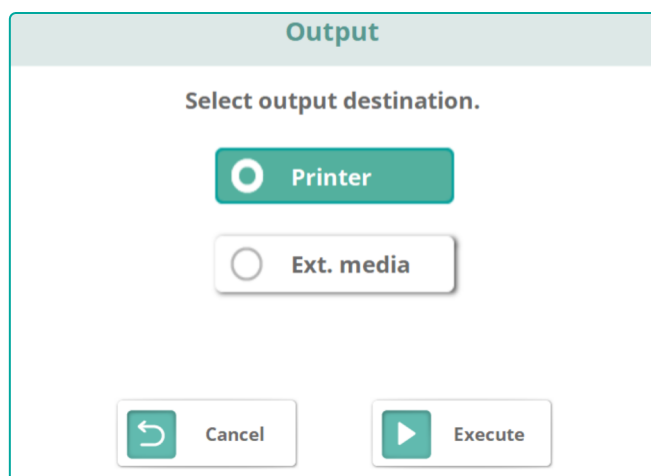
Output the time course to the selected output destination. There are the following two output methods:

- Print using the printer.
- Save to external media.



(1) The [Time course] screen is displayed.

(2) Touch {Output}.



(3) Select the output destination.

- Printer
- External media

(4) Touch the {Execute} button.

3.2.4. Display the calibration curve of replicate data

Display the calibration curve for the replicate data.

Process data

Selection: Select data.

RegSamp: FIT Date range: ~ 2026/02/13 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot.	Dil
26/02/03 12:15	010-04	0-00026	EUIJCOA	0.0 [-]			501	

(2)

Measurement data Replicate

Number of samples: (3)

Recal Pos. rate Time course Cutoff calc. CalCurve

Register Delete Output Back

(1) Display the replicate data.

See Section 3.2.1

(2) Select one row of the replicate data for which the calibration curve is to be displayed.

(3) Touch {CalCurve}.

CC graph

Meas. date/time: 2026/02/02 15:43

Reagent lot/Cal. lot: 501 / 503

	TheoVal	Back-fit	DA value
STD.6	1000.0	1000.0	DA1: 2545 DA2: 72
STD.5	500.0	500.0	1338
STD.4	250.0	250.0	493
STD.3	125.0	125.0	181
STD.2	62.5	62.5	76
STD.1	0.0	0.0	-1

QC Lot Value DA

QC.1		
QC.2		
QC.3		

DA 2545

CONC. 1000

Clear Recal

Store Print Back

(4) The calibration curve of the selected replicate data is displayed.

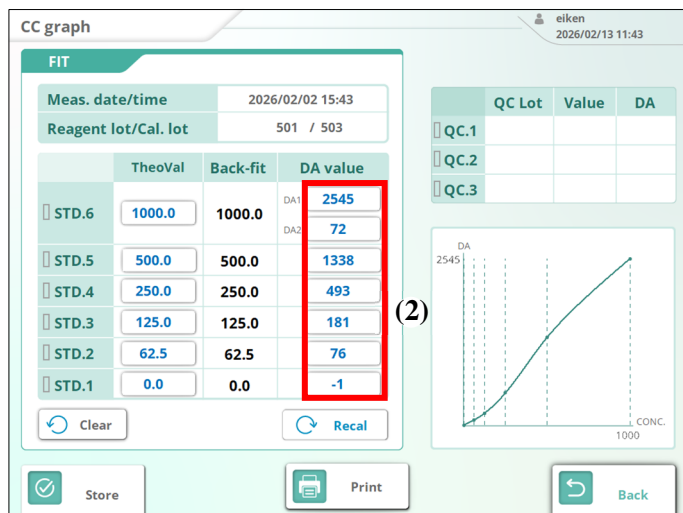
3.2.4.1. Edit the calibration curve of replicate data

Edit the calibration curve of replicate data.



Editing of the calibration curve can only be performed when the logged-in account permission is set to "Admin."

It cannot be performed when the account permission is set to "User."



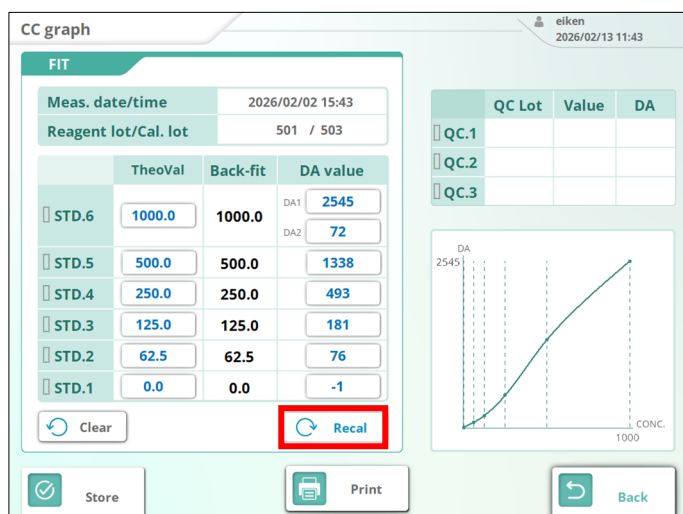
- (1) Display the calibration curve for the replicate data.

See Section 3.2.4

- (2) Edit the DA values.

<Procedure>

- Touch the input field next to STD1 to STD6 to be edited and enter the value.
- * The numeric keypad is displayed.



- (3) Touch {Recal}.

CC graph

Meas. date/time 2026/02/02 15:43
Reagent lot/Cal. lot 501 / 503

	TheoVal	Back-fit	DA value
STD.6	1000.0	1000.0	DA1 2545 DA2 72
STD.5	500.0	500.0	1338
STD.4	250.0	250.0	493
STD.3	125.0	125.0	181
STD.2	62.5	62.5	76
STD.1	0.0	0.0	-1

Clear Recal

Store Print Back

QC Lot Value DA

QC.1
QC.2
QC.3

- (4) The recalculated fitted values, QC data, and calibration curve graph are displayed.

CC graph

Meas. date/time 2026/02/02 15:43
Reagent lot/Cal. lot 501 / 503

	TheoVal	Back-fit	DA value
STD.6	1000.0	1000.0	DA1 2545 DA2 72
STD.5	500.0	500.0	1338
STD.4	250.0	250.0	493
STD.3	125.0	125.0	181
STD.2	62.5	62.5	76
STD.1	0.0	0.0	-1

Clear Recal

Store Print Back

QC Lot Value DA

QC.1
QC.2
QC.3

- (5) To perform recalculation of replicate data using the edited calibration curve, touch {Store}.

CC graph

Storing calibration curve

Meas. date/time 2026/02/02 15:43
Reagent lot/Cal. lot 501 / 503

	TheoVal	Back-fit	DA value
STD.6	1000.0	1000.0	DA1 2545 DA2 72
STD.5	500.0	500.0	1338
STD.4	250.0	249.9	493
STD.3	125.0	125.0	181
STD.2	62.5	62.4	76
STD.1	0.0	0.0	-1

Clear Recal

Store Print Back

QC Lot Value DA

QC.1
QC.2
QC.3

- (6) When the edited calibration curve is registered in the System, "Storing calibration curve" is displayed on the screen.

3.2.4.2. Recalculate replicate data using the edited calibration curve

Recalculate the replicate data using the edited calibration curve.

Process data

[Select/Range selection] button: Clear selection

RegSamp: FIT Date range: ~ 2026/02/17 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot	Dil
26/02/03 12:15	010-04	0-00026	EUJC0A	0.0 [-]			501	

(2)

Measurement data Replicate

Number of samples= 1

Recal Pos. rate Time course Cutoff calc. CalCurve

Register Delete Output Back

- (1) Edit the calibration curve and save it in the System.

➡ See Section 3.2.4.1

- (2) Select or range-select the replicate data to be recalculated using the edited calibration curve.
- (3) Touch {Recal}.

Recalculate

Specify conditions.

Cutoff 1 0 FACTOR A 1.000

Cutoff 2 0 FACTOR B 0.00

Cutoff 3 0

Recal Cancel

- (4) If it is necessary to change the calculation conditions, enter the values and touch {Recal}.

* The numeric keypad is displayed.

Process data

[Select/Range selection] button: Clear selection

RegSamp: FIT Date range: ~ 2026/02/17 Select Srch

Date/Time	Rack	SEQ	SampleID	Value(ng/mL)	Flag	Comment	Lot	Dil
26/02/03 12:15	010-04	0-00026	EUJC0A	0.0 [-]			501	

Measurement data Replicate

Number of samples= 1

Recal Pos. rate Time course Cutoff calc. CalCurve

Register Delete Output Back

- (5) The replicate data recalculated using the edited calibration curve are displayed.
- (6) To update the measurement data with the recalculated results, touch {Register}.

3.3. Quality Control Processing

The between/within-day data and X-R control chart of measured QC samples are displayed in quality control (QC).

QC also allows for editing between/within-day data, and changing the range of the X-R control chart.



- QC data are stored by analysis item.
- The maximum number of daily sales records that can be displayed is 5,000.
- The maximum number of records displayed for intraday data is 10.



- When the logged-in account is set to User," the available buttons are restricted.
(Refer to the following table)

Screen	Button functions				
	Registration	Delete	Output	Edit	X-R control chart
Between-day data	x	x	○		○
Within-day data	x	x	○	x	○

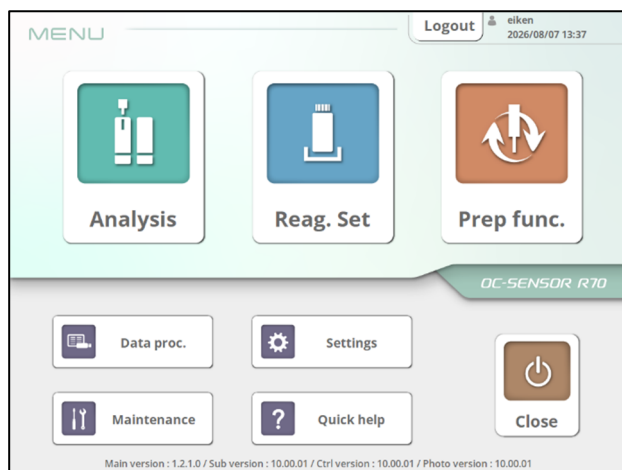
3.3.1. Display the [Quality control processing] screen

The [Quality control processing] screen can be opened through the following two paths:

- Open from the [MENU] screen
- Open from the [Analysis top] screen

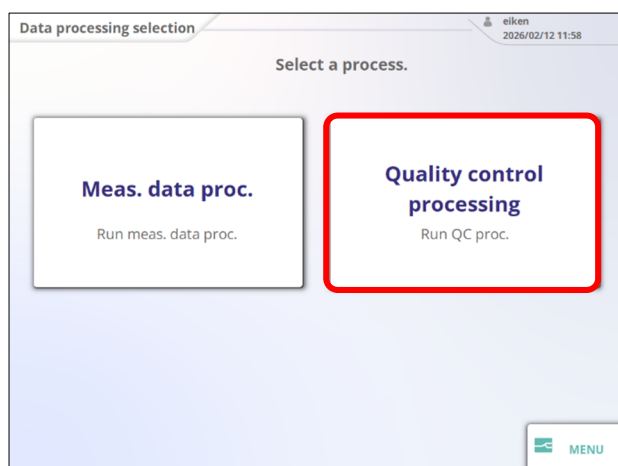
■ Open from the [MENU] screen

1) From the [MENU] screen, touch [Data Processing].



2) Touch the [Quality Control Processing] button.

*The Quality Control Processing screen will be displayed.



[Data processing selection] screen

3.3.2. Display quality control data

Display the quality control data by specifying the following items on the [Quality control processing] screen.

<Specified items>

- Analysis item
- QCNo.
- QC lot
- Processing months

Quality control processing

Selection: Select data.

Analysis item: FIT (selected), QC lot: QC1, ProcMon: 12

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

Register Delete Output Edit Back

- (1) Select the analysis item to be displayed from the pull-down menu.

Quality control processing

Selection: Select data.

Analysis item: QC1 (selected), QC lot: QC1, ProcMon: 12

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

Register Delete Output Edit Back

- (2) Select the QC No. to be displayed from the pull-down menu.

Quality control processing

Selection: Select data.

FIT QC1 QC lot **407** ProcMon 12

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

- (3) Select the QC lot to be displayed from the pull-down menu.

Quality control processing

Selection: Select data.

FIT QC1 QC lot ProcMon **12**

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

- (4) Touch the input field for ProcMon and enter the number of processing months.

Quality control processing

Selection: Select data.

FIT QC1 QC lot ProcMon 12

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

- (5) Displays QC data for the selected criteria in ascending order by measurement date and time.

3.3.3. Display QC data as between-day data

Display Qc data as between-day data (average values of within-day data).

Quality control processing eiken
2026/02/13 11:49

Selection: Select data.

FIT QC1 QC lot ProcMon 12 Select

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

Register Delete Output Edit Back

(1) Display the QC data.

See Section 3.3.2

(2) Touch the {Between-day} tab.

Quality control processing eiken
2026/02/13 11:49

Selection: Select data.

FIT QC1 QC lot ProcMon 12 Select

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

Register Delete Output Edit Back

(3) The average value of the specified QC data is displayed for each measurement date.

3.3.4. Display QC data as within-day data

Display QC data as within-day data.

Quality control processing

[Select/Range selection] button: Clear selection

FIT QC1 QC Lot 407 ProcMon 12 Select

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
26/02/13	150.4						

Between-day Within-day

X-R chart

Register Delete Output Edit Back

(1) Display the QC data.

See Section 3.3.2

(2) Select one row of the QC data for which within-day data are to be checked, and touch the {Within-day} tab.

QC proc

FIT QC1 QC Lot 407

Meas date: 26/02/13

Meas Time	Average	Meas Time	Average
12:26	150.4		

Day difference Within the day

X-R Control chart

Installation Remove Output Edit Return

(3) The within-day measurement data for the selected measurement date are displayed.

3.3.5. Delete QC data

Delete QC data. The following QC data can be deleted:

- (1) Between-day data
- (2) Within-day data

* When within-day data are edited, the average value of the corresponding between-day data is automatically updated.



QC data can be deleted only when the logged-in account permission is set to "Admin."
It cannot be performed when the account permission is set to "User."

■ Between-day data

- (1) Display the QC data (between-day).
➡ See Section 3.3.3
- (2) Select or range-select the QC data for the date(s) to be deleted, and touch {Delete}.

Quality control processing

Selection: Select data.

FIT QC1 QC lot ProcMon 12 Select

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

Register Delete Output Edit Back

Quality control processing

Selection: Select data.

FIT QC1 QC lot ProcMon 12 Select

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0
24/12/23	150.0	25/01/10	155.0	25/01/17	155.0		

Between-day Within-day

X-R chart

Register Delete Output Edit Back

- (3) To apply the deletion to the QC data, touch {Register}.

■ Within-day data

- (1) Display the QC data (within-day).

➡ See Section 3.3.4

- (2) Select the QC data for the time to be deleted, and touch {Delete}.

QC proc

elken
2026/02/18 09:26

FIT - QC1 - QC Lot 407

Meas date: 26/02/13

Meas Time	Average
11:43	150
13:58	155
14:00	154
14:02	152
14:05	150

Meas Time	Average
14:07	150
14:09	156
14:11	160
14:13	155

Day difference Within the day

X.R Control chart

Installation Remove Output Edit Return

- (3) To apply the deletion to the QC data, touch {Register}.

QC proc

elken
2026/02/18 09:26

FIT - QC1 - QC Lot 407

Meas date: 26/02/13

Meas Time	Average
11:39	158
11:43	150
13:58	155
14:00	154
14:02	152

Meas Time	Average
14:05	150
14:07	150
14:09	156
14:11	160
14:13	155

Day difference Within the day

X.R Control chart

Installation Remove Output Edit Return

3.3.6. Edit QC data

Edit QC data.

Only within-day data can be edited. When within-day data are edited, the average value of the corresponding between-day data is automatically updated.

The screenshot shows the 'QC proc' screen. At the top, there are tabs for 'FIT', 'QC1', and 'QC Lot 407'. Below this, a section titled 'Meas date: 26/02/13' contains two tables. The left table, labeled 'Day difference', has columns 'Meas Time' and 'Average' with rows for 09:34 (153.1), 12:40 (153.3), and 17:05 (153.4). The right table, labeled 'Within the day', is empty. At the bottom, there are buttons for 'Installation', 'Remove', 'Output', 'Edit', and 'Return'. A small 'X-R Control chart' icon is also visible.

(1) Display the within-day data.

→ See Section 3.3.4

(2) Select the within-day data to be edited and touch {Edit}.

The screenshot shows the 'Edit within-day data' screen. It has a title bar 'Edit within-day data' and a subtitle 'Edit the measurement values.' Below this, there are tabs for 'F-Hb', 'QC1', and 'QC lot 407'. A section titled 'Meas. dt: 26/02/13' shows an 'Avg. 150.4'. Below this is a grid of 10 numbered input fields (No.1 to No.10). No.1 is 146.8, No.2 is 151.4, and No.3 is 153.0. A red box highlights the input fields. At the bottom, there are buttons for 'Recalculat' and 'Cancel'.

(3) Touch the input field of the within-day data to be changed and edit the measured value using the numeric keypad. After editing, touch {Recal}.

The screenshot shows the 'QC proc' screen after editing. The 'Day difference' table remains the same. The 'Within the day' table now has data: 09:34 (157.0), 12:40 (153.3), and 17:05 (153.4). The 'Installation' button at the bottom is highlighted with a red box.

(4) The recalculated within-day data are displayed.

(5) To update the QC data with the recalculated results, touch {Register}.

3.3.7. Display the X-R control chart

Display the X-R control chart of the QC data.

The graphs can be displayed separately for between-day and within-day data.

■ For between-day

- (1) Display the between-day data.
- (2) Touch {X-R chart}.

Quality control processing

Selection: Select data.

FIT QC1 QC lot ProcMon 12 Select

Meas. date	Average	Meas. date	Average	Meas. date	Average	Meas. date	Average
24/12/10	153.0	24/12/23	150.0	25/01/10	155.0	25/01/17	155.0
24/12/11	152.0	24/12/24	151.0	25/01/11	151.0	25/01/18	152.0
24/12/12	153.0	24/12/25	153.0	25/01/12	153.0	25/01/19	153.0
24/12/13	152.0	24/12/26	150.0	25/01/13	150.0	25/01/20	150.0
24/12/20	151.0	24/12/27	156.0	25/01/14	151.0	25/01/21	151.0
24/12/21	156.0	24/12/28	158.0	25/01/15	156.0	25/01/22	156.0
24/12/22	154.0	24/12/29	154.0	25/01/16	154.0	25/01/23	154.0

Between-day Within-day

X-R chart

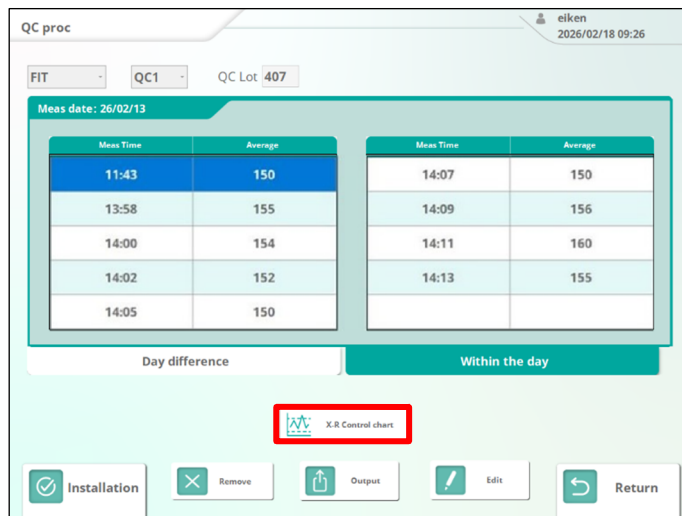
Register Delete Output Edit Back



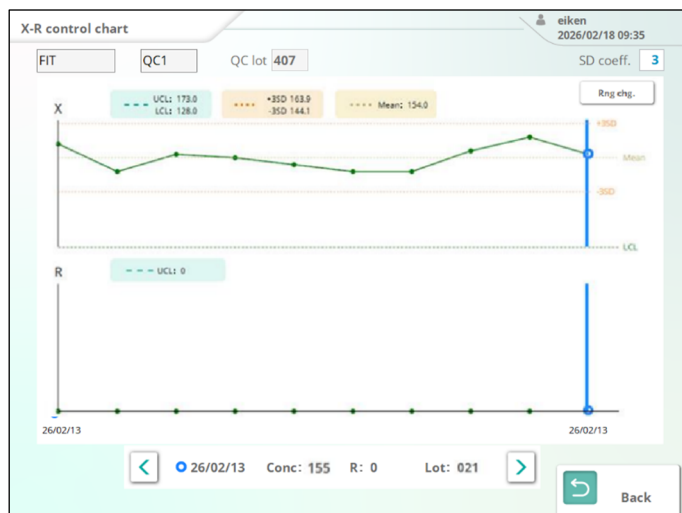
- (3) The X-R control chart of between-day data is displayed.

■ For within-day

- (1) Display the within-day data.
- (2) Touch {X-R chart}.



- (3) The X-R control chart of within-day data is displayed.



■ Details of X-R control chart



Move the [] displayed on the X-R control chart using [] [] buttons.
The cursor value information is displayed at the bottom of the graph.

a: X graph

<Details of display>

- UCL (Upper control limit): The upper control limit registered in "QC settings"
- LCL (Lower control limit): The lower control limit registered in "QC settings"
- $\pm \square SD$ (Coefficient $\times$ standard deviation): Standard deviation coefficient $\times$ standard deviation of the displayed data
- Mean : Average value of the displayed data

b: R graph

<Details of display>

- UCL (Upper control limit): The upper control limit of the R graph

c: Cursor value information

	26/02/13	Conc: 154	R: 10	Lot: 021
	(A)	(B)	(C)	(D)

<Between-day data>

- (A) Measurement date
- (B) Concentration (average)
- (C) R (range)
- (D) Lot number

<Within-day data>

- (A) Measurement time
- (B) Concentration (average)
- (C) R (range)
- (D) Lot number

3.3.8. Change the X-R control chart range

Change the vertical axis range of the X-R control chart.



(1) Display the X-R control chart.

(2) Touch {Rng chg}.

(3) Enter each value.

(4) Touch {Execute}.

3.4. Rack Information

The rack information screen allows for the checking of information for racks that have already been analyzed.

 The rack information is cleared when the System is powered off.

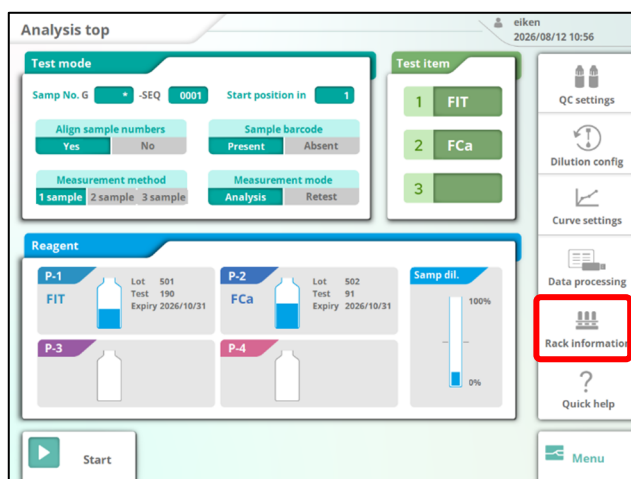
3.4.1. Display the [Rack information] screen.

The [Rack information] screen can be opened through the following two paths:

- Open from the [Analysis top] screen
- Open from the [Analysis status] screen

■ Open from the [Analysis top] screen

- (1) From the [Analysis top] screen, touch {Rack information}.



[Analysis top] screen

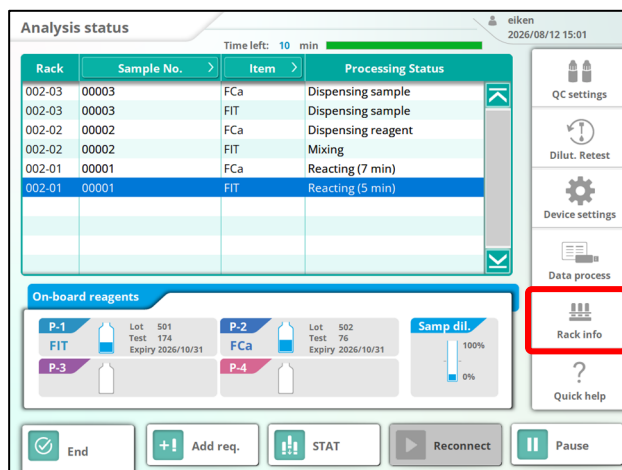
- (2) The [Rack information] screen is displayed.

- (3) To return to the [Analysis top] screen, touch {Back}.



[Rack information] screen

■ Open from the [Analysis status] screen



[Analysis top] screen

- (1) From the [Analysis status] screen, touch {Rack info}.

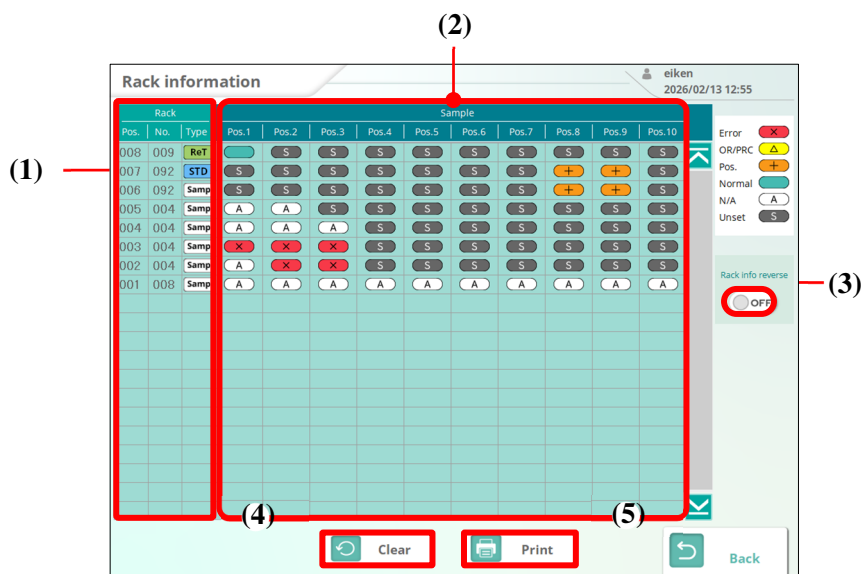


[Rack information] screen

- (2) The [Rack information] screen is displayed.
- (3) To return to the [Analysis status] screen, touch {Back}.

3.4.2. Understanding the [Rack information] screen

This section explains the contents of the [Rack information] screen.



Name	Details
(1) Rack info	Displays the rack No. and measurement rack information. Samp Sample rack QC QC rack STD STD/QC rack Dlt Dilute test rack ReT Retest rack
(2) Sample information	Displays analysis information for the samples in the rack. X Error sample Δ OR/PRC sample + (Positive sample) Normal Normal A N/A S Unset
(3) Rack info reverse	When the reverse rack print button is ON, the rack information displayed on the screen is printed from the bottom upward.
(4) Clear	Deletes the rack information.
(5) Print	Outputs the rack information to the printer.

3.5. Analysis Method Using Sample Cups

When analyzing a sample using a sample cup, change the following settings before measurement.



Caution



Required

- When performing analysis using sample cups, avoid sample mix-ups. Failure to observe this precaution may lead to misdiagnosis.

1) Change the rack to be used

Sample cups cannot be installed onto the sample rack normally used.

When analyzing samples using sample cups, use one of the following racks: STD/QC rack, dilution retest rack, or the retest rack.

When using the STD/QC rack, dilution retest rack, or the retest rack, change the rack No. settings so that the rack is recognized as a sample rack.

➤ See Section 6.1.4

2) Change the sample barcode settings

Barcodes cannot be attached to sample cups. Open "Sample barcode settings" and set the following items.

➤ See Section 6.1.2

■ Sample barcode setting items

Item	Selection
Sample barcode	Absent
Sample barcode duplicate check	Disable

4. Auxiliary function

4.1. Initialize

Initialize each system component (moves them to the standby position).

➤ See Section 2.6.5

4.2. Prime

There are two kinds of priming. “Normal priming” removes air bubbles in the piping, while “activate priming” introduces purified water and wash solution to the piping.

- Normal prime... Used to remove air bubbles from the piping, for example, when the System is used after being left unused for a period of time.
- Activate priming... Used when purified water and wash solution are introduced into the piping for the first time.

➤ See Section 2.6.6

4.3. Cell Blank

When cell blank is executed, the cells are cleaned and evaluated on a pass/fail basis.

➤ See Section 2.6.7

If “Cell blank measurement” is checked in shutdown mode, cell blank measurement is automatically executed at system startup.

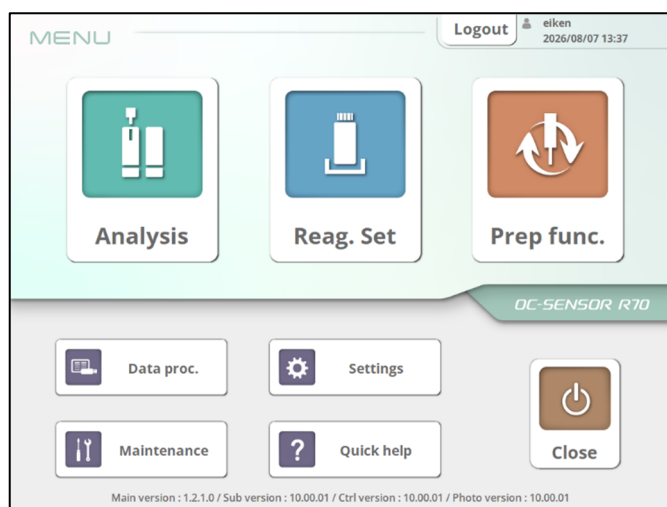
➤ See Section 2.11

5. Maintenance

This section describes the maintenance procedures for the System.

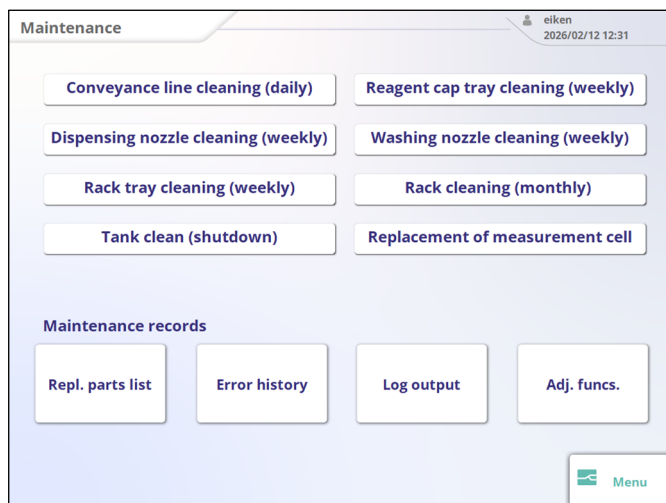
5.1. Open the [Maintenance] screen

From the [MENU] screen, touch {Maintenance} button to open the [Maintenance] screen.



[MENU screen]

(1) Touch the {Maintenance} button.



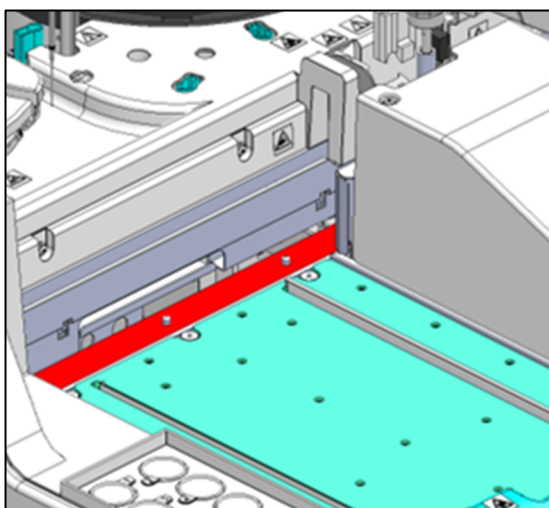
[Maintenance screen]

(2) The maintenance screen is displayed.

5.2. Cleaning Procedure

This section describes how to clean the System.

5.2.1. Conveyance line cleaning (daily)

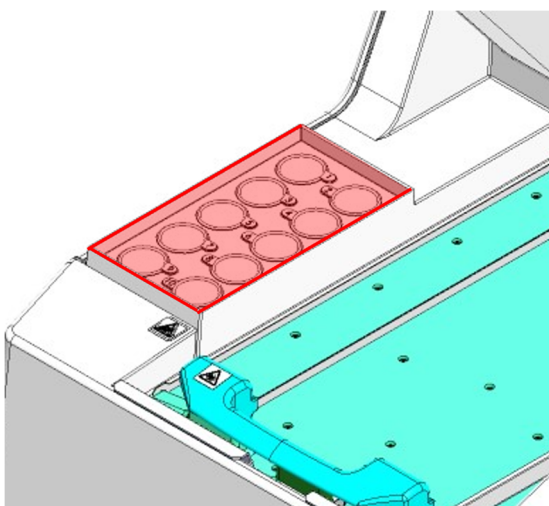


■ Procedure

- (1) After wiping away the dirt with purified water, clean the conveyor line (area indicated by the red frame in the left figure) with a cloth lightly moistened with ethanol.

 Wring the cloth thoroughly.

5.2.2. Reagent cap tray cleaning (daily)

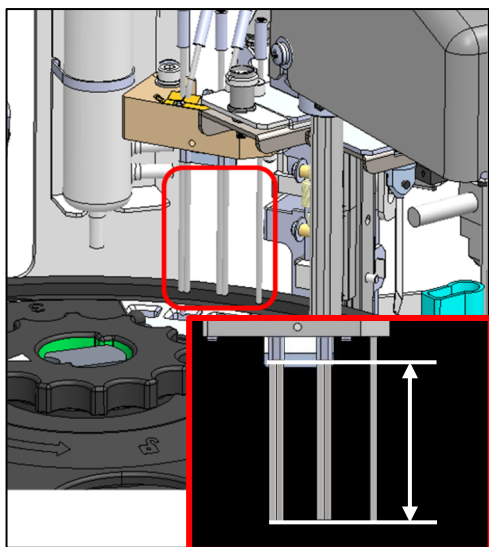


■ Procedure

After wiping away the dirt with purified water, clean the reagent cap tray (area indicated by the red frame in the left figure) with a cloth lightly moistened with ethanol.

 Wring the cloth thoroughly.

5.2.3. Washing nozzle cleaning (weekly)



■ Procedure

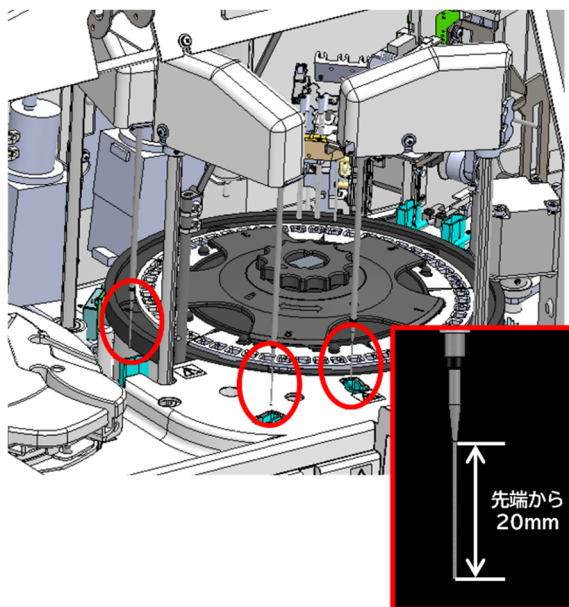
- (1) After wiping away the dirt with purified water, clean the washing nozzle with a cloth lightly moistened with ethanol.

⚠ Wring the cloth thoroughly.

⚠ Handle the washing nozzle with care.

The nozzle tip is sharp and may cause injury.

5.2.4. Dispensing nozzle cleaning (weekly)



■ Procedure

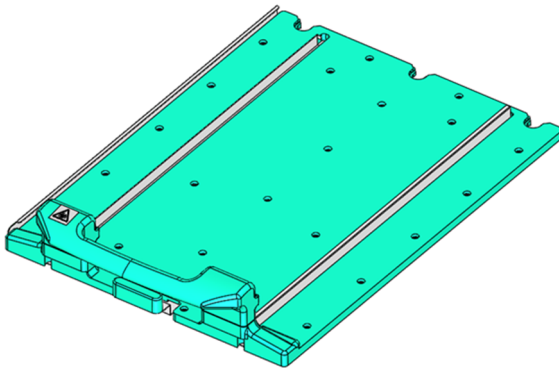
- (1) After wiping away the dirt with purified water, clean 20 mm of the tip of the dispensing nozzle with a cloth lightly moistened with ethanol.

⚠ Wring the cloth thoroughly.

⚠ Handle the sample, R1, and R2 nozzles with care.

The nozzle tip is sharp and may cause injury.

5.2.5. Rack tray cleaning (weekly)

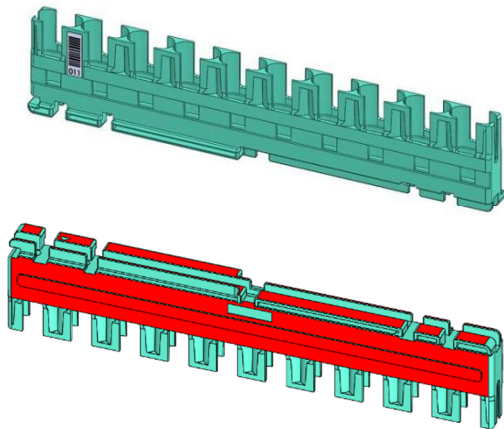


■ Procedure

- (1) After wiping away the dirt with purified water, clean the rack tray with a cloth lightly moistened with ethanol.

 Wring the cloth thoroughly.

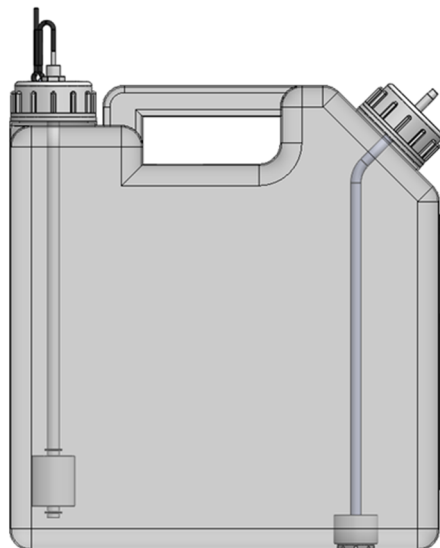
5.2.6. Rack cleaning (weekly)



■ Procedure

- (1) Check that there is no foreign matter in the rack holes.
- (2) Check for rack damage and peeling barcodes.
- (3) After wiping away the dirt with purified water, clean underside slide and side surfaces (red side) with a cloth lightly moistened with ethanol.

5.2.7. Tank clean (monthly)



■ Procedure

<Normal cleaning>

Clean the tank thoroughly with tap water, then rinse it with purified water.

<Cleaning when the tank is heavily soiled>

- (1) Clean the tank thoroughly with tap water.
- (2) Fill the tank with tap water + LX wash solution.
Tap water: 2 L, wash solution: 20 mL
- (3) Close the tank lid tightly and shake the tank.
(If heavily soiled, let it sit for 1 hour.)
- (4) Rinse thoroughly with tap water to remove all wash solution.
- (5) Rinse lightly with purified water.

5.3. Replacement of Measurement Cells

If 10 or more cells are found unusable during cell blank measurement, the message "More than 10 contaminated measurement cells detected. To prevent decreased throughput, please replace the measurement cells." will be displayed. Replace the measurement cells according to the following procedure.

After replacing the cells, perform a cell blank measurement to confirm that there are no issues with the new cells.

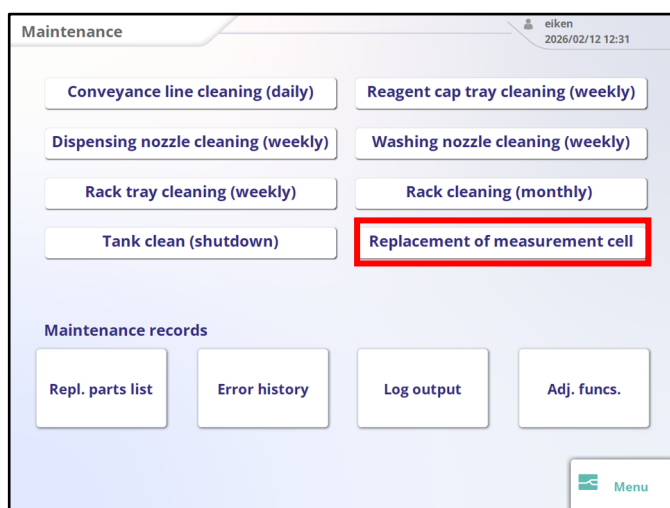


Caution



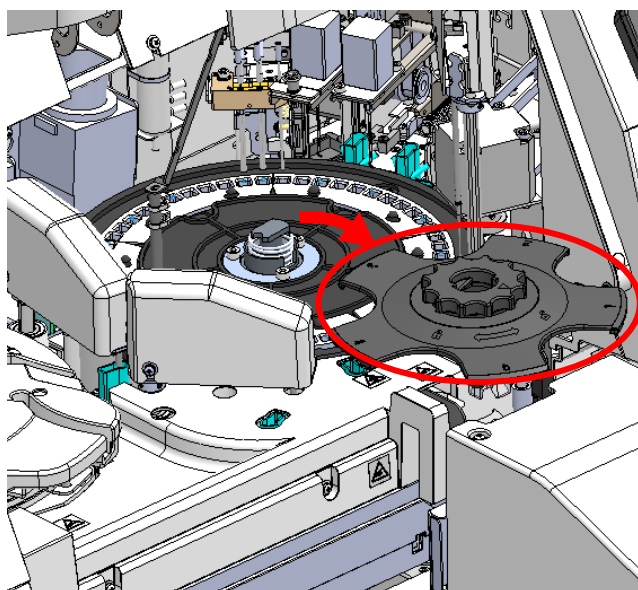
Required

- When installing measurement cells, ensure that they are seated properly and do not float.
 - Do not touch the measurement surface of the cells.
- Failure to observe this precaution may lead to affecting measurement results.



[Maintenance screen]

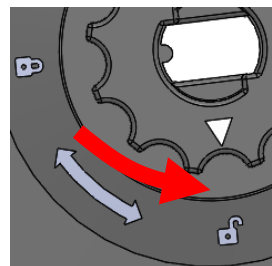
- (1) From the maintenance screen, touch "Replacement of measurement cells."



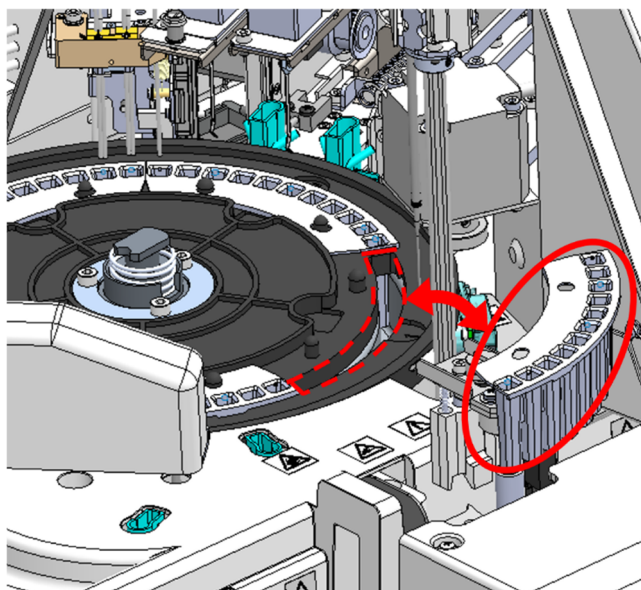
- (2) Replace the cells.

<Procedure>

- Open the protective cover.
- While holding the reaction table, unlock the cell holder lock.

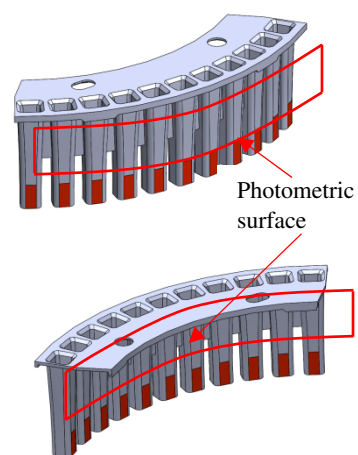


- Replace the cell holder.

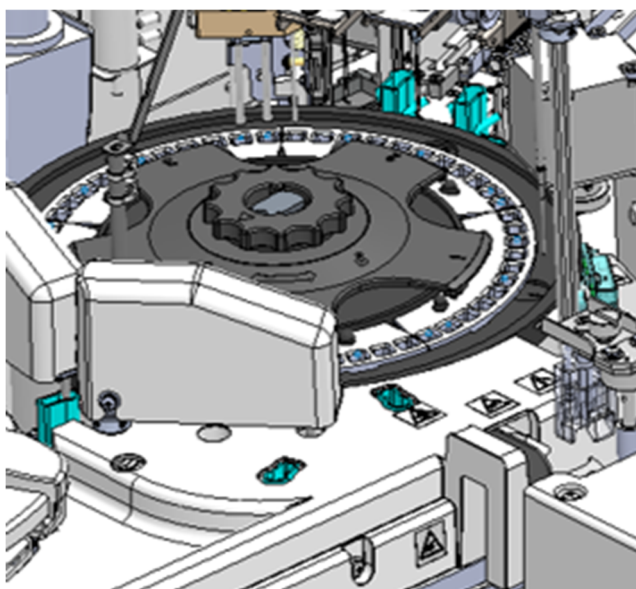


(D) Remove the old measurement cells and replace them with new ones.

- Ensure there are no scratches or stains on the cell photometry area.
- Avoid touching surrounding parts during cell installation.



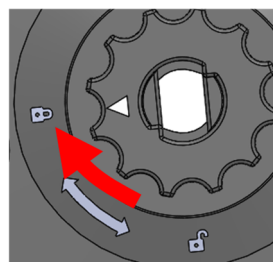
- Replace all five cells.



(E) Attach the cell holder.

<Procedure>

- a) Attach the cell holder.
- b) While holding the reaction table, lock the cell holder.



- c) Close the safety guard.

5.4. Maintenance

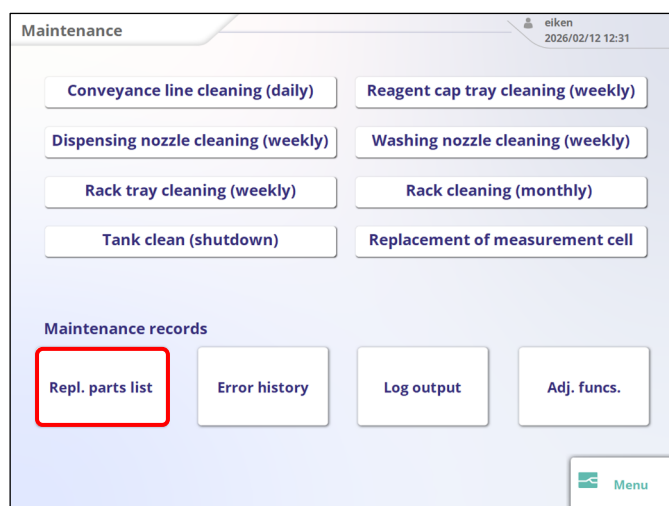
The maintenance records include the [Replacement Parts List] (administrators only), [Error History], [Log Output], and [Create Management USB], which allow you to check the status of the device.

5.4.1. Open the [Repl. parts list] screen

The [Replacement Parts List] screen displays the pre-registered part names, the date of the last replacement, the number of months in use, and the number of times used.

From the [Maintenance] screen, touch {Repl. parts list} to open the [Parts list] screen.

Parts that have reached their replacement timing (exceeding the preset usage period or usage count) are highlighted in yellow.



- (1) Open the [Maintenance] screen.

➡ See Section 5.1

- (2) Touch {Repl. parts list}.

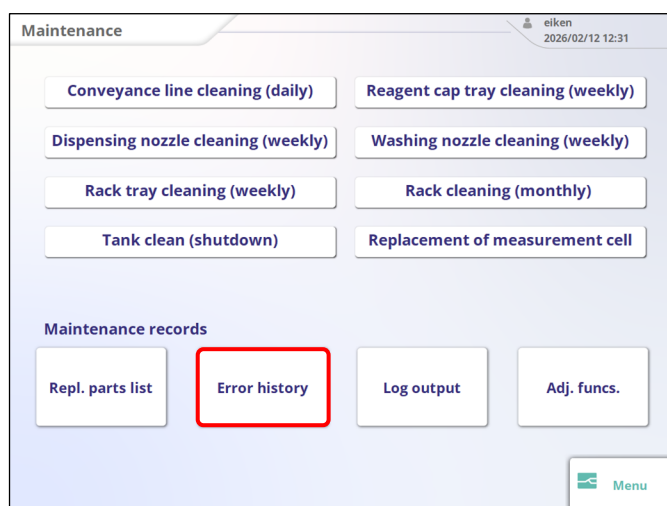
- (3) The [Repl. parts list] screen is displayed.
- (4) Parts that have exceeded their replacement interval are highlighted in yellow.



If any parts are past their replacement date, please contact the manufacturer.

5.4.2. Open the [Error history] screen

On the [Maintenance] screen, tap [Error history], and the [Error history] screen will open.



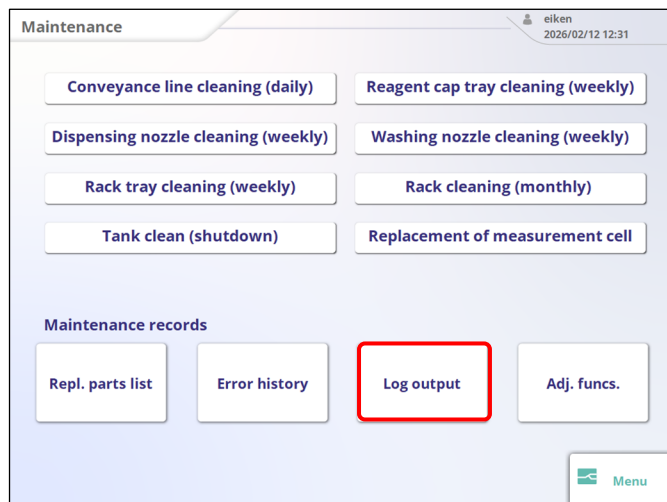
(1) Open the [Maintenance] screen.
■ See Section 5.1

(2) Touch {Error history}.

(3) The [Error history] screen is displayed.

5.4.3. Open the [Log output] screen

On the [Maintenance] screen, tap [Log output], and the [Log output] screen will open.



(1) Open the [Maintenance] screen.

➡ See Section 5.1

(2) Touch {Log output}.

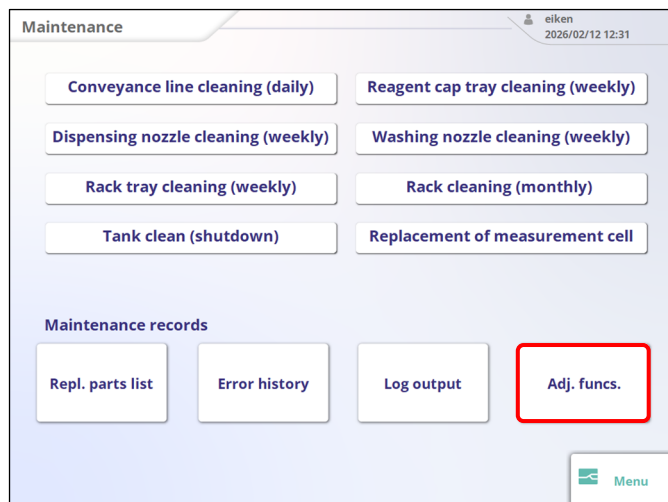
(3) The [Log output] screen is displayed.

(4) Specify the date range.

(5) Connect the management USB drive and tap [Run] to output the data within the specified range.
If an error occurs and the data export fails, please reconnect the management USB drive and try exporting the data again.

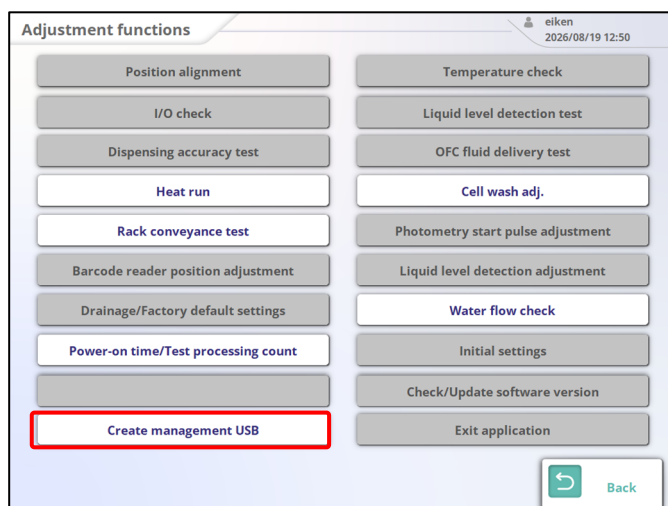
5.4.4. Open the [Adjustment functions] screen

On the [Maintenance] screen, tap [Adj. funcs.], and the [Adjustment functions] screen will open.



(1) Open the [Maintenance] screen.
→ See Section 5.1

(2) Touch {Adj. funcs.}.



(3) The [Adjustment functions] screen is displayed.

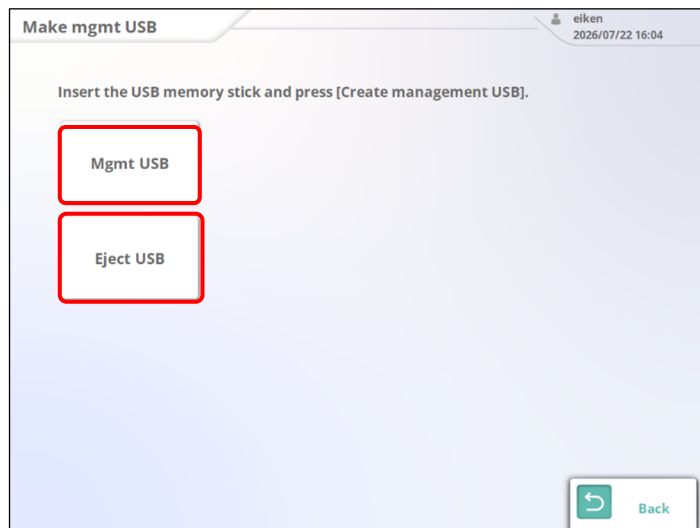
⊘ Except for functions that use the management USB, please do not use or change the settings for the following items unless you receive specific instructions from us.

- Heat run
- Rack conveyance test
- Power-on time/Test processing count
- Cell wash adj.
- Water flow check

Using these functions or changing their settings may affect the operation or performance of the device.

5.4.4.1. Create management USB drive

On the [Adjustment functions] screen, tap [Create management USB], and the [Make mgmt. USB] screen will open.



- (1) Connect the USB flash drive to the device.
- (2) Tap [Create Mgmt USB] to designate the connected USB flash drive as the management USB drive.
- (3) Tap [Eject USB] to safely remove the USB device.
- (4) Tap [Back] to return to the [Adjustments functions] screen

6. Settings

This section describes the details of the various settings.

6.1. Analysis Settings

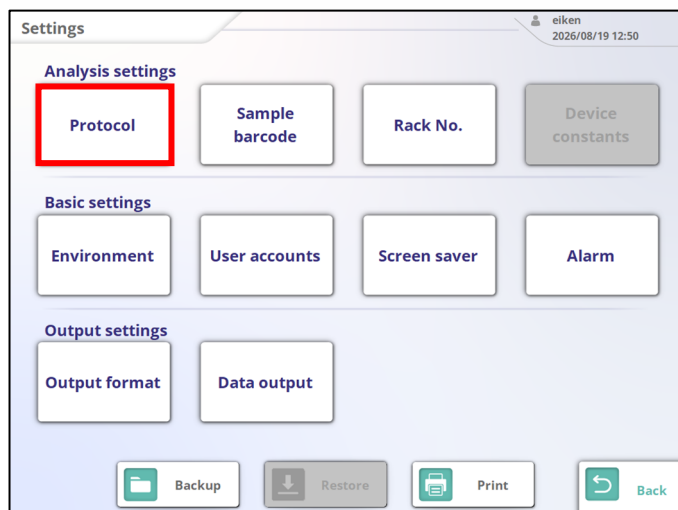
This section describes the settings for items related to analysis.

6.1.1. Protocol settings

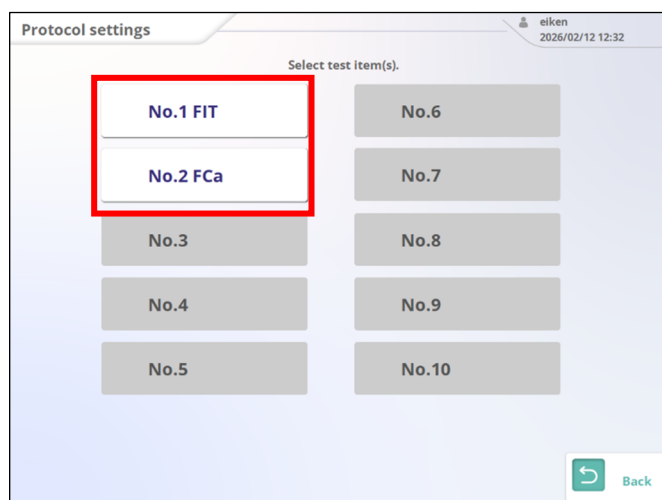
Protocol settings consist of the following three main categories:

- Conditions for measuring samples (including STAT samples), STD samples, and QC samples
- Standards for calibration curve creation
- General conditions when measuring samples, STD samples, and QC samples (manufacturer settings)

The settings screen consists of two pages. Switch between pages using the tabs.



(1) From the settings menu, touch {Protocol}.



(2) Touch the analysis item to set.

Protocol Settings [FIT] eiken 2026/02/12 12:33

page 1 **page 2**

Sample repl. ct.	10
QC replicate count	3
STD repl. ct.	3

Cutoff 1	100
Cutoff 2	
Cutoff 3	
Upper meas. lim.	1000.0
Lower meas. lim.	30.0

RBC method check	On Off
RBC coeff.	1.10
PRC method check	On Off
PRC coeff.	1.30
FACTOR A	1.000
FACTOR B	0.00

Register Mfr settings Back

(3) Set each item.

Protocol Settings [FIT] eiken 2026/02/12 12:33

page 1 **page 2**

STD conc. [ng/mL]	
STD-6	1000.0
STD-5	500.0
STD-4	250.0
STD-3	125.0
STD-2	62.5
STD-1	0.0

STD specifications	
STD-6 DA low lim.	2000
STD-6 DA high lim.	4000
STD-6-3 ± theor.	5 [%]
STD-1 DA low lim.	-50
STD-1 DA high lim.	50
STD-2 ± theor.	10 [%]

Register Mfr settings Back

(4) Touch the [page 2] tab, and set each item.

(5) Touch {Register} to save the settings.

■ [page1] tab

Setting item	Setting range	Description	
Sample repl. ct.	1-10	Sets the number of measurements for the same sample.	
STD repl. ct.	1-10	Sets the number of measurements for STD samples.	
QC replicate count	1-10	Sets the number of measurements for QC samples.	
Cutoff 1	0-9999999 (integer)	Sets the judgment criterion for Cutoff 1.	
		1+	Measured data is "above Cut off 1 value" or "Cut off 2 or lower"
		-	Measured data is "setting value or lower"
Cutoff 2	0-9999999 (integer)	Sets the judgment criterion for Cutoff 2. Unchecking the check box disables judgment for Cutoff 2 and Cutoff 3.	
		2+	Measured data is "above setting value," "larger than Cut off 1," or "Cut off 3 or less" If set to "*", Cut off 2 judgment will not be performed. Cut off 1 < Cut off 2
Cutoff 3	0-9999999 (integer)	Sets the judgment criterion for Cutoff 3. Unchecking the check box disables judgment for Cutoff 3.	
		3+	Measured data is "above setting value" If set to "*", Cut off 3 judgment will not be performed. Cut off 2 < Cut off 3
Upper meas. lim.	0.0-99999999.9	Sets the upper limit of the measured value.	
		OR	Displayed when measured data is larger than "Max Value."
Lower meas. lim.	0.0-99999999.9	Sets the lower limit of the measured value during dilution retest.	
		UR	Displayed when measured data is "Min Value" or lower during dilute testing.
RBC method check	On/Off	Enables or disables the RBC method check.	
RBC coeff.	1.00-2.00	Sets the coefficient for the RBC method.	

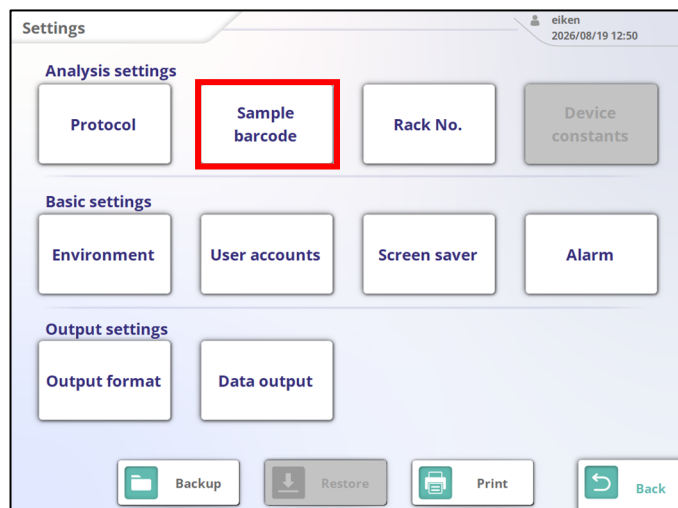
PRC method check	On/Off	Enables or disables the PRC method check.
FACTOR A	0.001-99999.999	Value used in the calculation of measured values. <Formula> Measured value = FACTOR A × concentration value + FACTOR B
FACTOR B	-999.999-999,999	

■ [page2] tab

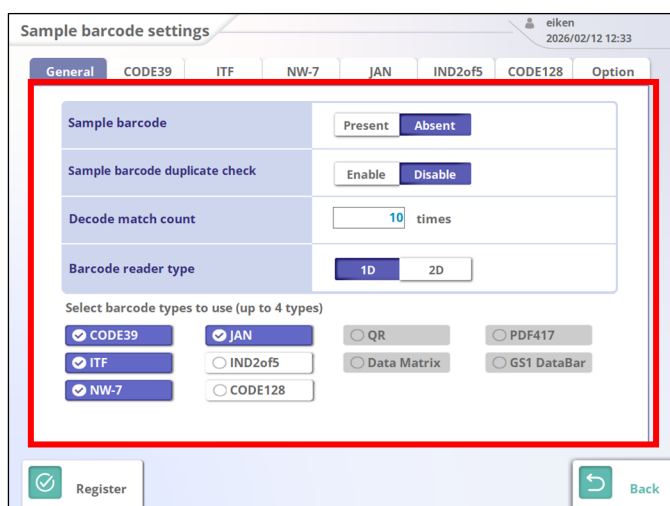
Setting item	Setting range	Description
STD concentration		
STD - 6	0, 1-9999999.9	Sets the concentration values described in the calibrator usage instructions.
STD - 5		
STD - 4		
STD - 3		
STD - 2		
STD - 1		
STD specifications		Sets specification values for each STD point. STD pass/fail judgment is performed based on the specified values.
STD-6 DA low lim.	-9999-99999	Checked using the DA1 value.
STD-6 DA high lim.	-9999-99999	Checked using the DA1 value. Set so that the lower limit is less than the upper limit.
STD-6~3 ± theor. ± □ %	0-100	Checked based on deviation from the theoretical value.
STD-1 DA low lim.	-9999-99999	Checked using the DA1 value.
STD-1 DA high lim.	-9999-99999	Checked using the DA1 value. Set so that the lower limit is less than the upper limit.
STD-2 ± theor. ± □ %	0-100	Checked based on deviation from the theoretical value.

6.1.2. Sample barcode settings (general items)

This section describes the general settings for reading sample barcodes.



- (1) From the settings menu, touch {Sample barcode}.



- (2) Set the items in the {General} tab.

■ Sample barcode setting items (General)

Setting item	Selection/Settings	Description
Sample barcode	Present Absent	The sample barcode is affixed. The sample barcode is not affixed.
Sample barcode duplicate check	Enable: Disable	Checks whether the same sample barcode has been read between system startup and power-off. If a duplicate barcode is detected, analysis of the corresponding sample is not performed.

		Does not check whether the same sample barcode has been read. However, duplicate checking is not performed in retest or dilution retest modes, even when enabled.
Decode match count	Numeric input	Recommended setting: approximately 10.
Barcode reader type	1D: 2D (option):	Uses only 1D barcodes. Uses both 1D and 2D barcodes.
Select barcode types to use		Select the barcodes to be used. Up to four barcode types can be selected simultaneously.

■ About decode match count

When a barcode reader reads a sample barcode once, it performs up to 700 scans. The number of times the barcode is successfully read during these scans is referred to as the decode count. The decode match count is the number of successful reads required for the barcode to be recognized as valid.

Increasing the decode match count helps prevent barcode misreading; however, it also increases the likelihood of "barcode reading errors."

6.1.3. Sample barcode settings (detailed settings by each barcode type)

In [Sample barcode settings], in addition to the general settings, there are items that are configured according to the barcode type.

The available barcode types are CODE39, ITF, JAN, NW-7, IND2of5, and CODE128. The barcodes supported by the optional 2D code reader are QR, Data Matrix, and PDF 417.

Barcode selection is performed by switching the [Barcode name] tabs.

- (1) Open the [Sample barcode settings] screen and touch the tab for the barcode type to be configured.

Example: Touch the [NW-7] tab.
(The following explanation uses NW-7 as an example.)

- (2) Set each item.

For CODE39, JAN, and ITF, the check digit calculation method cannot be changed.

When Check digit validation: Enable is selected, the last character of the barcode (the character immediately before the stop character) is validated as the check digit.

(3) Touch {Register} to save the settings.

■ Sample barcode setting items (detailed settings)

Setting item	Input range/selection	Description
Number of barcode digits	See next page	Sets the number of digits of the sample barcode. If “*” is entered, the digit check is disabled. The allowable input range varies depending on whether “Start/Stop character deletion” is enabled or disabled.
Start/Stop character deletion	Enable: Absent	Sets whether to delete the start/stop characters. (Effective when NW-7 is selected.) Deletes the start/stop character. Does not delete the start/stop character.
Check digit validation	Enable: Disable	Sets whether to perform check digit validation. Performs check digit validation. Does not perform check digit validation.
Check digit calculation method	See next page	Sets the check digit calculation method. (Effective when NW-7 is selected.)

■ Input range for sample barcode digit count

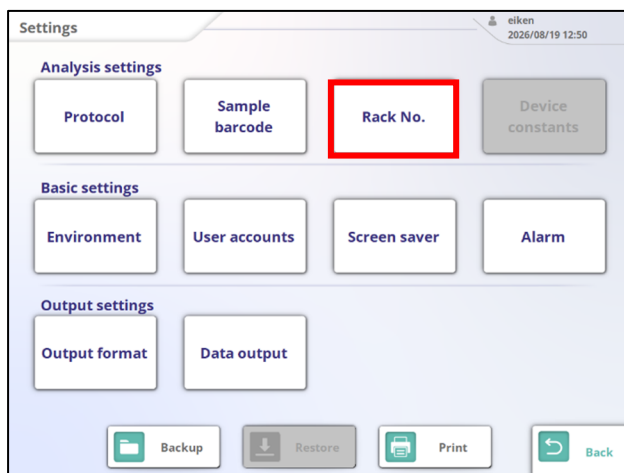
Barcode type	Start/Stop character deletion	Input range
NW-7	Enable	5-17
	Disable	5~15
CODE39	Invalid	5-15
CODE128		
ITF		6-14
JAN		8, 13
IND2of5		6-15
QR		6-50
Data Matrix		
PDF 417		

■ Barcode types and check digit calculation methods

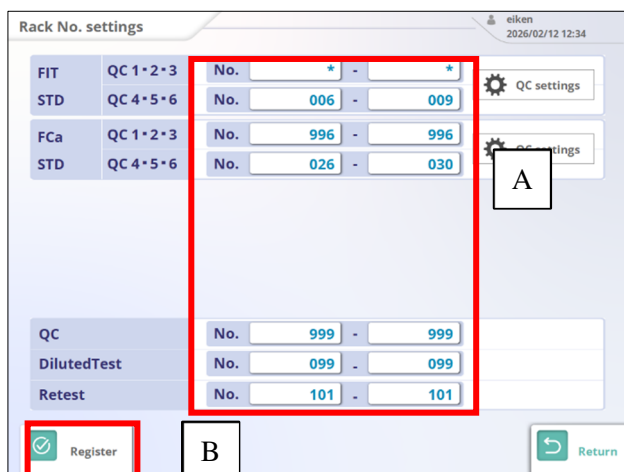
Barcode type	Calculation method
CODE39	Modulus 43 (fixed)
ITF	Modulus 10/3 weight (fixed)
NW-7	Modulus 10/3 weight
	Modulus 16
	7 check DR
	Weighted modulus 11
JAN	Modulus 10/3 weight
IND2of5	Modulus 10/3 weight (fixed)
CODE128	No check digit
QR	No check digit
Data Matrix	No check digit
PDF 417	No check digit

6.1.4. Rack No. settings

Configure the rack numbers to be used for measurement.



- (1) From the settings menu, touch the {Rack No.} button.



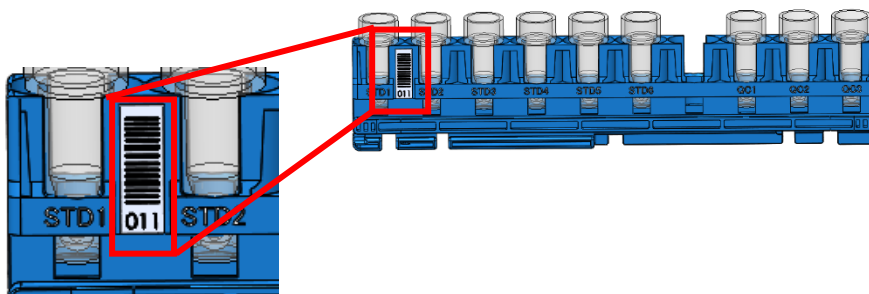
- (2) Set the rack No.

(A) Touch the input field and enter the corresponding rack No. using the numeric keypad.

(B) Touch {Register} to save the settings.

- (3) A dialogue box will appear; to register, tap the {Register} button. To cancel, tap the {Cancel} button.

[Rack No. setting] screen



Display position of rack No.

<Rack name and use>

Setting items	Input Range	Use
STD/QC1, QC2, QC3	1 ~ 999*	Use during STD/QC measurement. Can be set for each analysis item. QC1, QC2, and QC3 registered in QC settings are used.
STD/QC4, QC5, QC6		Use during STD/QC measurement. Can be set for each analysis item. QC4, QC5, and QC6 registered in QC settings are used.
QC		Use when performing QC measurement simultaneously for multiple analysis items.
Dilution retest		Use when performing dilution retest. Up to 5 racks can be registered.
Retest		Use when performing retest. Up to 10 racks can be registered.



If a rack No. that is not registered is read, it is processed as a "Sample" rack.



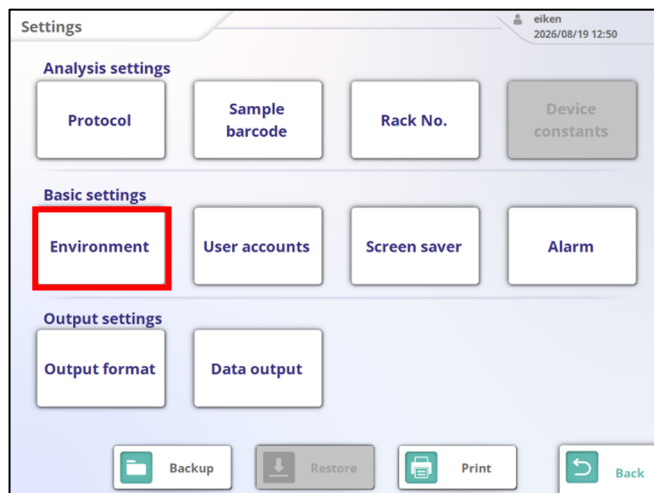
If you enter "***", the rack will be disabled.

6.2. Basic Settings

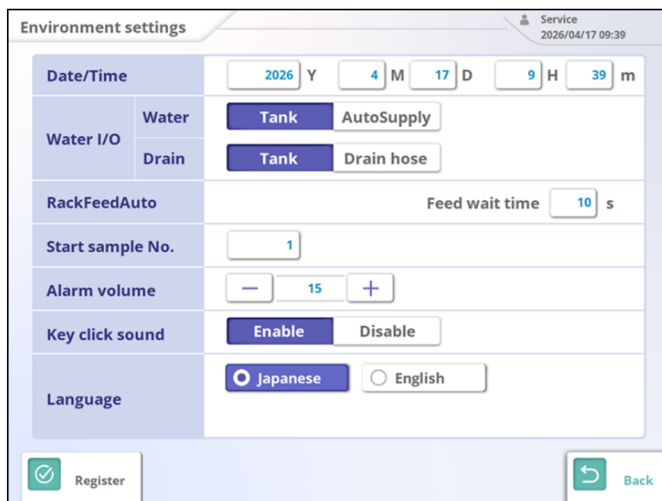
The section describes the basic settings.

6.2.1. Environment settings

Configure the operating environment of the System.



- (1) From the settings menu, touch {Environment}.



- (2) Set each item and touch {Register}.
*Please note that any changes made to the date or time settings will be applied automatically.

■ Environment setting items

Setting item	Input range/selection	Contents
Date/Time	Year: 0-9999 Month: 1-12 Day: 1-31 Hours: 0-23 Minutes: 0-59	Sets the date and time of the System. *If you change the date or time, the time setting will be finalized at that point.
Water I/O		
Supply	Tank:	Water is supplied from the tank.
drainage	Automatic water supply:	Water is supplied automatically. *If the water supply method is set to automatic, monitoring will not be performed using the liquid level sensor.
	Tank:	Drain into the tank.
	Drain hose:	Drain water using the drain hose. * If the drain method is set to drain hose, monitoring will not be performed using the liquid level sensor.
Automatic rack supply	1 ~ 60	Sets the waiting time before rack supply after a rack is placed on the supply tray.
Sample No. at startup	1 ~ 99999	Sets the sample No. at system startup.
Alarm volume	0 ~ 100	Sets the volume for alarms and button click sounds. If set to "0", the volume will be muted.
Key click sound	Yes: No:	Sets whether or not to hear a clicking sound when entering text (keyboard/numeric keypad). A clicking sound will be heard. A clicking sound will not be heard.
Language		Sets the display language.

6.2.2. User account settings

This section describes how to configure login accounts. Up to 20 accounts can be registered.

The account information that can be registered or viewed differs depending on the login permission.

Account setting permissions by login privilege

Operation	Processing target		Account privilege	
	Target	Permission	Admin	User
New registration	—	Admin	○	×
		User	○	○
Edit	Self	-	○	○
	Other	Admin	○	×
		User	○	×
Delete	Self	-	○	○
	Other	Admin	○	×
		User	○	○

×: Not allowed ○: Allowed

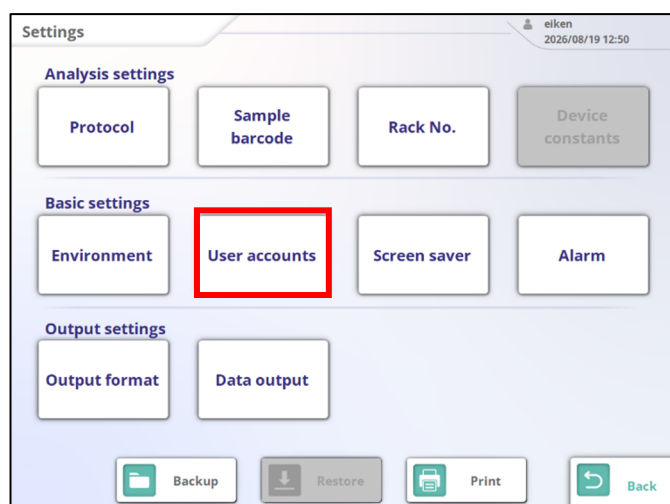
*1: If only one administrator is registered, the account cannot be deleted.

*2: General users cannot change their own permissions.

If a logged-in user deletes their own user information, they will be logged out and redirected to the MENU screen.

<Setting procedure>

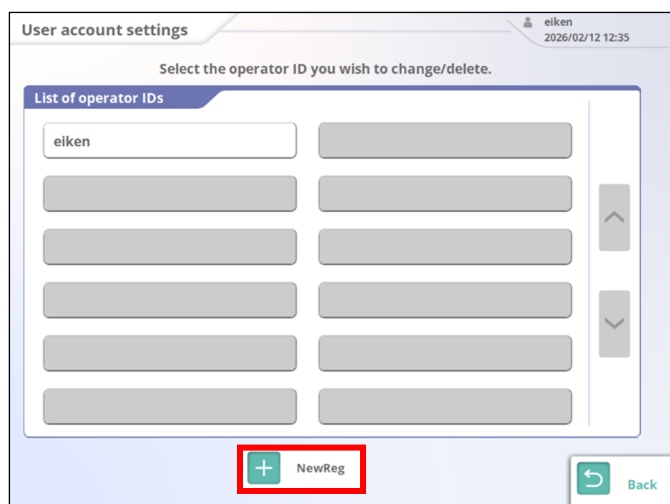
- (1) From the setting menu, touch {User accounts}.



- (2) Set up the account.

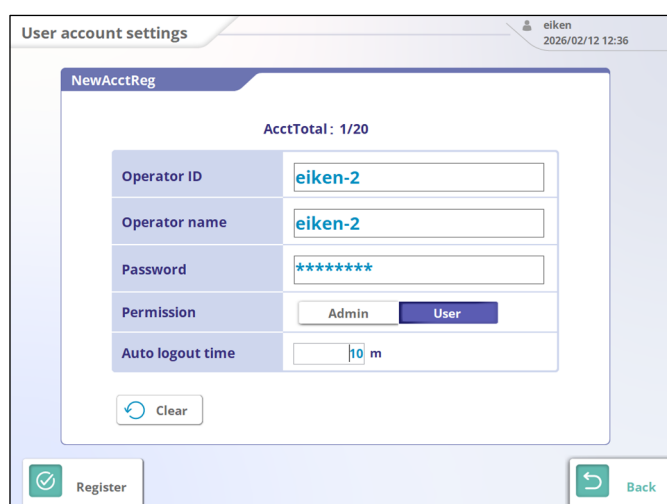
■ **New registration**

- (A) Touch {New Reg}.



- (B) Enter each item.

- (C) Touch {Register}.



User account settings

Select the operator ID you wish to change/delete.

List of operator IDs

eiken-2	eiken

+ NewReg

Back

■ Edit/Delete

- (1) Touch the operator ID to be edited or deleted.

User account settings

Account information

Operator ID	eiken-2
Operator name	eiken-2
Password	*****
Permission	Admin User
Auto logout time	10 m

Register

Delete account

Back

<To edit>

- (A) Edit the required items.
- (B) Touch {Register} to save the changes.

<To delete>

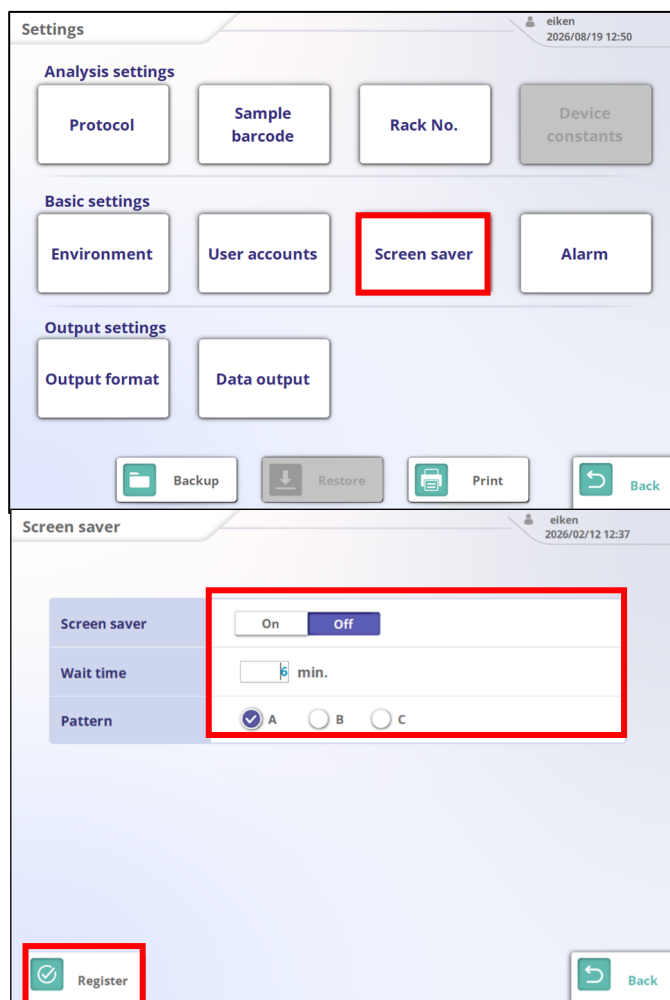
Touch {Delete account}.

User account settings

Setting item	Selection and Settings	Contents
Operator ID	1 character or more Alphanumeric characters/symbols	Sets the operator ID at login.
Operator name	1 character or more Alphanumeric characters/symbols	Sets the operator name at login.
Password	8 character or more Alphanumeric characters/symbols	Sets the password for login.
Permission	Admin: User:	Selects the account privilege. All functions are available. Some functions are restricted.
Auto logout time	Enable/Disable 0-99 min	Set the automatic logout time when no screen transition occurs from the main menu for a specified period. * If set to 0 minutes, automatic logout does not occur.

6.2.3. Screen saver settings

When no key operation is performed on the [MENU] screen for a certain period, the screen saver is activated.



(1) From the settings menu screen, touch {Screen saver}.

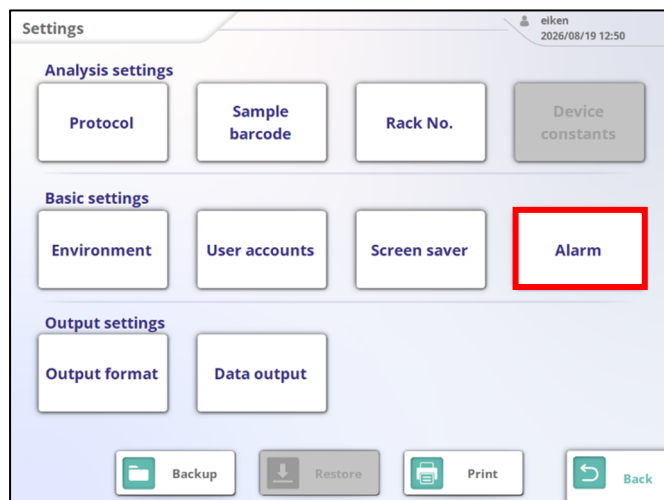
(2) Set each item and touch {Register}.

Screensaver settings

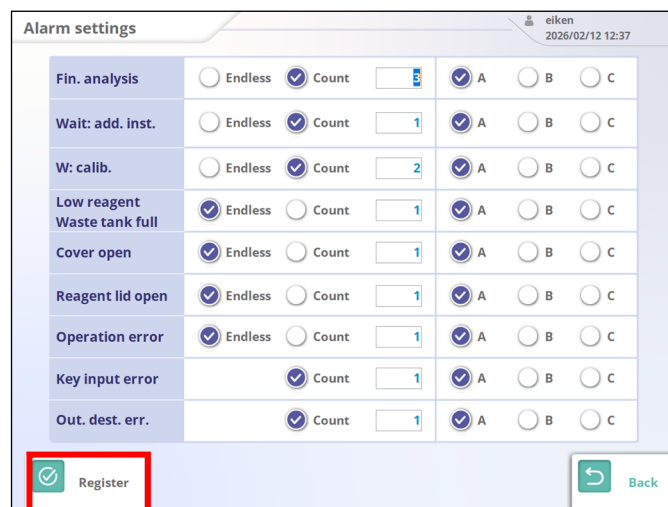
Setting items	Selection and Settings	Contents
Screen saver	Yes: No:	Run the screensaver. Do not run the screensaver.
Wait time	Input range: 1 to 99	The screen saver will start after the set wait time.
Pattern	A B C	It works in pattern A. It works in pattern B. It works in pattern C.

6.2.4. Alarm settings

Set the number of alarm sounds and alarm patterns for events such as completion of analysis and operation errors.



- (1) From the settings menu screen, touch {Alarm}.



- (2) Set each item and touch {Register}.
- * When an alarm pattern is selected, the selected alarm sounds once.
 - Endless
The alarm continues to sound until the error is cleared.
 - Count
The alarm sounds the specified number of times.

■ Alarm setting items

Setting item	Selection and Settings	Contents
Fin. analysis	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when analysis of samples placed on the rack tray is completed and the System enters standby status. The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.
Wait: add. inst.	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when rack supply from the supply unit is completed and additional rack installation becomes possible. The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.
W: calib.	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when operator judgment is required after calibration curve creation. No sound is generated when operator judgment is set to OFF. The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.
Low reagent drain tank full	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when the System detects a shortage of reagents, wash solution, or purified water, or when the drain tank is full. The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.

Cover open	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when the protective cover is open at the start of operation. The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.
Reagent lid open	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when the reagent refrigerator is open at the start of operation. The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.
Operation error	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when an error occurs during operation. The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.
Key input error	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when an invalid input value is entered. The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.
Out. dest. err.	Endless: Number of times (input range: 1 to 99): Pattern A: Pattern B: Pattern C:	Notification sound when an error occurs at a data output destination (printer, online, or external media). The alarm will continue to ring until you close the screen. The alarm will ring the specified number of times. Alarm sound pattern A will ring. Alarm sound pattern B will ring. Alarm sound pattern C will ring.

6.3. Output Settings

The section describes the output settings.

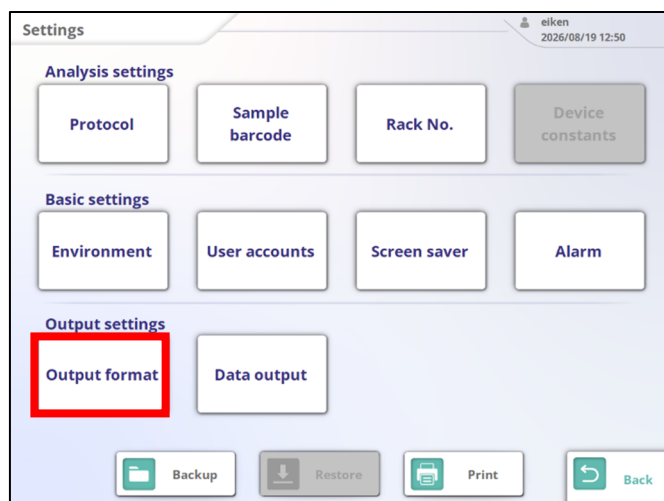
6.3.1. Output format settings

Configure the output format for data such as rack No., sample No., and sample ID for each output destination (printer, external media, and online).

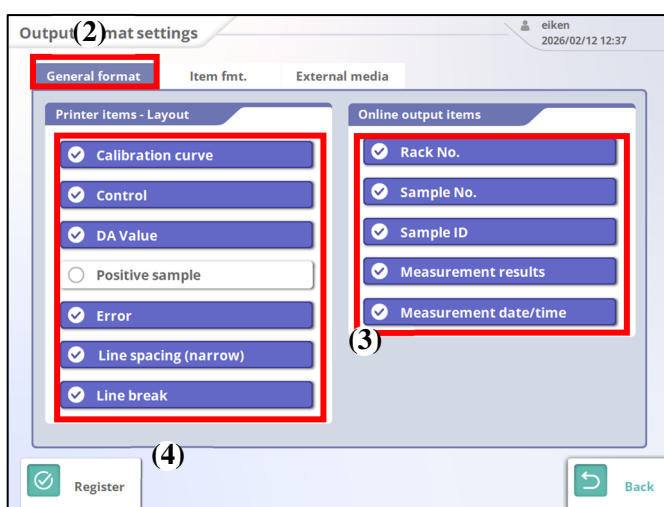
Only users with administrator privileges can change this setting.

6.3.1.1. General format

Set the output items for printer and online outputs.



- (1) From the settings menu screen, touch {Output format}.



- (2) Touch the {General format} tab.
- (3) Check the output items for each output type:
- Printer items - Layout
 - Online output items
- (4) Touch {Register}.

■ Printer output items/formats

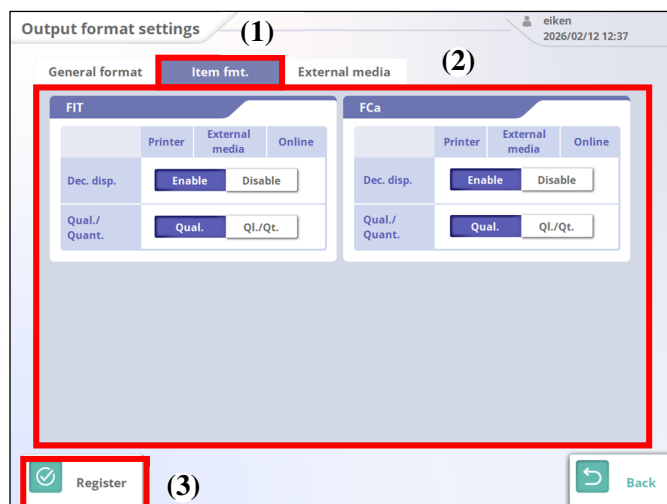
Setting item	When selected
Calibration curve	Prints calibration curve data during calibration curve creation.
Control	Prints measurement data from QC measurement.
DA value	Prints only the DA values.
Positive sample	Prints only positive samples.
Error	Prints error information when an error occurs.
Line spacing (narrow)	Reduces line spacing when printing.
Line break	Inserts line breaks between measurement data and between analysis items during multi-item analysis.

■ Online output items

Setting item	When selected
Rack No.	Outputs the rack No. online.
Sample No.	Outputs the sample No. online.
Sample ID	Outputs the sample ID online.
Measurement results	Outputs the measurement results online.
Measurement date/time	Outputs the measurement date and time online.

6.3.1.2. Item-specific format

Configure the output format (printer, external media, online) for each analysis item.



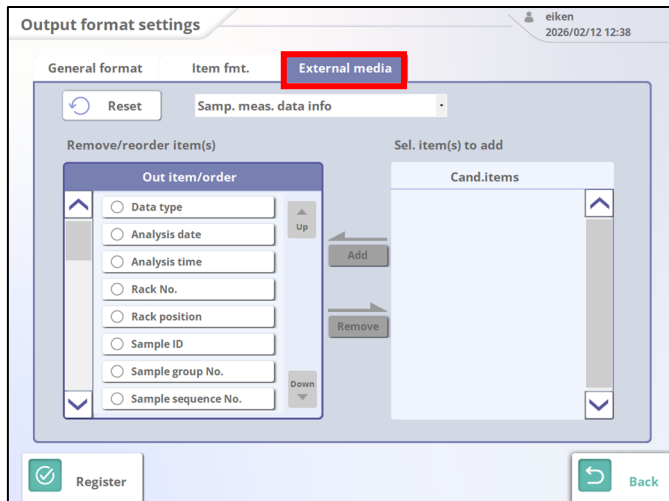
- (1) Touch the {Item fmt.} tab.
- (2) Set the output format for each analysis item.
- (3) Touch {Register}.

■ Item-specific format setting items

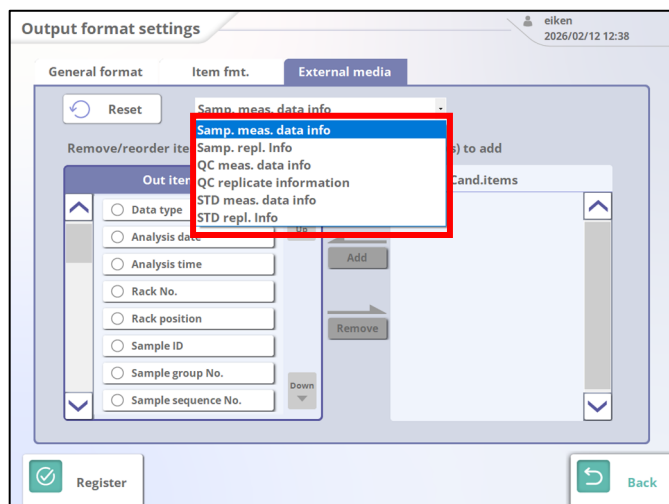
Setting item	Selection and Settings	Contents
Dec. disp.	Enable:	Displays measurement data with one decimal place.
	Disable:	Displays measurement data as integers.
Ql./Qt.	Qual.:	Outputs qualitative results only.
	Qual./Quant.:	Outputs both qualitative and quantitative results.

6.3.1.3. External media

Configure the items and order of data to be output to external media.



(1) Touch the {External media} tab.



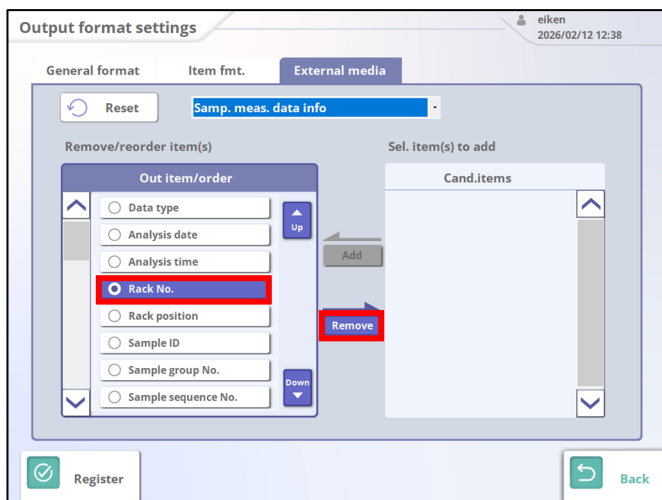
(2) Open the pull-down menu, and select the data information to be configured.

<Selectable data information>

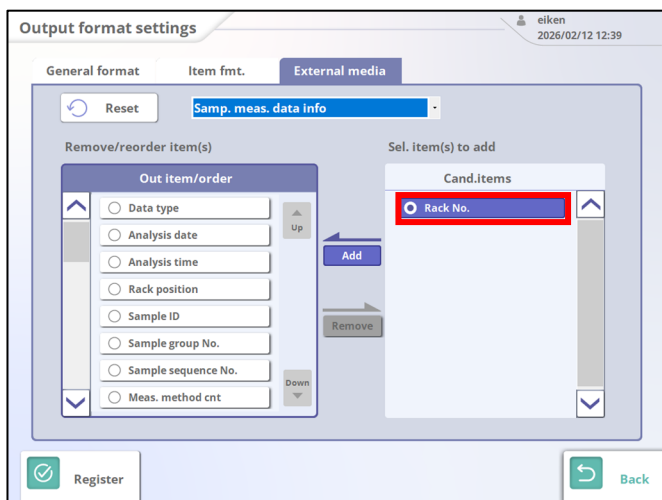
- Samp. meas. data info
- Samp. repl. info
- QC meas. data info
- QC replicate information
- STD meas. data info
- STD repl. info

- To remove output item moves to the "Cand. items".

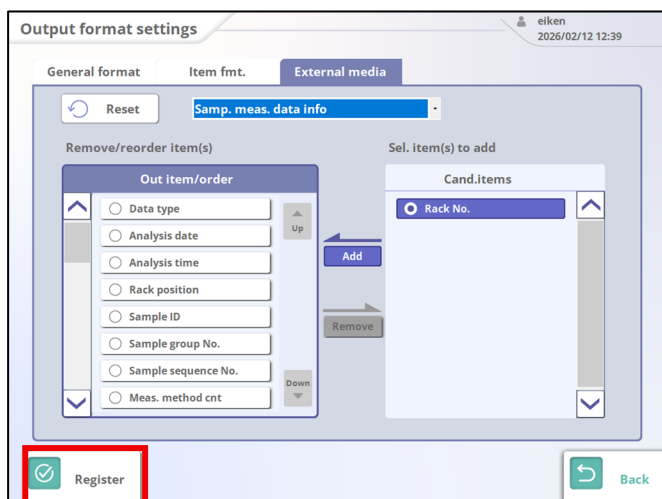
(1) Select the output item to be excluded and touch {Remove}.



(2) The selected item moves to the "Cand. items".

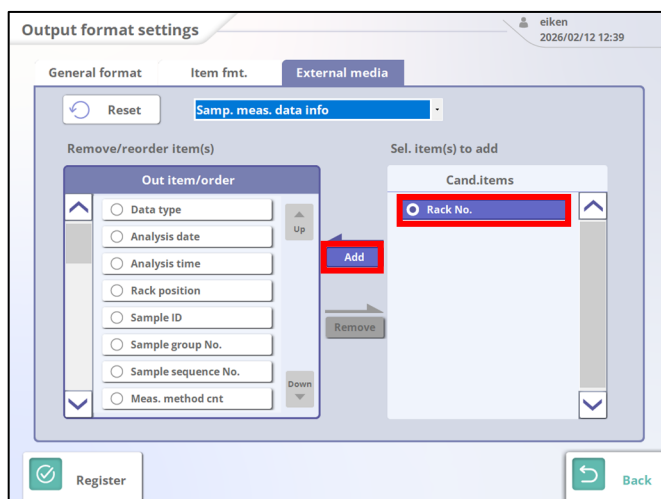


(3) Touch the {Register} button.

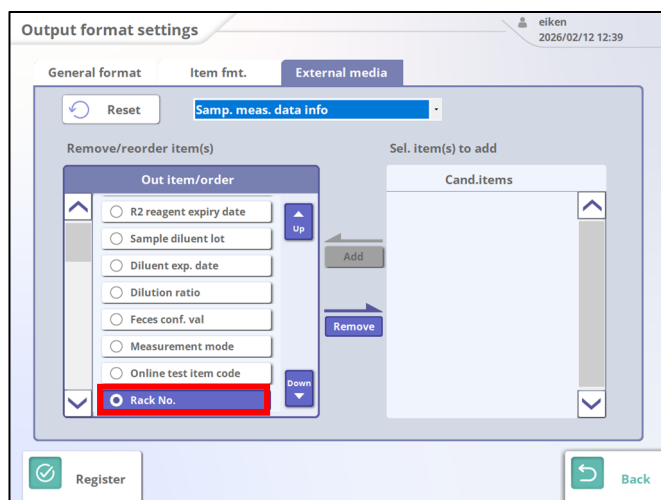


■ To add output items

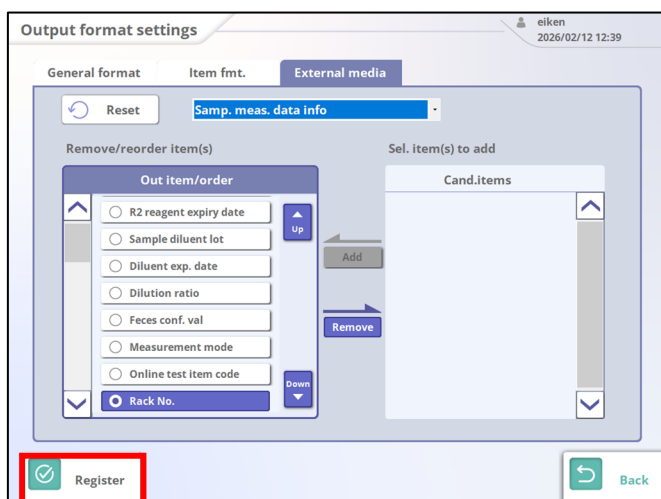
- (1) Select the output item to be added from the [Cand. items] list and touch {Add}.



- (2) The selected item moves to the [Output item/order] list.

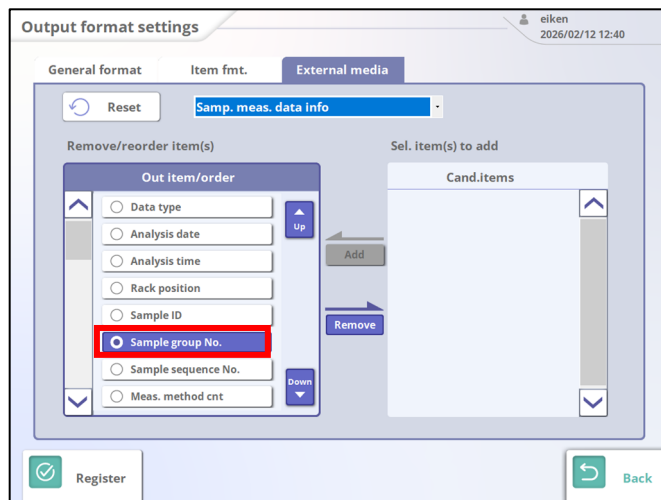


- (3) Touch {Register}.

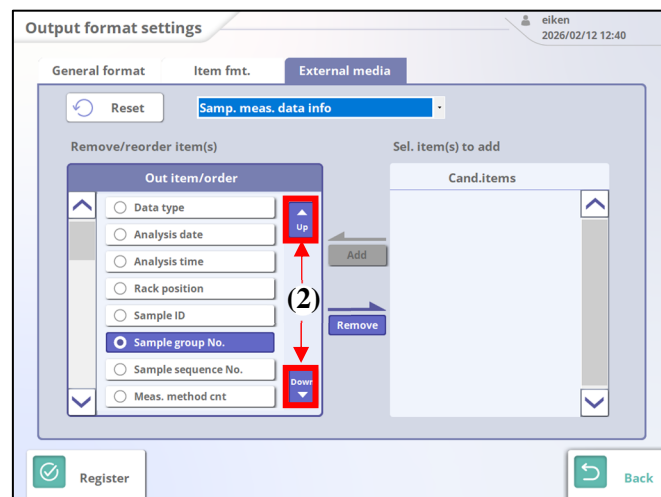


■ To change the order of the output items

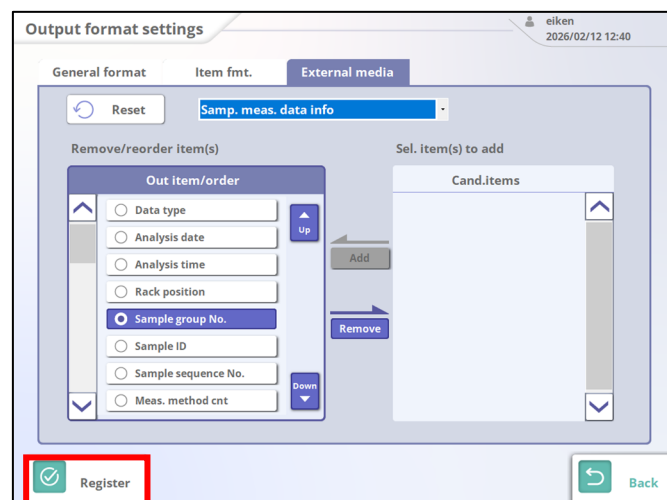
- (1) Select the output item to be reordered from the [Cand. items] list.



- (2) Touch {Up} or {Down} to change the order.



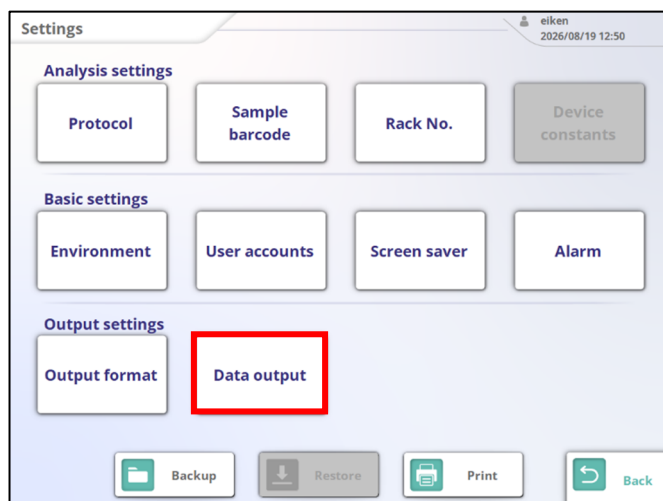
- (3) Touch {Register}.



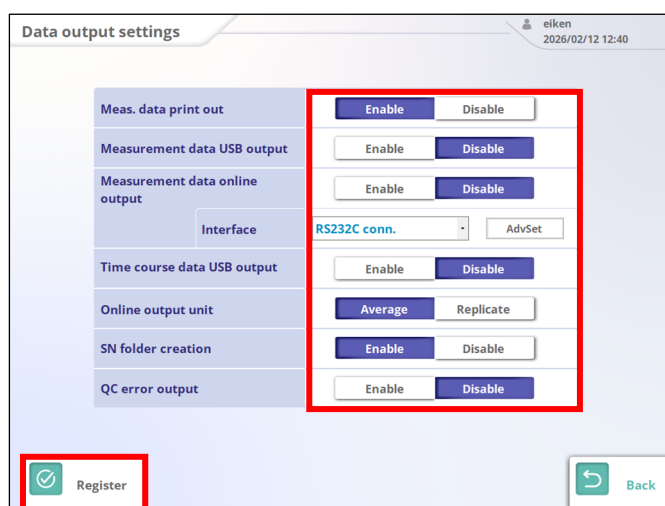
6.3.2. Data output settings

Configure the output method for measurement data.

Only users with administrator privileges can change this setting.



- (1) From the settings menu screen, touch {Data output}.



- (2) Set each item.

- (3) Touch {Register}.

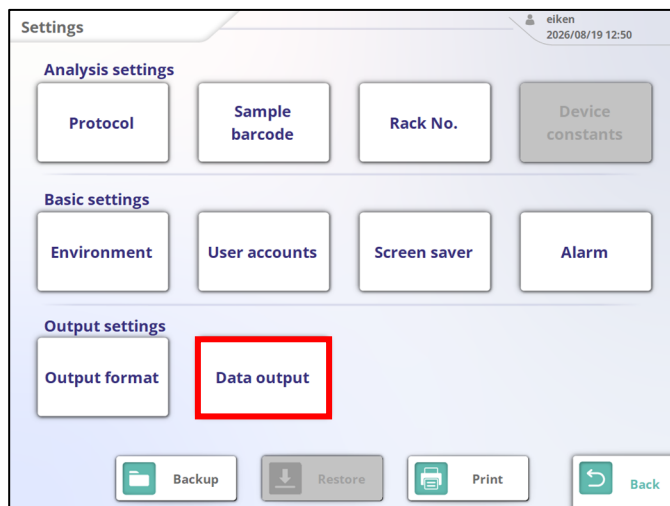
■ Data output setting items

Setting item	Selection and Settings	Contents
Meas. data print out	Enable: Disable:	Prints the measurement data using the printer. Does not print measurement data using the printer.
Measurement data USB output	Enable: Disable:	Automatically outputs measurement data to USB at the end of analysis. Does not automatically output measurement data to USB at the end of analysis.
Measurement data online output	Enable: Disable:	Outputs measurement data online. Does not output measurement data online.
Interface	- LAN connection - RS-232C conn.	When [Measurement data online output] is set to Enable, select the interface used for output. - LAN connection - RS-232C conn.
Online output unit	Average: Replicate:	Outputs the average value of the measurement results online. Outputs all measurement results online.
SN folder creation	Enable: Disable:	Creates an SN folder when outputting measurement data to USB. Do not create an SN folder.
QC error output	Enable: Disable:	Outputs an error when values exceed the upper or lower control limits set in QC settings. Does not output an error when values exceed the QC control limits.

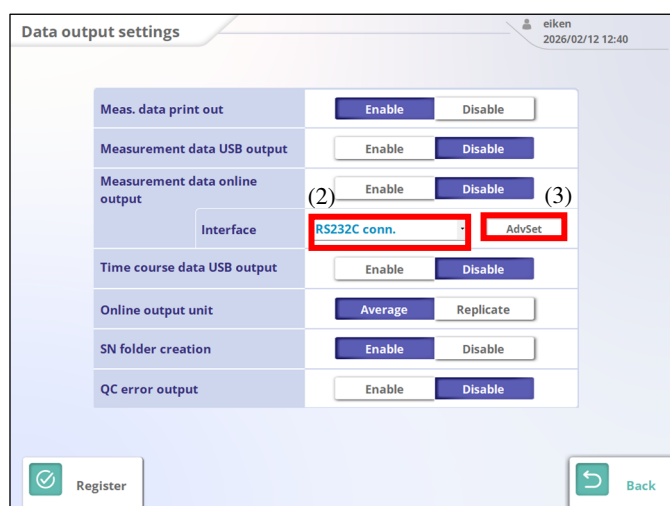
6.3.3. Detailed online settings

Configure the detailed settings for online communication.

Only users with administrator privileges can change this setting.



- (1) From the settings menu screen, touch {Data output}.



- (2) Select the interface used for online communication.

- (3) Touch {AdvSet}.
 LAN connection → LAN connection detailed settings
 RS232C → RS232C connection detailed settings

■ LAN connection

(1) Set each item.

(2) Touch {Complete}.

Setting item	Selection and Settings	Contents
Comm. mode	- HL7 - PLEDIA_LAN	Select the communication mode. - HL7 Communication mode - PLEDIA_LAN Communication mode
Order req.	On: Off:	Sends measurement order requests. Does not send measurement order requests.
LAN1/LAN2	LAN1: LAN2:	Configure LAN1. Configure LAN2.
DHCP settings	Enbl: Dsbl:	Enables DHCP settings. Disables DHCP settings.
IP address	-	Sets the IP address.
Subnet mask	-	Sets the subnet mask address.
Gateway	-	Sets the gateway address.
DNS server	-	Sets the DNS server address.
MAC address	-	Displays the MAC address.
Computer name	-	Sets the computer name.
Message format	Standard: MLLP:	Standard format MLLP format
Port No.	-	Sets the port numbers used for test notification and test request.
Check LAN	-	This is used for factory calibration.

■ RS232C Connection

The screenshot shows the 'Data output settings' window for RS232C connection. The window is titled 'Data out. set. RS232C conn.' and contains the following settings:

- Comm. Mode: PLEDIA(DIANA)
- Order req.: On
- Port name: COM1
- Baud rate: 9600
- Data length: 8
- Parity: NONE
- Stop bits: 1
- Delimiter: STX/ETX
- Check character: SUM
- Transmission protocol: ACK/NAK
- Item delimiter: No

At the bottom, there are three buttons: 'Complete' (with a checkmark icon), 'Check RS-232C', and 'Back' (with a circular arrow icon).

Setting item	Selection and Settings	Contents
Comm. mode	Select the communication mode. - ASTM - PLEDIA (DIANA) - io comp. mode - ASTM (I/O compatible) - ASTM (DIANA compatible)	- ASTM mode - PLEDIA (DIANA) mode - io comp. mode - ASTM (I/O compatible) - ASTM (DIANA compatible)
Order req.	On: Off:	Sends measurement order requests. Does not send measurement order requests.
Port name	-	Selects the port.
Baud rate	2400: 4800: 9600: 19200: 38400:	Selects the baud rate. 2400 baud rate 4800 baud rate 9600 baud rate 19200 baud rate 38400 baud rate
Data length	7: 8:	Selects the data length. 7bit 8bit

Parity	None: ODD: EVEN:	Selects the parity. No parity check is performed. Check with odd parity. Check with even parity.
Stop bits	1: 2:	Selects the stop bits. 1 bit 2 bit
Delimiter	STX/ETX: CR/LF: CF:	Selects the delimiter.
Check character	None: BCC: SUM:	Selects the check character. No check character is used
Transmission procedure	NONE: ACK/NAK:	Selects the transmission procedure. No procedure. Uses ACK/NAK method.
Item delimiter	Yes: No:	Selects whether to use an item delimiter. Separates items. Does not separate items.
Check RS-232C	-	This is used for factory calibration.

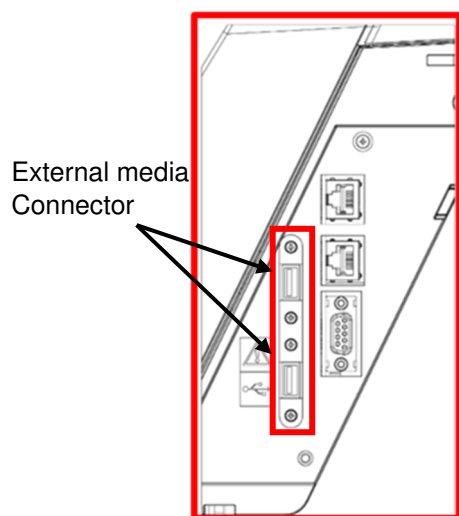
6.4. Back Up and Restore Settings to External Media

This section describes how to back up and restore setting information using external media.

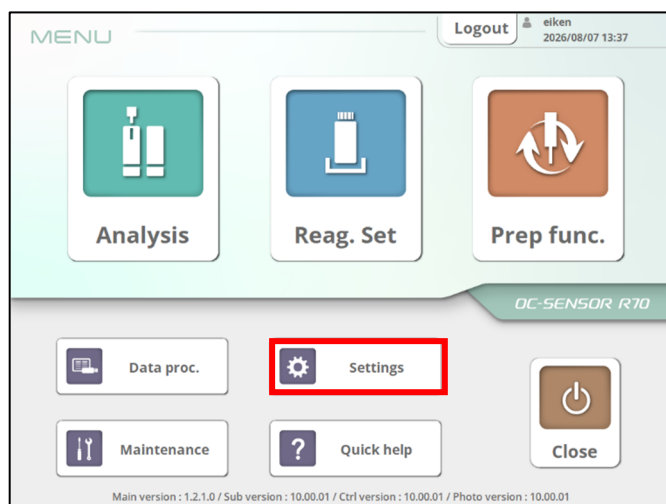
6.4.1. Back up settings information to external media

Back up the setting information to external media.

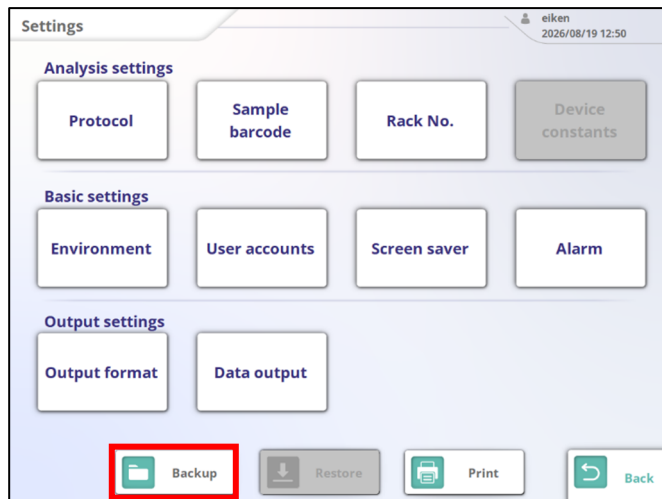
Only users with administrator privileges can change this setting.



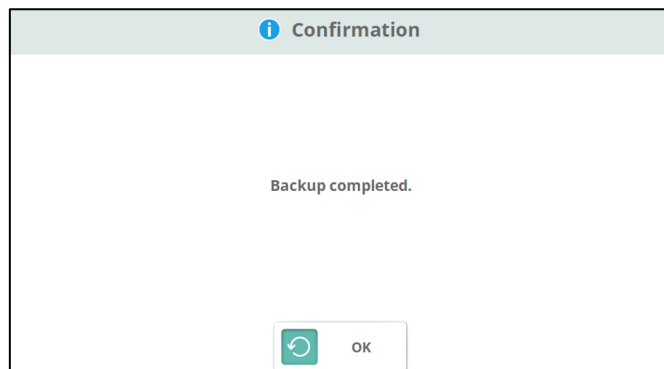
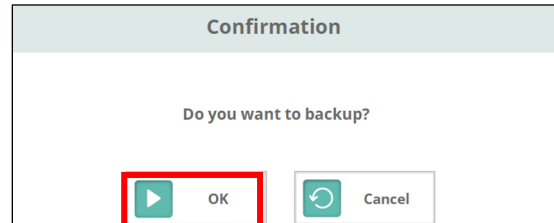
- (1) Connect the external media to the external media connector on the right side of the System.



- (2) From the main menu, touch {Settings}.



- (3) Touch {Backup}.
The [Confirmation] screen is displayed.
Touch {OK}.

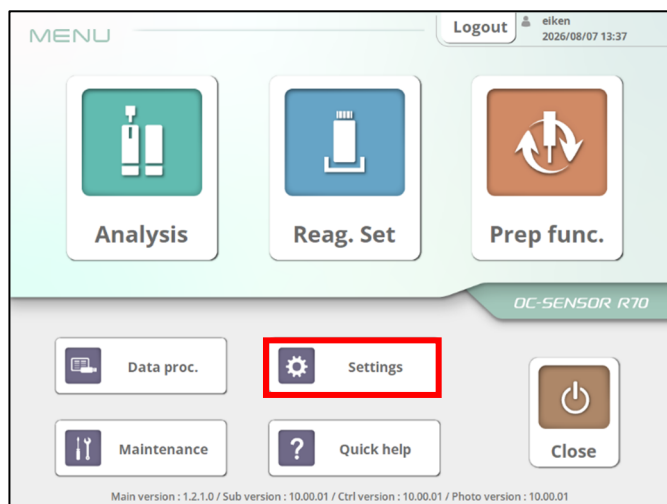


- (4) After the backup is completed, "Backup completed." is displayed.
Press {OK} to close the screen.

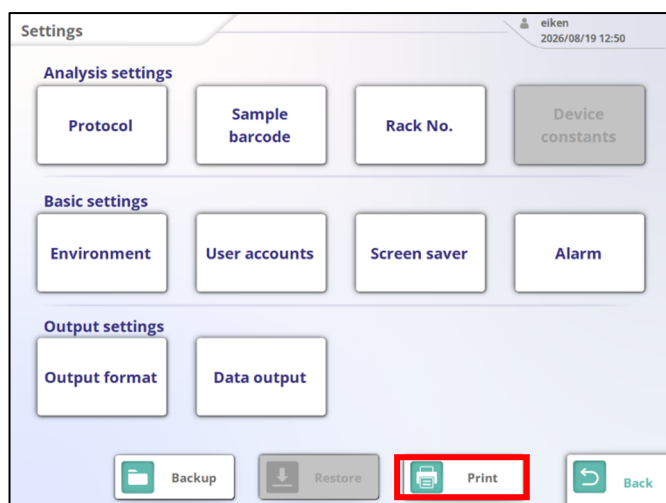
6.5. Print Setting Information

This section describes how to print setting information.

Only users with administrator privileges can change this setting.



- (1) From the main menu, touch {Settings}.



- (2) Touch {Print}.
- The setting information is printed using the printer.

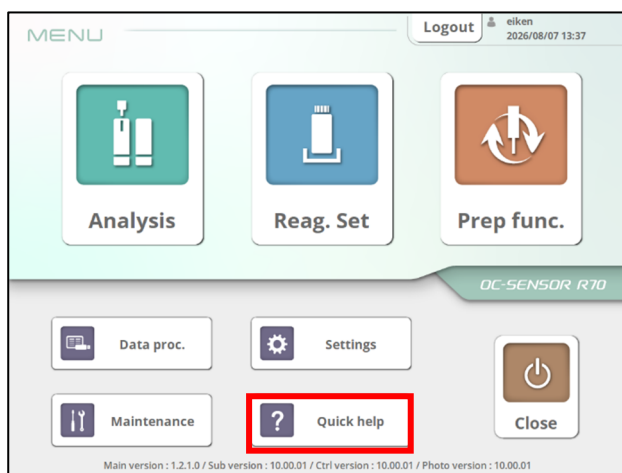
7. Quick Help

The [Quick help] screen is used to confirm the analysis flow and how to operate the System including sample installment.

7.1. Open Quick Help Screen

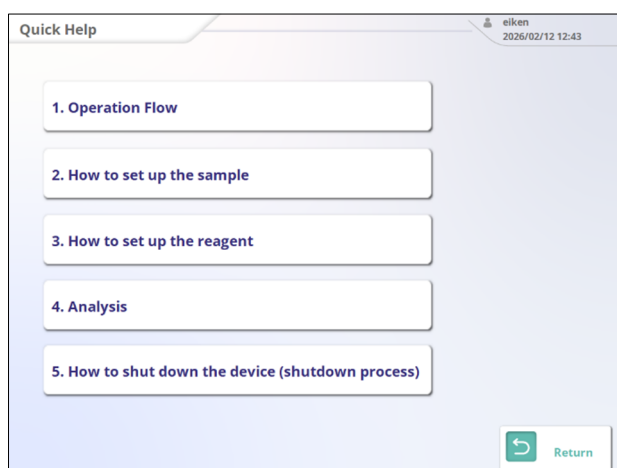
The [Quick help] screen can be opened through the following three paths:

- Open from the [MENU] screen
- Open from the [Analysis top] screen
- Open from the [Analysis status] screen



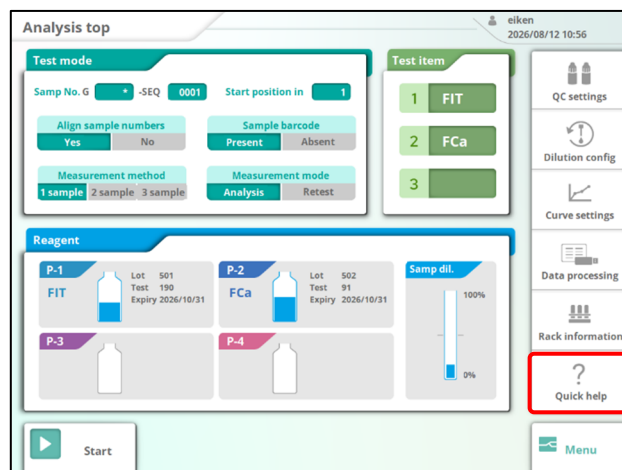
[MENU screen]

- Open from the [MENU] screen
 - (1) From the [MENU] screen, touch {Quick help}.



[Quick help] screen

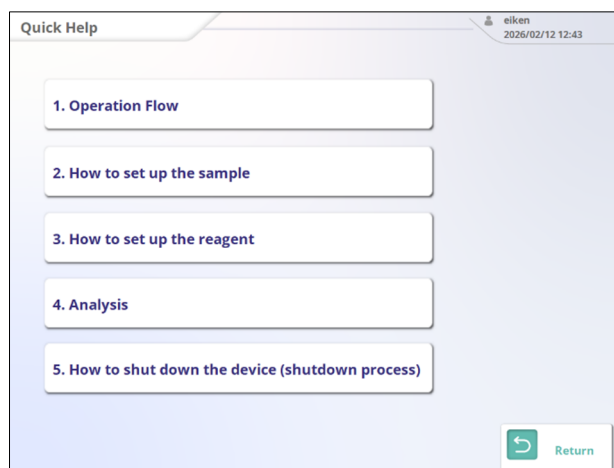
- (2) The quick help screen is displayed.



[Analysis top] screen

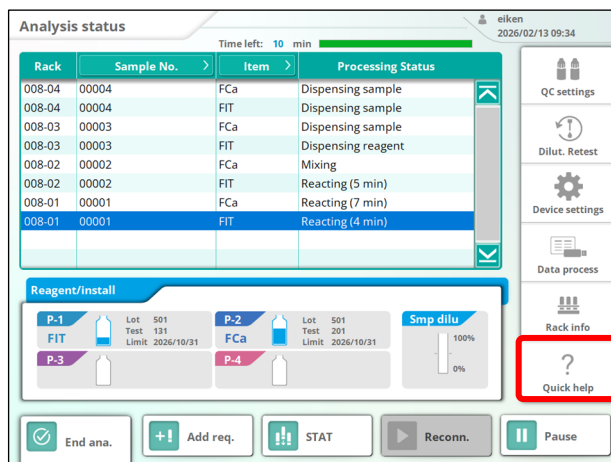
■ Open from the [Analysis top] screen

- (1) From the [Analysis top] screen, touch {Quick help}.



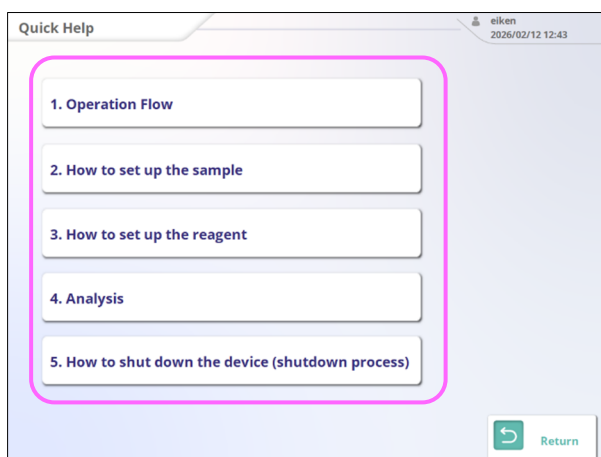
[Quick help] screen

- (2) The quick help screen is displayed.



■ Open from the [Analysis status] screen

- (1) From the [Analysis top] screen, touch {Quick help}.

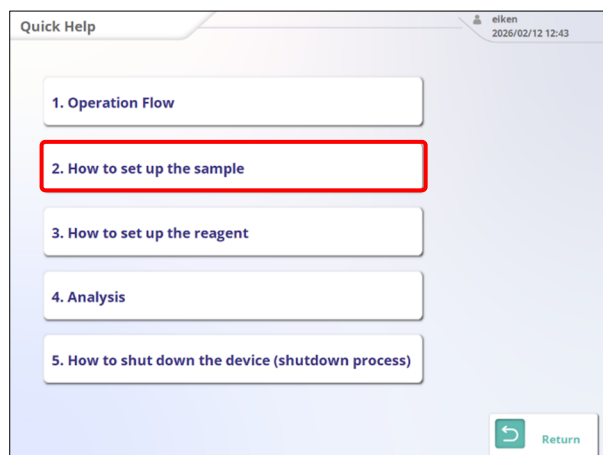


- (2) The quick help screen is displayed.

[Quick help] screen

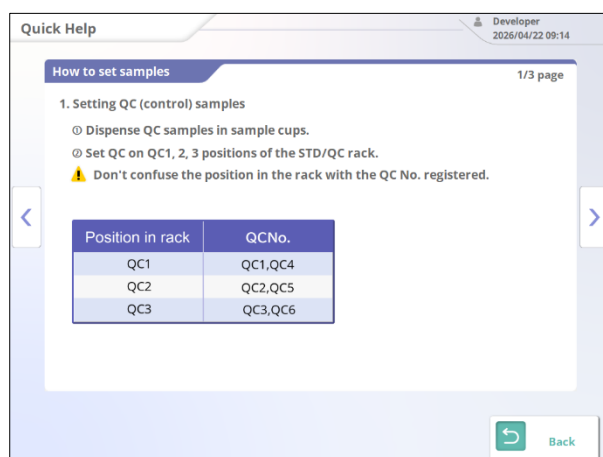
7.2. How to Use the Quick Help Screen

On the quick help screen, touch the item you want to check to view the corresponding information.



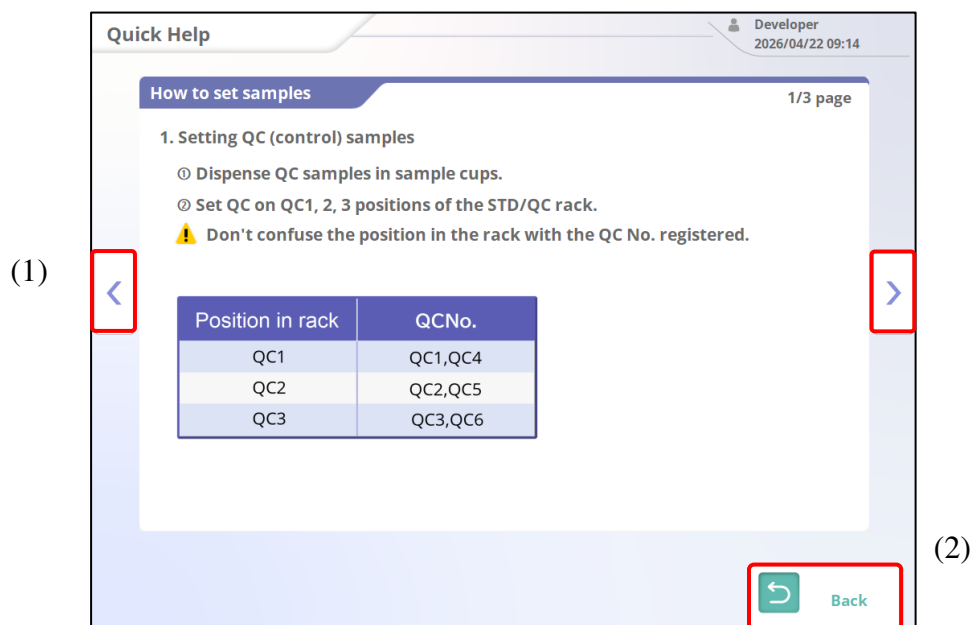
(1) From the [Quick help] screen, touch the item you wish to check.

* The following example explains how to view "2. Sample installation procedure."



(2) The description of the selected item is displayed.

<How to use the screen>

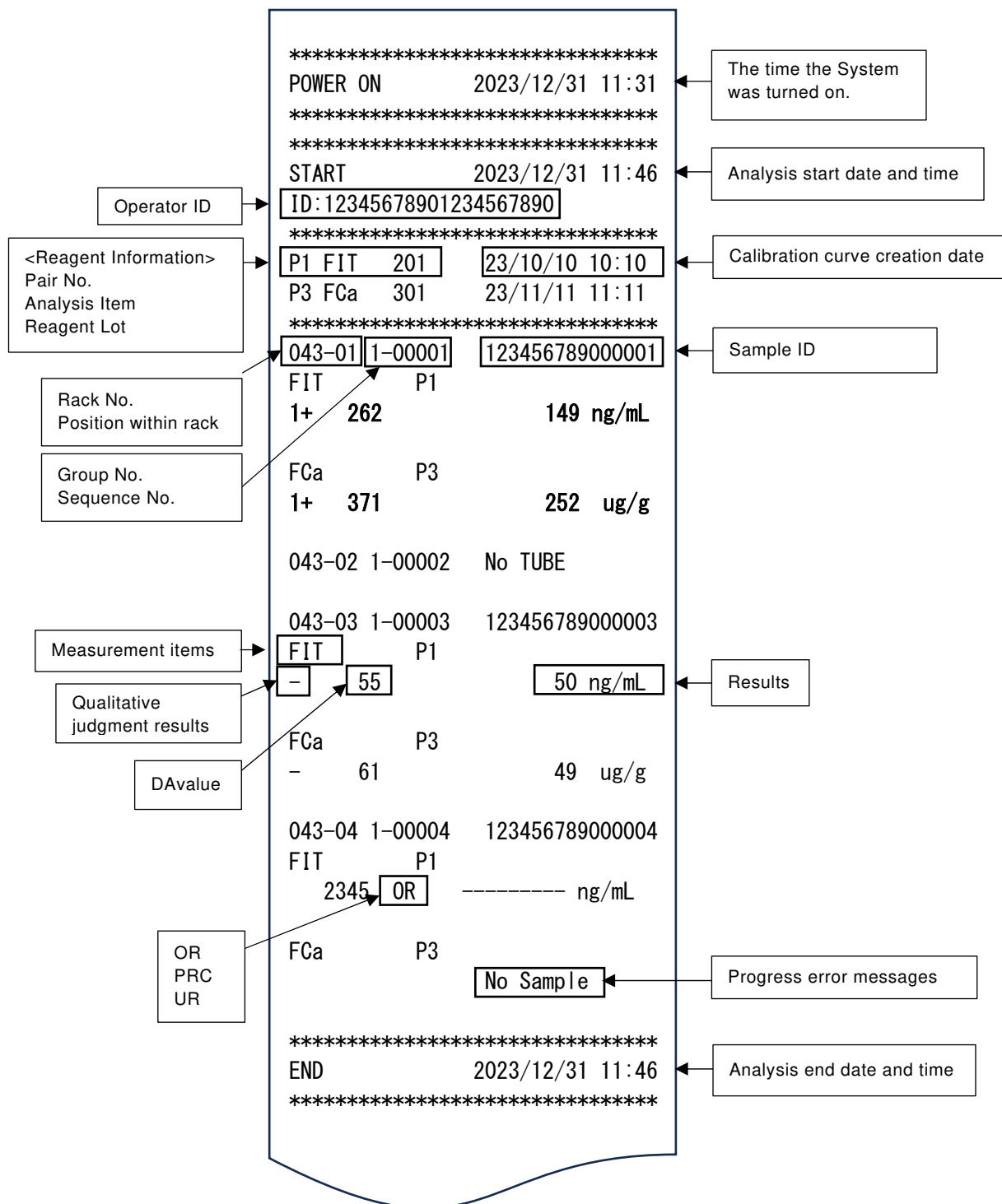


Name	Details
(1) Page forward/back	Allows to move forward or backward through pages within each item.
(2) Back	Returns to the quick help screen.

8. Printing Information

This section explains examples of what is printed and what is printed.

8.1. During sample analysis



8.2. Positive sample printing

- * When the number of replicates is 1, the positive "analysis result" will be printed in bold.

005-01	00001	123456789000001
FIT		
1-	107	75 ng/mL
FCa		
1+	371	252 ug/g

Analysis results are in bold

When the number of replicates is >1, if the mean value is a positive sample, only the mean value line will be printed in bold.

005-01	00001	123456789000001
FIT		
1+	262	149 ng/mL
1+	259	148 ng/mL
1+	264	150 ng/mL

1+	261	149 ng/mL
	1.6	1.1

Only the average value row is bold

SD of DA values

CV value of measured value

8.3 Printing when diluting and retesting

* If the first-stage simultaneous analysis is "None," the diluted retest results will be printed. In the case of a diluted retest, the dilution ratio will be printed next to the analysis item.

005-01	00001	123456789000001
FIT	(A10)	
1+	115	837 ng/mL
FCa	(A10)	
-	61	49 ug/g

Dilution ratio is printed. A* (Dilution ratio in *)

* If simultaneous first-stage analysis is enabled, the measurement results for the first and second dilution ratios will be printed, and the final result will be printed together.

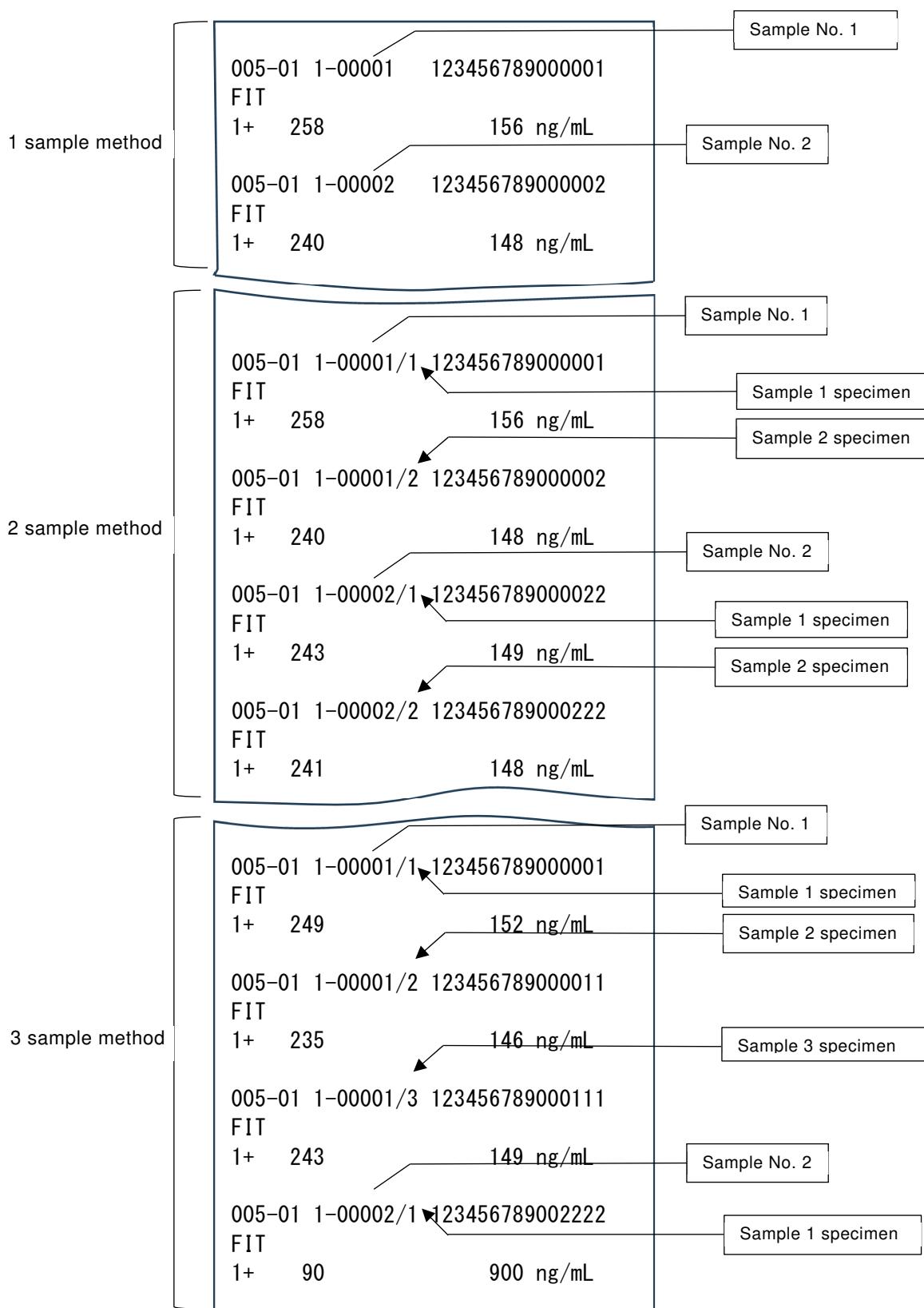
005-01	00001	123456789000001
FIT	(A10)	
1+	115	837 ng/mL
FIT	(A100)	
1+	18	963 ng/mL
FCa	(A10)	
-	61	49 ug/g
=====		
005-01	00001	123456789000001
FIT	(A10)	
1+	18	968 ng/mL
FCa	(A10)	
-	61	49 ug/g
~~~~~		

1st row

2nd row

Final results are printed together

## 8.4 Printing of 1 sample, 2 sample, and 3 sample methods



## 8.5 Printing when creating a calibration curve

*****

FIT STD START  
ID: 12345678901234567890

*****

P1 FIT 201

*****

070-01 STD1

-8	0
-9	1
-8	-2

-----

-8	0
0.0	0.0

-----

070-06 STD6 2330 57

2349 56

2316 53

-----

2330 56

0.0 0.0

-----

*****

FIT CAL. CURVE

*****

	ng/mL	DA1	Rs lt.	DX%
STD1	0	-8	0	
STD2	63	61	63	0.0
STD3	125	149	125	0.0
STD4	250	398	250	0.0
STD5	500	1120	500	0.0
STD6	1000	2330	1000	0.0

CAL CURVE TYPE = 3-SPLINE

2023/12/31 11:46 REAG. LOT. 201

DA

2449

CONC.

1000

Calibration curve graph

Start creating the calibration curve

Reagent lot

DA2 value

DA1 value

DA1 value used for calibration curve calculation

DA2 value used for calibration curve calculation

CV value of DA1

CV value of DA1

Calibration Curve Information (from left):

- STD Points
- Theoretical Value
- DA1
- Fitted Value
- DX%

Types of calibration curves

Calibration curve creation date

Calibration curve preparation reagent lot

- * If the number of STD replicates is  $\geq 3$ , the average DA value among the replicates is printed, excluding the maximum and minimum values.

*****			
FIT    STD START			
ID:12345678901234567890			
*****			
P1 FIT    201			
*****			
070-01	STD1	-8	0
		-9	1
		-8	-2
-----			
		-8	0
		0.0	0.0

Excluding  
maximum/minimum DA  
values

Prints average value

- * If the number of STD replicates is less than 3, the average value among the replicates will be printed.

*****			
FIT    STD START			
ID:12345678901234567890			
*****			
P1 FIT    201			
*****			
070-01	STD1	-8	0
		-10	2
-----			
		-9	1
		0.0	0.0

Prints average value



## 8.6. Printing during QC measurement

*****			Starting QC measurements
FIT	QC	C1/C2/C3	
*****			
070-08	C-8000		
	107	70 ng/mL	Value
	105	69 ng/mL	
	108	70 ng/mL	
-----			
	107	70 ng/mL	Average of the measured values
	0.5	0.7	
070-09	C-8001		CV value of measured value
	331	144 ng/mL	
	331	144 ng/mL	
	333	145 ng/mL	
-----			
	332	144 ng/mL	
	0.5	0.3	
070-10	C-8002		
	1706	462 ng/mL	
	1650	451 ng/mL	
	1720	464 ng/mL	
-----			
	1692	459 ng/mL	
	5.7	1.2	

QC Sample No.  
C-Sequence No.

## 8.7. Printing of fluctuations in the positivity rate

You can print out information on fluctuations in the positivity rate from the positivity rate fluctuation screen.

* By sample type/daily

[Pos rate] (Sample)	
Daily FIT	
2024/6/10	100.0%
2024/6/11	59.5%
2024/6/12	30.0%
2024/6/13	40.2%

Processing unit

Positive rate

* By patient / weekly

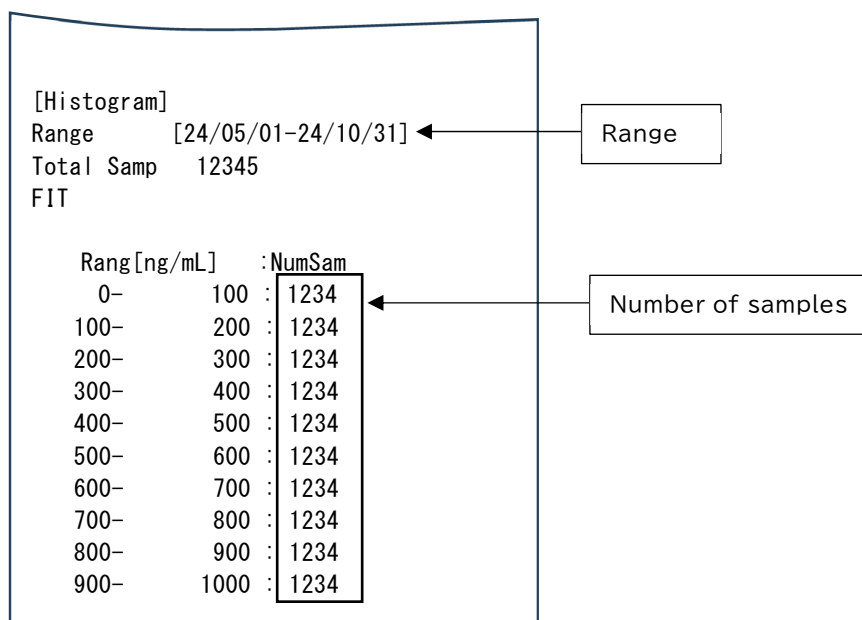
[Pos rate] (Patient)	
Weekly FIT	
2024/6/10	95.0%
2024/6/11	20.5%
2024/6/12	35.0%
2024/6/13	10.0%

* By sample type / monthly

[Pos rate] (Sample)	
Monthly FIT	
2024/6/10	10.0%
2024/6/11	39.0%
2024/6/12	20.0%
2024/6/13	15.2%

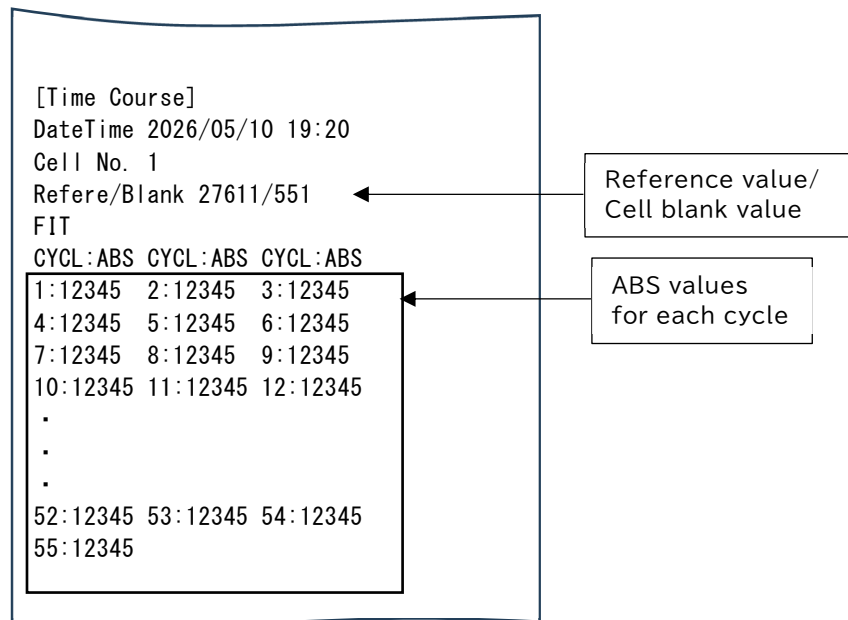
## 8.8. Printing histograms

You can print histogram data directly from the histogram screen.



## 8.9. Printing time course

You can print time course information from the time course screen.



## 8.10. Printing error messages

The error message is printed as follows.

```
*****
POWER ON      2026/12/31 11:31
*****
*****
START        2026/12/31 11:46
ID:12345678901234567890
*****
P1 F-Hb    201    26/10/10 10:10
P3 F-Tf    301    26/11/11 11:11
*****
043-01 1-00001 123456789000001
F-Hb      P1
1+   262          149 ng/mL

F-Tf      P3
1+   111          97 ng/mL

043-02 1-00002  No TUBE
*****
END        2026/12/31 11:46
*****
```

Progress error messages

For details on the types of error messages, please refer to [11.2 Error (Analysis Progress Error)].



## 9. External Media Output

Based on the control limits set on the [QC measurement] screen ({Settings} tab), the System saves the information pertaining to the following to external media:

- Sample measurement data
- Sample replicate
- QC measurement data
- QC replicate
- STD measurement data
- STD replicate
- Time-course data

The information output is variable-length.

### 9.1. Sample Measurement Data Information

Save the sample measurement data.

■ File name: ocsamp.csv

No.	Item name	Remarks ( $\Delta$ = blank [20H])	Output
1	Data type	Analysis data, re-measurement data: 'N $\Delta$ ' STAT data: 'S $\Delta$ ' Retest data (including dilution retest): 'A $\Delta$ ' If the data has been edited, set E in $\Delta$ . (Example) Edit analysis data: 'NE'	Yes
2	Analysis date	Date of analysis (Example) April 23, 2026 → 2026/04/26	-
3	Analysis time	Time of analysis (24-hour format) (Example) 2:05 PM → 14:05	-
4	Rack No.	Barcode information affixed to the rack	-
5	Rack position	Position in the rack: 1–10	-
6	Sample ID	Barcode information affixed to the sample bottle (*1)	Yes
7	Sample group No.	Sample classification: 0–9 (When the sample group No. is *, output is "0")	-
8	Sample sequence No.	Measurement sequence No.: 1-99999 Sample: 1–99999, STAT sample: 1–99999	-
9	Measurement method counter	Sample classification by measurement method: 1–3 (Information indicating which sample number).	Yes
10	Replicate count	Number of replicates for replicate measurement: 1-10	-
11	DA value	Value of the 3rd photometry point – the 1st photometry point. See [10.2 DA Value Calculation].	Yes
12	Measurement value	Calculated measured value: up to 7 digits for integer part + 1 decimal place (Decimal places can be changed in "Output format settings")	Yes
13	Flag	Qualitative result obtained by converting the measured value using cutoff values $\Delta$ –, $\Delta$ +, 1+, 2+, 3+	Yes
14	SD value	SD of the measured values (statistic)	Yes

15	CV value	CV of the measured values (statistic)	Yes
16	Error code	See the "Error Code List for External Media Output" at the end of this section.	Yes
17	Test item code	Code of the measured test item Not output in the case of an order error (CSV output becomes ", , ")	-
18	Test item name	Name of the measured test item Not output in the case of an order error (CSV output becomes ", , ")	Yes
19	Test result unit	Unit of the measured test result.	Yes
20	Normal value range 1	Configured cutoff 1 value.	Yes
21	Normal value range 2	Configured cutoff 2 value. ("*" if not set)	Yes
22	Normal value range 3	Configured cutoff 3 value. ("*" if not set)	Yes
23	Operator ID	Outputs the ID of the operator who performed the analysis.	Yes
24	R1 reagent lot	Lot number of the R1 reagent used.	Yes
25	R1 reagent expiry date	Expiry date of the R1 reagent used.	Yes
26	R2 reagent lot	Lot number of the R2 reagent used.	Yes
27	R2 reagent expiry date	Expiry date of the R2 reagent used.	Yes
28	Sample diluent lot	Lot number of the sample diluent used. (If not used, ", , " is output)	Yes
29	Diluent exp. date	Expiry date of the sample diluent used. (If the expiry date cannot be determined, ", , " is output)	Yes
30	Dilution factor	Sample dilution factor for retest (dilution test). (Outputs "0" during normal analysis) 0, 1, 10, 20, 100, 200, 400	Yes
31	Reserve1		Yes
32	Measurement mode	Outputs "A" for current mode.	Yes
33	Online test item code	Online-specific code corresponding to the measured test item code. Not output in the case of an order error. (CSV output becomes ", , ")	Yes
34	Online test item name	Online-specific name corresponding to the measured test item name. Not output in the case of an order error. (CSV output becomes ", , ")	Yes

- Item names are written as a header at the beginning of the file, followed by data.
- Each item is separated by a comma (,).
- The output order and contents depend on the output item selection settings in output format settings.
- A delimiter CR/LF is appended after the final output item, and EOF is appended at the end of the file.
- All items except analysis date, analysis time, rack No., test item code, and test item name are zero-suppressed.
- Items marked "Yes" in the output-enabled column can be set to not output in output format settings.

(*1) When a 2D code is used, up to 50 characters are output for the sample ID.



## 9.2. Sample Replicate Information

Save replicate information for samples.

■ File name: ocrsamp.csv

No.	Item name	Remarks ( $\Delta$ = blank [20H])	Output
1	Data type	Analysis data, re-measurement data: 'N $\Delta$ ' STAT data: 'S $\Delta$ ' Retest data (including dilution retest): 'A $\Delta$ ' If the data has been edited, set E in $\Delta$ . (Example) Edit analysis data: 'NE'	Yes
2	Analysis date	Date of analysis. (Example) April 23, 2026 → 2026/04/26	-
3	Analysis time	Time of analysis (24-hour format). (Example) 2:05 PM → 14:05	-
4	Relative cell No.	See "9.2. Sample Replicate Information."	Yes
5	Rack No.	Barcode information affixed to the rack.	-
6	Rack position	Position in the rack: Displayed as 1-10.	-
7	Sample ID	Barcode information affixed to the sample bottle. (*1)	Yes
8	Sample group No.	Sample classification: : Displayed as 0-9. (When the sample group No. is *, output is "0")	-
9	Sample sequence No.	Measurement sequence number: Displayed as 1-99999. - This the reservation number. Display: Sample:1-99999, STAT sample: 1-99999.	-
10	Replicate counter	Number of replicates for replicate measurement: Displayed as 1-10.	-
11	A0 value	See [10.2 DA Value Calculation].	Yes
12	A1 value	See [10.2 DA Value Calculation].	Yes
13	A2 value	See [10.2 DA Value Calculation].	Yes
14	A3 value	See [10.2 DA Value Calculation].	Yes
15	DA1 value	See [10.2 DA Value Calculation].	Yes
16	DA2 value	See [10.2 DA Value Calculation]. (Output can be enabled or disabled in "Output format settings – External media.")	Yes
17	Measurement value	Calculated measurement value. Displayed as up to 7 digits for integer part + 1 decimal place (Decimal places can be changed in "Output format settings")	Yes
18	Flag	Qualitative result obtained by converting the measured value using cutoff values (*1) Displayed as $\Delta -$ , $\Delta +$ , 1+, 2+, 3+.	Yes
19	Error code	See the "Error Code List for External Media Output" at the end of this section.	Yes

20	Test item code	Code of the measured test item. Not output in the case of an order error (CSV output becomes “ , , ”)	-
21	Test item name	Name of the measured test item. Not output in the case of an order error . (CSV output becomes “ , , ”)	Yes
22	Test result unit	Unit of the measured test result.	Yes
23	Normal value range 1	Configured cutoff 1 value.	Yes
24	Normal value range 2	Configured cutoff 2 value. (“*” if not set)	Yes
25	Normal value range 3	Configured cutoff 3 value. (“*” if not set)	Yes
26	Operator ID	Outputs the ID of the operator who performed the analysis if the operator function is enabled.	Yes
27	R1 reagent lot	Lot number of the R1 reagent used.	Yes
28	R1 reagent expiry date	Expiry date of the R1 reagent used.	Yes
29	R2 reagent lot	Lot number of the R2 reagent used.	Yes
30	R2 reagent expiry date	Expiry date of the R2 reagent used.	Yes
31	Sample diluent lot	Lot number of the sample diluent used. (If not used, “ , , ” is output)	Yes
32	Sample diluent expiry date	Expiry date of the sample diluent used. (If the expiry date cannot be determined, “ , , ” is output)	Yes
33	Dilution factor	Sample dilution factor for retest (dilution test). (Outputs “0” during normal analysis) Displayed as 0, 1, 10, 20, 100, 200, 400.	Yes
34	Reserve1		Yes
35	Measurement mode	Outputs “A” for current mode.	Yes
36	Online test item code	Online-specific code corresponding to the measured test item code. Not output in the case of an order error (CSV output becomes “ , , ”)	Yes
37	Online test item name	Online-specific name corresponding to the measured test item name. Not output in the case of an order error (CSV output becomes “ , , ”)	Yes

- Item names are written as a header at the beginning of the file, followed by data.
- Each item is separated by a comma (,).
- The output order and contents depend on the output item selection settings in output format settings.
- All items except analysis date, analysis time, rack No., test item code, and test item name are zero-suppressed.
- Items marked “Yes” in the output-enabled column can be set to not output in output format settings.

- “Sample unset” is output in the sample replicate information.
- (*1) When a 2D code is used, up to 50 characters are output for the sample ID.

### 9.3. QC Measurement Data Information

Save the QC measurement data information.

■ File name: ocqc.csv

No.	Item name	Remarks	Output
1	Data type	QC data: 'Cx'x: QC number from 1 to 6	Yes
2	Analysis date	See "9.1. Sample Measurement Data Information."	Yes
3	Analysis time	See "9.1. Sample Measurement Data Information."	Yes
4	Rack No.	See "9.1. Sample Measurement Data Information."	Yes
5	Rack position	See "9.1. Sample Measurement Data Information."	Yes
6	Sample sequence No.	See "9.1. Sample Measurement Data Information."	Yes
7	QC lot	QC lot	Yes
8	Replicate count	See "9.1. Sample Measurement Data Information."	Yes
9	DA value	See "9.1. Sample Measurement Data Information."	Yes
10	Measurement value	See "9.1. Sample Measurement Data Information."	Yes
11	Flag	See "9.1. Sample Measurement Data Information."	Yes
12	SD value	See "9.1. Sample Measurement Data Information."	Yes
13	Error code	See the "Error Code List for External Media Output" at the end of this section.	Yes
14	Test item code	Code of the measured test item	Yes
15	Test item name	Name of the measured test item	Yes
16	QCID	Barcode information affixed to the QC container (*1)	Yes
17	Test result unit	Units of the measured test results	Yes
18	Operator ID	See "9.1. Sample Measurement Data Information."	Yes
19	QC expiry date	Expiry date of QC	Yes
20	R1 reagent lot	See "9.1. Sample Measurement Data Information."	Yes
21	R1 reagent expiry date	See "9.1. Sample Measurement Data Information."	Yes
22	R2 reagent lot	See "9.1. Sample Measurement Data Information."	Yes
23	R2 reagent expiry date	See "9.1. Sample Measurement Data Information."	Yes
24	Measurement mode	Outputs "A" for current mode.	Yes
25	Online test item code	Online-specific code corresponding to the measured test item code. Not output in the case of an order error. (CSV output becomes " , ")	Yes
26	Online test item name	Online-specific name corresponding to the measured test item name. Not output in the case of an order error. (CSV output becomes " , ")	Yes

- Item names are written as a header at the beginning of the file, followed by data.
  - Each item is separated by a comma ( , ).
  - All items except analysis date, analysis time, rack No., test item code, and test item name are zero-suppressed.
  - Items marked "Yes" in the output-enabled column can be set to not output in output format settings.
- (*1) When a 2D code is used, the QCID is output with the number of digits read (up to 50 digits).

## 9.4. QC Replicate Information

Save information for each QC replicate.

■ File name: ocrqc.csv

No.	Item name	Remarks	Output
1	Data type	See "9.3. QC Measurement Data Information."	Yes
2	Analysis date	See "9.1. Sample Measurement Data Information."	Yes
3	Analysis time	See "9.1. Sample Measurement Data Information."	Yes
4	Relative cell No.	See "9.2. Sample Replicate Information."	Yes
5	Rack No.	See "9.1. Sample Measurement Data Information."	Yes
6	Rack position	See "9.1. Sample Measurement Data Information."	Yes
7	Sample sequence No.	See "9.1. Sample Measurement Data Information."	Yes
8	QC lot	See "9.3. QC Measurement Data Information."	Yes
9	Replicate counter	See "9.3. Sample Replicate Information."	Yes
10	A0 value	See [10.2 DA Value Calculation].	Yes
11	A1 value	See [10.2 DA Value Calculation].	Yes
12	A2 value	See [10.2 DA Value Calculation].	Yes
13	A3 value	See [10.2 DA Value Calculation].	Yes
14	DA1 value	See [10.2 DA Value Calculation].	Yes
15	DA2 value	See [10.2 DA Value Calculation].	Yes
16	Measurement value	See "9.1. Sample Measurement Data Information."	Yes
17	Error code	See the "Error Code List for External Media Output" at the end of this section.	Yes
18	Test item code	Code of the measured test item	Yes
19	Test item name	Name of the measured test item	Yes
20	QCID	ID for QC	Yes
21	Test result unit	Units of the measured test results	Yes
22	Operator ID	See "9.1. Sample Measurement Data Information."	Yes
23	QC expiry date	See "9.3. QC Measurement Data Information."	Yes
24	R1 reagent lot	See "9.1. Sample Measurement Data Information."	Yes
25	R1 reagent expiry date	See "9.1. Sample Measurement Data Information."	Yes
26	R2 reagent lot	See "9.1. Sample Measurement Data Information."	Yes
27	R2 reagent expiry date	See "9.1. Sample Measurement Data Information."	Yes
28	Measurement mode	Outputs "A" for current mode.	Yes
29	Online test item code	Online-specific code corresponding to the measured test item code. Not output in the case of an order error. (CSV output becomes " , ")	Yes
30	Online test item name	Online-specific name corresponding to the measured test item name. Not output in the case of an order error. (CSV output becomes " , ")	Yes

- Item names are written as a header at the beginning of the file, followed by data.
- Each item is separated by a comma (, ).
- All items except analysis date, analysis time, rack No., test item code, and test item name are zero-suppressed.
- Items marked “Yes” in the output-enabled column can be set to not output in output format settings.

(*1) When a 2D code is used, the QCID is output with the number of digits read (up to 50 digits).

## 9.5. STD Measurement Data Information

Save STD measurement data information.

■ File name: ocstd.csv

No.	Item name	Remarks	Output
1	Analysis date	See "9.1. Sample Measurement Data Information."	Yes
2	Analysis time	See "9.1. Sample Measurement Data Information."	Yes
3	Rack No.	See "9.1. Sample Measurement Data Information."	Yes
4	Rack position	See "9.1. Sample Measurement Data Information."	Yes
5	STD point No.	Measurement point No. (STD1 to STD6): 1-6	Yes
6	DA1 value	See [10.2 DA Value Calculation].	Yes
7	DA2 value	See [10.2 DA Value Calculation].	Yes
8	DA1 back-fit value	Concentration value obtained by applying DA1 to the calibration curve	Yes
9	DA1 CV value	CV of DA1 (statistic)	Yes
10	DA2 CV value	CV of DA2 (statistic)	Yes
11	DA1 SD value	SD of DA1 (statistic)	Yes
12	DA2 SD value	SD of DA2 (statistic)	Yes
13	Theoretical value	STD concentration	Yes
14	Replicate count	Number of STD replicates	Yes
15	Error code	See the "Error Code List for External Media Output" at the end of this section.	Yes
16	Test item code	Code of the measured test item	Yes
17	Test item name	Name of the measured test item	Yes
18	R1 reagent lot	See "9.1. Sample Measurement Data Information."	Yes
19	R1 reagent expiry date	See "9.1. Sample Measurement Data Information."	Yes
20	R2 reagent lot	See "9.1. Sample Measurement Data Information."	Yes
21	R2 reagent expiry date	See "9.1. Sample Measurement Data Information."	Yes
22	Calibrator lot	Calibrator lot	Yes
23	Calibrator expiry date	Expiry date of calibrator lot	Yes
24	Measurement mode	Outputs "A" for current mode.	Yes
25	Online test item code	Online-specific code corresponding to the measured test item code. Not output in the case of an order error. (CSV output becomes ", ,")	Yes
26	Online test item name	Online-specific name corresponding to the measured test item name. Not output in the case of an order error. (CSV output becomes ", ,")	Yes

- Item names are written as a header at the beginning of the file, followed by data.
- Each item is separated by a comma ( , ).

- All items except analysis date, analysis time, rack No., test item code, and test item name are zero-suppressed.
- Items marked “Yes” in the output-enabled column can be set to not output in output format settings.



## 9.6. STD Replicate Information

Save information for each STD replicate.

■ File name: ocrstd.csv

No.	Item name	Remarks	Output
1	Analysis date	See "9.1. Sample Measurement Data Information."	Yes
2	Analysis time	See "9.1. Sample Measurement Data Information."	Yes
3	Relative cell No.	See "9.2. Sample Replicate Information."	Yes
4	Rack No.	See "9.1. Sample Measurement Data Information."	Yes
5	Rack position	See "9.1. Sample Measurement Data Information."	Yes
6	STD point No.	See "9.5. STD Measurement Data Information."	Yes
7	Replicate counter	See "9.2. Sample Replicate Information."	Yes
8	A0 value	See [10.2 DA Value Calculation].	Yes
9	A1 value	See [10.2 DA Value Calculation].	Yes
10	A2 value	See [10.2 DA Value Calculation].	Yes
11	A3 value	See [10.2 DA Value Calculation].	Yes
12	DA1 value	See [10.2 DA Value Calculation].	Yes
13	DA2 value	See [10.2 DA Value Calculation].	Yes
14	Error code	See the "Error Code List for External Media Output" at the end of this section.	Yes
15	Test item code	Code of the measured test item	Yes
16	Test item name	Name of the measured test item	Yes
17	R1 reagent lot	See "9.1. Sample Measurement Data Information."	Yes
18	R1 reagent expiry date	See "9.1. Sample Measurement Data Information."	Yes
19	R2 reagent lot	See "9.1. Sample Measurement Data Information."	Yes
20	R2 reagent expiry date	See "9.1. Sample Measurement Data Information."	Yes
21	Calibrator lot	See "9.5. STD Measurement Data Information."	Yes
22	Calibrator expiry date	See "9.5. STD Measurement Data Information."	Yes
23	Measurement mode	Outputs "A" for current mode.	Yes

- Item names are written as a header at the beginning of the file, followed by data.
- Each item is separated by a comma ( , ).
- After the comma following the error code, a delimiter (CR/LF) is appended after the test item name, and an EOF is appended at the end of the file.
- All items except analysis date, analysis time, rack No., test item code, and test item name are zero-suppressed.
- Items marked "Yes" in the output-enabled column can be set to not output in output format settings.

## 9.7. Time Course Data Information

Save the information of the time course data.

■ File name: tcourseabs###.csv

■ File name: tcourseadc###.csv

* ### indicates the wavelength; create a separate file for each wavelength.

* Create only the CSV file for the selected wavelength.

No.	Item name	Remarks	Output
1	Channel	Input channel No.	-
2	Wavelength	Wavelength	-
3	Cell	Relative cell No.	-
4	Reference	Reference value used for ABS calculation	-
5	Blank	Target cell blank value	-
6	1 Cycle	See [10.2 DA Value Calculation]. *Use the same cycle number as the photometry cycle (T1, T2, T3, etc.).	-
7	2 Cycle	See [10.2 DA Value Calculation].	-
.	.	.	-
.	.	.	-
.	.	.	-
n	n Cycle	See [10.2 DA Value Calculation] ↑	-

- No header is included; data only are output.
- Each item is separated by a comma ( , ).
- A delimiter CR/LF is appended after the test item name, and EOF is appended at the end of the file.
- All items except analysis date, analysis time, test item code, and test item name are zero-suppressed.

## 9.8. Histogram Information

Save histogram information.

■ File name: ochstgrm.txt

No.	Item name	Remarks	
1	Title 1	Outputs “Histogram”	
2	Line break	CR/LF	
3	Title 2	Outputs “Date range”	
4	Comma	(,)	
5	Date range start	The first date of the calculation target data.	
6	Comma	(,)	
7	Date range end	The final date of the calculation target data.	
8	Line break	CR/LF	
9	Title 3	Outputs “Test item information”	
10	Comma	(,)	
11	Test item code	Code of the measured test item	
12	Comma	(,)	
13	Test item name	Name of the measured test item	
14	Line break	CR/LF	
15	Title 4	Outputs "Measurement range" and "Number of samples."	
16	Line break	CR/LF	
17		*Repeat 17-1 to 17-4 for the number of measurement ranges.	
	1	Measurement range	Upper and lower limits for each class: lower limit value – upper limit value
	2	Comma	(,)
	3	Number of samples	Number of samples in the class.
	4	Line break	CR/LF
18	Title 5	Outputs “Total number of samples”	
19	Comma	(,)	
20	Total number of samples	Total number of samples.	
21	Line break	CR/LF	

- As shown in the output example, the title "Histogram" is added at the beginning.

## 9.9. Positive Variation Rate Information

Save the positive variation rate information.

■ File name: ocprmps.txt

No.		Item name	Remarks
1		Title 1	Outputs “Positive rate variation by subject”
2		Line break	CR/LF
3		Title 2	Outputs “Date”
4		Comma	(,)
5		*Repeat 5-1 to 5-2 for the number of aggregation units.	
	1	Date	When the positive rate is calculated on a weekly or monthly basis, the start date of the week or month.
	2	Comma	(,)
6		Line break	CR/LF
7		Title 3	Outputs “Test item information”
8		Comma	(,)
9		Test item code	Code of the measured test item
10		Comma	(,)
11		Test item name	Name of the measured test item
12		Line break	CR/LF
13		Title 4	Outputs “Positive rate (%)”
14		Comma	(,)
15		*Repeat 15-1 to 5-2 for the number of aggregation units.	
	1	Positive rate (%)	Rate of positive subjects among the total number of subjects (Number of positive subjects ÷ Total number of subjects × 100)
	2	Comma	(,)
16		Line break	CR/LF

- Depending on the file type, the following characters are used in place of "#" in the file name:  
t: Positive rate variation for all subjects  
0-9: Positive rate variation for the group number indicated by the digit  
(0 indicates subjects with no group specified)
- As shown in the output example, the title "Positive Rate Variation by Subject" is added at the beginning of the file.

## 9.10. Error Code List for External Media Output

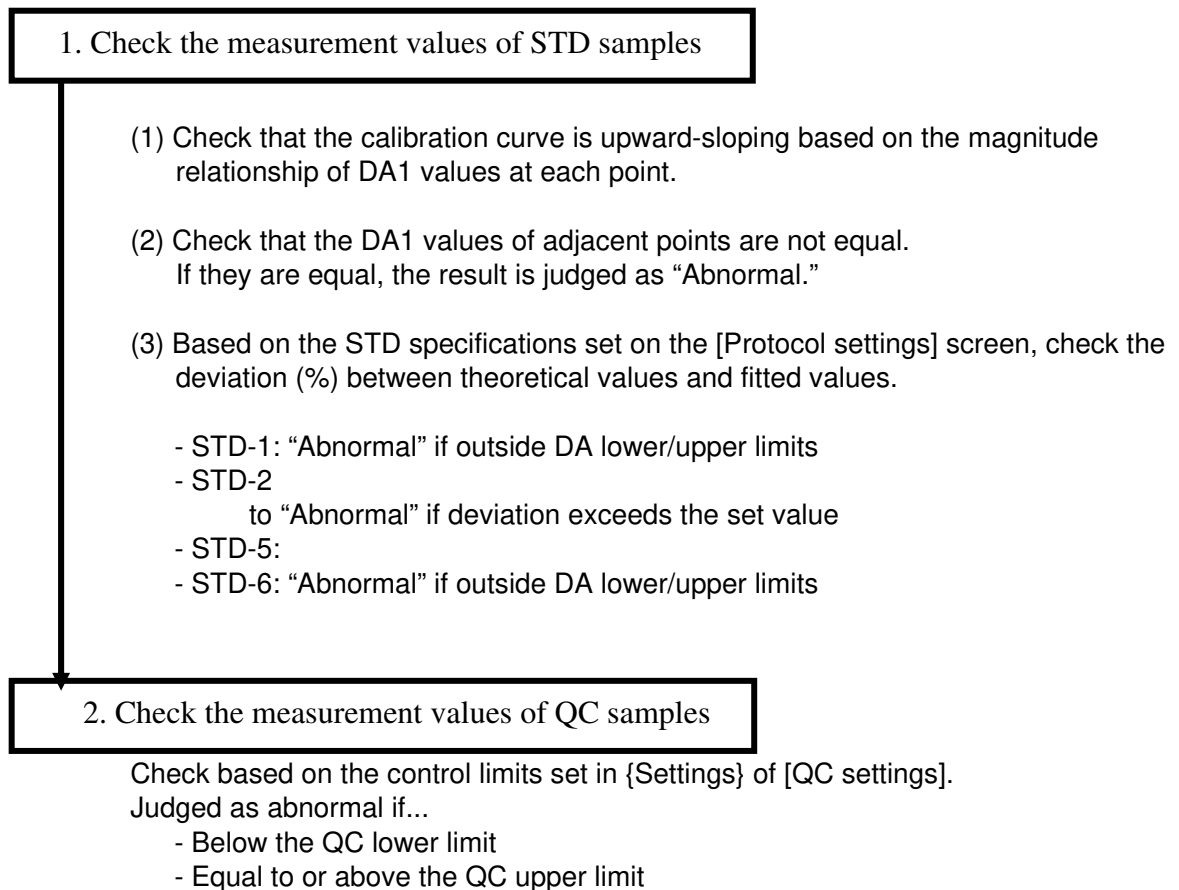
Code	Error content	Measurement value output	Remarks
10	Sample barcode read error	Yes	
20	Sample barcode duplicate error (Check within-day)	-	Does not occur when "Duplicate check: Disable"
01	Insufficient sample / No sample	-	No dispensing is performed.
02	No reagent error	-	
03	RBC (Prozone)	Yes	
04	PRC (Prozone)	Qualitative result only	
05	OR (Over-range)	Qualitative result only	
06	UR (Under range)	-	
07	Sample dispensing error (Sample nozzle jamming, etc.)	-	No dispensing is performed. Puncture errors are also included.
08	Reagent dispensing 1 and 2 error (Reagent nozzle jamming, etc.)	-	No dispensing is performed.
09	Mixer 1 and 2 error (Mixer jamming, etc.)	-	Mixing (agitation) is not performed.
0A	Reagent blank error (A1 check)	-	Reagent blank abnormal
0B	No calibration curve	-	Including mismatch of calibration curve lot No valid calibration curve exists. Calculation was outside of the calculable range (primary and cubic equation only)
0C	No order	-	Received an instruction without an order from the host system.
0D	Control limit value error	Yes	
30	Order error	-	Order request communication failed or returned order did not match the requested sample ID or test code
90	Uninstalled Error	-	Does not occur when "Numbering" is set to "Yes."
11	Composite error of "10" + "01"	-	
12	Composite error of "10" + "02"	-	
13	Composite error of "10" + "03"	Yes	
14	Composite error of "10" + "04"	-	
15	Composite error of "10" + "05"	-	
16	Composite error of "10" + "06"	-	
17	Composite error of "10" + "07"	-	
18	Composite error of "10" + "08"	-	
19	Composite error of "10" + "09"	-	
1A	Composite error of "10" + "0A"	-	
1B	Composite error of "10" + "0B"	-	

- * Codes 11–1B represent composite errors caused by two simultaneous errors; no additional combinations occur.
- * A reagent missing error occurs when the remaining reagent volume is 0 µL at the time of dispensing.
- * Errors marked “Yes” in the measurement value output column output both the measurement value and judgment result.
- * When ‘Numbering’ is set to “Yes,” sample bottles are detected and samples numbers are assigned only to occupied positions.
- * When “Disable” is selected, empty positions are also counted, and error code “90” is output for empty positions.
- * If an end ring is set on the rack while “Numbering” is set to “No,” no data output is performed from the end-ring position to the final rack position.

## 10. Calculation Processing

### 10.1. Measurement Value Check for STD and QC Samples

Check whether measurement results for STD or QC samples are valid.



#### Regarding STD Measurement Values

1. When the replicate count is 3 or more, the maximum and minimum values are excluded before calculating the mean and SD.
2. When the replicate count is 2, no exclusion is applied.
3. If error data exists among replicates, the error data is excluded and the mean and SD are calculated. When the replicate count is 1, mean and SD calculations are not performed.

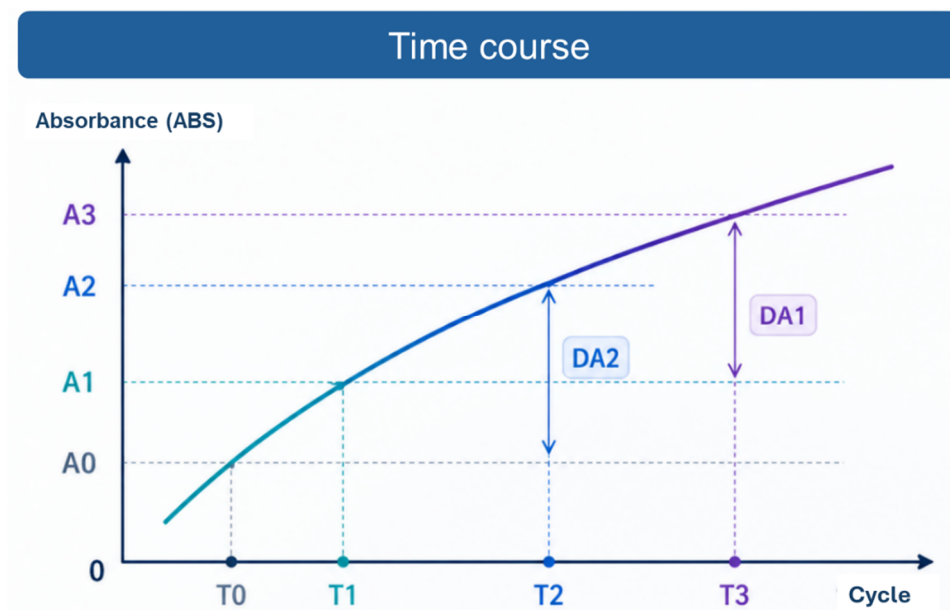
## 10.2. DA Value Calculation

The DA value represents the final measurement result. The measurement value (concentration: X) is calculated from the DA value and the calibration curve.

When reagents are dispensed into a measurement cell containing the sample, a latex agglutination reaction occurs, changing absorbance (ABS).

The time course represents the change in absorbance.

After the sample is dispensed into the measurement cell, the time course is monitored.



T0: 0th photometric point

A0: Absorbance of T0

T1: 1st photometric point

A1: Absorbance of T1

T2: 2nd photometric point

A2: Absorbance of T2

T3: 3rd photometric point

A3: Absorbance of T3

A0, A1, A2, and A3 are averages of absorbance values of consecutive cycles.

(Example) T0 = 8, T1 = 8, T2 = 9, T3 = 29 [cycle]

$$A0 = (\text{Absorbance at cycle 8} + \text{cycle 7}) \div 2$$

$$A1 = (\text{Absorbance at cycle 8} + \text{cycle 7}) \div 2$$

$$A2 = (\text{Absorbance at cycle 9} + \text{cycle 8}) \div 2$$

$$A3 = (\text{Absorbance at cycle 29} + \text{cycle 28}) \div 2$$

However, if cycle 1 or 2 is specified, the absorbance of that cycle is used.

The DA values are the amount of change in A0, A1, A2, and A3.

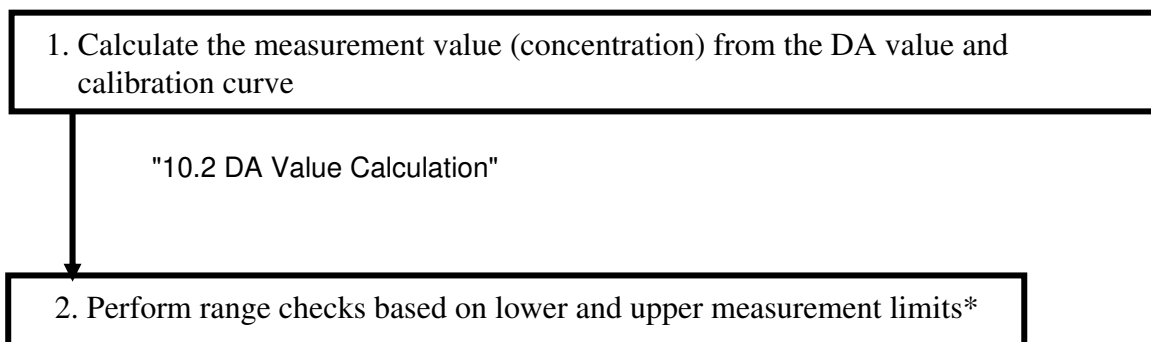
$$DA1: A3 - A1$$

$$DA2: A2 - A0$$



### 10.3. Measurement Value (Concentration) Calculation and Qualitative Judgment

The measurement value (concentration) is calculated from the DA value and the calibration curve, and a qualitative judgment is made by comparing the corrected measurement value with the cutoff value.



OR: Displayed when the measurement value exceeds the upper measurement limit.

Concentration value: Displayed when the measurement value is less than or equal to the upper measurement limit.

UR: Displayed when the measurement value is below the lower measurement limit.

*These values are prior to correction by FACTOR A/B or dilution.

## 10.4. Prozone Judgment

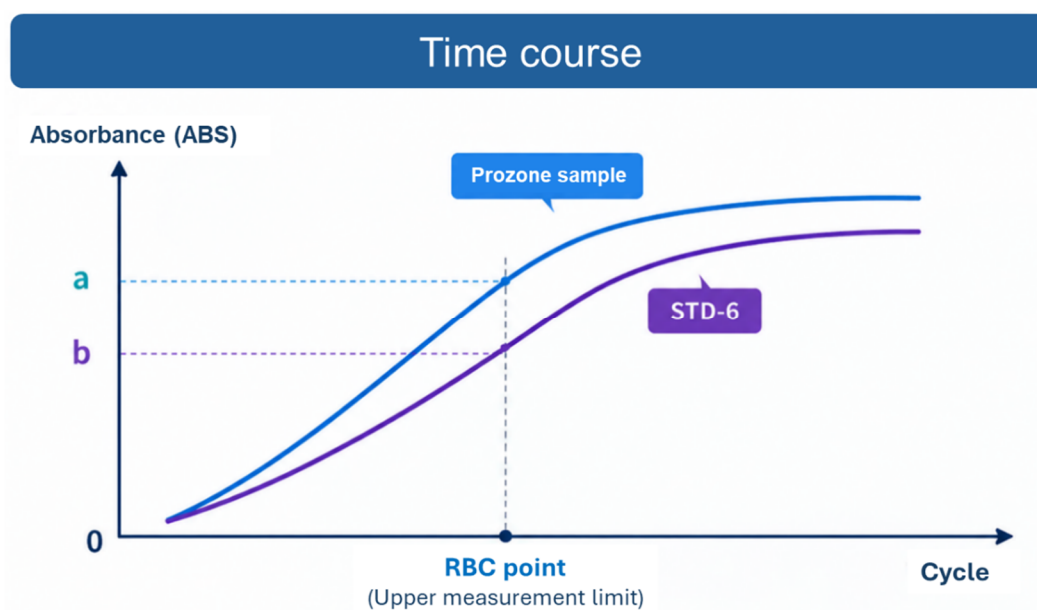
Prozone judgment is performed by two methods: the RBC method and the PRC method.

- RBC method: Compares absorbance at the RBC point between the sample and STD-6 (highest concentration point).
- PRC method: Compares DA2 values between the specimen and STD-6 (highest concentration point).

### ■ RBC method

By comparing the absorbance of the sample at the RBC point (a) with the absorbance of STD-6 (b), samples that satisfy the following relationship are determined to be prozone samples.

$$(b) \times \text{RBC coeff.} < (a)$$



**Note:** The RBC method coefficient is set in [RBC Method Coefficient] on Page 1 of the [Protocol Settings] screen.

**Note:** . The absorbance of the specimen (a) and the absorbance of STD-6 (b) are the average values of the RBC point and the previous (Example) When the RBC point is 5,  
 (a) and (b) are calculated as follows:  

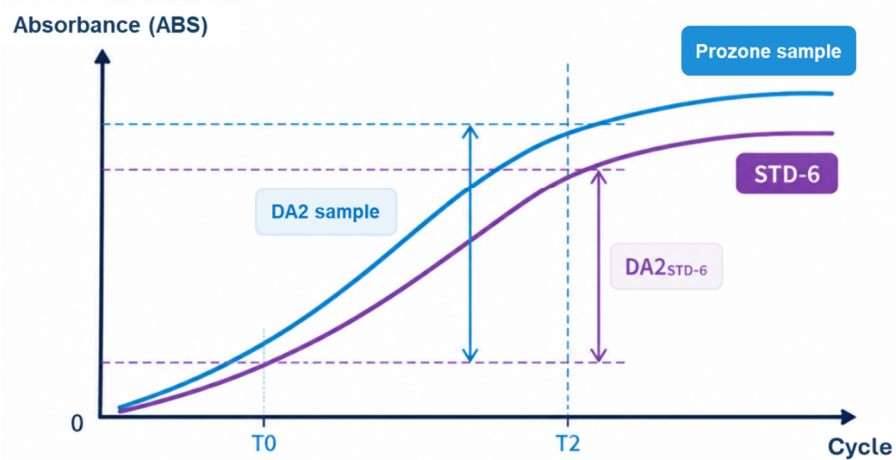
$$(5\text{th cycle absorbance} + 4\text{th cycle absorbance}) \div 2$$

## ■ PRC method

By comparing the DA2 value of the sample with the DA2 value of STD-6, samples that satisfy the following relationship are determined to be prozone samples.

$$DA2_{STD-6} \times \text{PRC coeff.} < DA2_{\text{sample}}$$

### Time course



$DA2_{\text{sample}}$ : DA2 value of prozone sample

$DA2_{STD-6}$ : DA2 value of STD-6

### 10.5. Reagent Blank Check (A1 Check)

Verify correct reagent dispensing using absorbance at the T1 cycle.  
Absorbance is calculated from the average ADC values of T1 and T1-1 cycles and compared against A1 check upper and lower limits.

In the following cases, a "Reagent blank error" occurs.

Absorbance of mean value < A1 check lower limit

or

Absorbance of mean value > A1 check upper limit

* Absorbance [ABS] =  $\text{Log10}(\text{reference value} \div \text{ADC Value}) \times 10,000 - \text{Cell Blank Value}$   
Reference value: LED output when measuring air  
ADC value: ADC value when measuring cell

### 10.6. Cell Blank Value Calculation

When cells are installed, each cell blank is measured and saved for later calculation.  
The cell blank value is calculated on a cell-by-cell basis.

Cell blank value =  $\text{Log10}(\text{reference value} \div \text{ADC value}) \times 10000$

Reference value: LED output when measuring air  
ADC value: ADC value when measuring an empty purified water cell

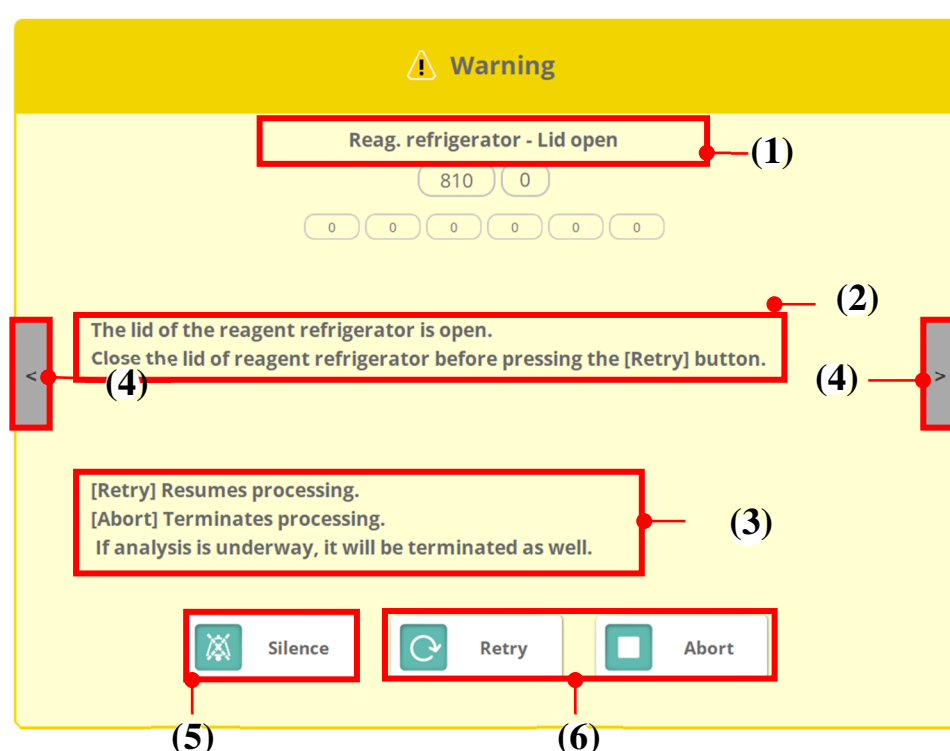
## 11. Error Handling

When an error occurs, the [Error] screen is displayed for operational errors, and the error is displayed on the [Analysis status] screen if it occurs during analysis progress.

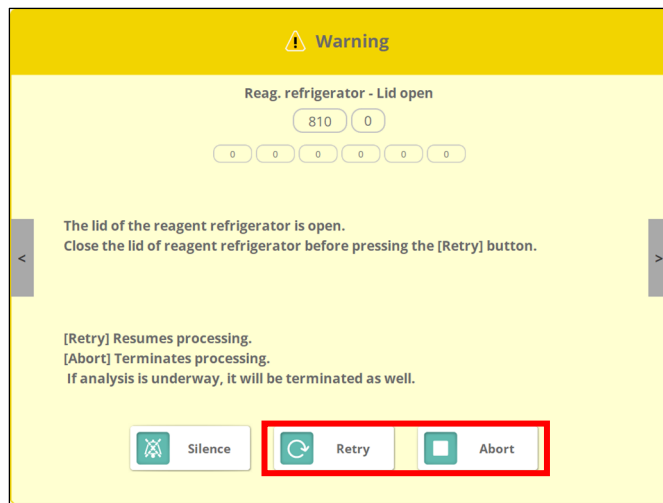
This section describes how to view the error screen, how to clear errors, and provides an error list.

### 11.1. Error (Operation Errors)

If an error occurs during operation, an error screen like the one shown below is displayed. Follow the on-screen instructions to clear the error.



Name	Details
(1) Error display	Displays the error number and name.
(2) Error details	Displays error details and corrective action.
(3) Clear button description	Displays processing performed when the clear button is pressed. Displayed buttons differ depending on the error content.
(4) Error switch	Switches between multiple error pages.
(5) Mute	Mutes the error sound.
(6) Clear button	① Clears the error according to the described method.



## ■ Clearing operation errors

- (1) Check the error and touch the error clear button.
- (2) The corresponding error-clearing process is executed.

## ■ Operation error list

Error No.	Screen Message Printed Message	Error details
162	No cell	No cells are installed. Press the [Abort] button.
		<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
231	Rack detected on conveyance line (rack arrival sensor)	Remove the rack and press the [Retry] button.
	Rack on line (arrival)	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
232	Rack detected on conveyance line (rack presence sensor)	Remove the rack and press the [Retry] button.
	Rack on line (presence)	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
233	Rack detected on conveyance line (rack remaining sensor)	Remove the rack and press the [Retry] button.
	Rack on line (remaining)	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
234	Rack full (rack full sensor)	Remove the rack and press the [Retry] button.
	Rack full	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
235	Supply tray not installed	Install the supply tray and press the [Retry] button.
	Supply tray not installed	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
236	Discharge tray not installed	Install the discharge tray and press the [Retry] button.
	Discharge tray not installed	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
237	Rack detected on conveyance line (discharge-ready sensor)	Remove the rack and press the [Retry] button.
	Rack on line (discharge-ready)	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
257	Replace wash solution with PW	Replace detergent with purified water. Replace the wash solution tank with the purified water tank and then press the [Continue] button.
		<Cancelling Procedure> [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
300	No supply unit tray	The rack supply tray is either floating or not properly installed. Install the rack supply tray correctly. If the same error occurs after pressing the [Continue] button, press the [Normal Exit] button and wait until the results of the sample being analyzed are available.
	No supply tray	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
301	Rack supply error	Failed to supply rack from the rack supply tray to the conveyance line. If the rack is tilted on the tray, reposition it properly. If there are any obstructions, remove them. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Rack supply error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
302	Rack supply bar - Origin error	The rack supply bar could not be returned to the front side correctly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.
	Rack supply bar Origin error	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
303	No discharge tray	The rack discharge tray is either floating or not properly installed. Install the rack discharge tray correctly. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	No discharge tray	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.



Error No.	Screen Message Printed Message	Error details
304	Puncturing mechanism - Origin error	Failed to move the puncturing mechanism to origin. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Puncturing Origin sensor error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
305	Rack conveyance X-axis bar in/out error	Failed to perform the in/out motion of the X conveyance bar correctly. Press the [Abort] button as can not continue.
	X-conveyance bar in/out error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
306	Rack conveyance X-axis PMC error	An error occurred in the X-axis of the rack conveyance. Press the [Abort] button as can not continue.
	X-conveyance PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
307	Squeeze mechanism - Origin error	Failed to move the squeeze mechanism to origin. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Squeeze Origin sensor error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
308	Rack conveyance X-axis step-out	The X-axis of convey rack step out detected. Press the [Abort] button as can not continue.
	X-conveyance step-out	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
309	Rack discharge error	Failed to discharge rack properly. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Rack discharge error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
310	Rack conveyance X-axis bar origin error	The X-axis origin detection for the rack transport bar did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.
	X-conveyance bar origin error	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
311	Discharge mechanism - Origin error	Failed to move the discharge mechanism to origin. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Discharge Origin sensor error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
313	Discharge tray - Rack full	The rack on the discharge tray is full. Remove the rack from the discharge tray or replace the discharge tray, then press the [Continue] button.
	Discharge tray Rack full	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
316	STAT rack present	A rack is remaining in the STAT rack installation position. Remove the rack and press the [Continue] button.
	STAT rack present	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
317	Squeeze mechanism - Limit sensor error	Abnormality was detected in the limit sensor of the squeeze mechanism . Press the [Close] button and wait until the results of the sample being analyzed are available. Pressing the [Abort] button will stop the measurement.
	Squeeze Limit sensor error	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
318	Puncturing mechanism - Limit sensor error	Abnormality was detected in the limit sensor of the Puncturing mechanism . Press the [Close] button and wait until the results of the sample being analyzed are available. Pressing the [Abort] button will stop the measurement.
	Puncturing sensor error	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
319	Barcode reader initial error	Barcode reader initialization failed. Press the [Abort] button as can not continue.
	Barcode reader initial error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
320	Rack barcode read error	The rack barcode could not be read. Check that the barcode on the ejected rack is correct. After checking, Press the [Continue] button.
	Rack barcode read error	<Cancelling Procedure> [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
322	Rack supply bar - Sensor error	The rack supply bar origin sensor and limit sensor are both ON at the same time, so operation is not possible. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Rack supply bar Sensor error	<Cancelling Procedure> [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
324	Samp cup Position error	The sample cups used for STD measurement are installed in the wrong position or the number of installed cups is insufficient.
	Samp cup Position error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
325	Insufficient reag. shortage for STD/QC	The remaining test count for reagents or diluent is insufficient to analyze STD or QC. Add more reagents.
	STD/QC reag. shoartage	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
326	CAL barcode not entered	Cal barcode not entered on the calibration curve setting screen
	CAL barcode not entered	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
327	CAL barcode expired	Cal barcode expired on the calibration curve setting screen
	CAL barcode expired	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
513	Reag. nozzle 1 - Syringe PMC error	An error occurred in the P-axis of the Reag nozzle 1. Press the [Abort] button as can not continue.
	Reag1 Syringe PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
514	Reag. nozzle 1 - Z-axis PMC error	An error occurred in the Z-axis of the Reag nozzle 1. Press the [Abort] button as can not continue.
	Reag1 Z-axis PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
515	Reag. nozzle 1 - $\theta$ -axis PMC error	An error occurred in the $\theta$ -axis of the Reag nozzle 1. Press the [Abort] button as can not continue.
	Reag1 T-axis PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
516	Reag. 1 - Remaining volume abnormal	An abnormality was detected in the remaining volume of reagent 1. Press the [Close] button and wait until the results of the sample being analyzed are available. Pressing the [Abort] button will stop the measurement.
	Reag1 remaining vol error	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
517	Reag. nozzle 1 - Jammed	Reagent nozzle 1 has jammed. Press the [Close] button and wait until the results of the sample being analyzed are available. Pressing the [Abort] button will stop the measurement.
	Reag1 Jamming	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
518	Diluent - Remaining volume abnormal	An abnormality was detected in the remaining volume of diluent. Press the [Close] button and wait until the results of the sample being analyzed are available. Pressing the [Abort] button will stop the measurement.   &lt;Cancelling Procedure&gt; [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Diluent remaining vol error	
519	Reag. nozzle 1 - Z-axis step-out	The Z-axis of reagent nozzle 1 step out detected. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag1 Z-axis step-out	
520	Reag. nozzle 1 - Z-axis origin error	Z-axis origin detection for reagent nozzle 1 did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag1 Z-axis origin error	
521	Reag. nozzle 1 - $\theta$ -axis origin error	$\theta$-axis origin detection for reagent nozzle 1 did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag1 T-axis origin error	
522	Reag. nozzle 1 - P-axis origin error	P-axis origin detection for reagent nozzle 1 did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag1 P-axis origin error	
524	Residual liquid in cell	Residual liquid has been detected in the cell. The cell wash nozzle may not be properly aspirated. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Residual liquid in cell	

Error No.	Screen Message Printed Message	Error details
525	Reag. 1 OFC - PW dispensing shortage	Purified water could not be detected in the Reagent 1 OF cell. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available. If you suspect that the prime was insufficient, stop the process and prime again.
	Reag1 OFC PW disp shortage	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
528	Reag. 1 shortage	The volume of Reagent 1 is insufficient. Press the [Continue] button and then add the reagent. If you want to end the analysis without adding any reagents, press the [Close] button. If you want to end the analysis immediately, press the [Abort] button.
	Reag1 shortage	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
529	Reag. nozzle 1 - Liquid level sensor error	Abnormality was detected in the liquid level sensor of the reagent nozzle 1. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Reag1 Liquid level error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
530	Reag. nozzle 1 - Bottle cap detection error	A cap was detected on the reagent bottle 1. Remove the cap from the bottle and reinsert it.
	Reag1 cap detection error	<Cancelling Procedure> [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
531	Reag. nozzle 1 - P-axis step-out	The P-axis of reagent nozzle 1 step out detected. Press the [Abort] button as can not continue.
	Reag1 P-axis step-out	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
532	Reag. 1 bubble detected	Bubbles were detected in a reagent 1 bottle. Remove the bubbles from the bottle before pressing the [Retry] button.
	Reag. 1 bubble detected	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
533	Diluent shortage	The volume of Diluent is insufficient. Press the [Continue] button and then add the reagent. If you want to end the analysis without adding any reagents, press the [Close] button. If you want to end the analysis immediately, press the [Abort] button.
	Diluent shortage	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
553	Reag. nozzle 2 - Syringe PMC error	An error occurred in the P-axis of the Reag nozzle 2. Press the [Abort] button as can not continue.
	Reag2 Syringe PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
554	Reag. nozzle 2 - Z-axis PMC error	An error occurred in the Z-axis of the Reag nozzle 2. Press the [Abort] button as can not continue.
	Reag2 Z-axis PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
555	Reag. nozzle 2 - $\theta$ -axis PMC error	An error occurred in the $\theta$ -axis of the Reag nozzle 2. Press the [Abort] button as can not continue.
	Reag2 T-axis PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
557	Reag. nozzle 2 - Jammed	Reagent nozzle 2 has jammed. Press the [Close] button and wait until the results of the sample being analyzed are available. Pressing the [Abort] button will stop the measurement.
	Reag2 Jamming	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
558	Reag. nozzle 2 - Liquid level sensor error	Abnormality was detected in the liquid level sensor of the reagent nozzle 2 If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Reag2 Liquid level error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
559	Reag. 2 - Remaining volume abnormal	An abnormality was detected in the remaining volume of reagent 2. Press the [Close] button and wait until the results of the sample being analyzed are available. Pressing the [Abort] button will stop the measurement.
	No Reag2	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
560	Reag. nozzle 2 - Z-axis step-out	The Z-axis of reagent nozzle 2 step out detected. Press the [Abort] button as can not continue.
	Reag2 Z-axis step-out	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
561	Reag. nozzle 2 - Z-axis origin error	Z-axis origin detection for reagent nozzle 2 did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.
	Reag2 Z-axis origin error	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
562	Reag. nozzle 2 - $\theta$ -axis origin error	$\theta$ -axis origin detection for reagent nozzle 2 did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.
	Reag2 T-axis origin error	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.



Error No.	Screen Message Printed Message	Error details
563	Reag. nozzle 2 - P-axis origin error	P-axis origin detection for reagent nozzle 2 did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag2 P-axis origin error	
566	Reag. 2 OFC - PW dispensing shortage	Purified water could not be detected in the Reagent 2 OF cell. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available. If you suspect that the prime was insufficient, stop the process and prime again.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag2 OFC PW disp shortage	
568	Reag. 2 shortage	The volume of Reagent 2 is insufficient. Press the [Continue] button and then add the reagent. If you want to end the analysis without adding any reagents, press the [Close] button. If you want to end the analysis immediately, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag2 shortage	
569	Reag. 2 Nozzle contact with liquid in cell	Reagent nozzle 2 has contacted the liquid in the cell. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	R2 contact with liquid in cell	
570	Reag. nozzle 2 - Bottle cap detection error	A cap was detected on the reagent bottle 2. Remove the cap from the bottle and reinsert it.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag2 cap detection error	

Error No.	Screen Message Printed Message	Error details
571	Reag. nozzle 2 - P-axis step-out	The P-axis of reagent nozzle 2 step out detected. Press the [Abort] button as can not continue.
	Reag2 P-axis step-out	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
572	Reag. 2 bubble detected	Bubbles were detected in a reagent 2 bottle. Remove the bubbles from the bottle before pressing the [Retry] button.
	Reag. 2 bubble detected	<Cancelling Procedure> [Retry] Resumes processing. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
600	Mixer nozzle - Y-axis PMC error	An error occurred in the Y-axis of the Mixer. Press the [Abort] button as can not continue.
	Mixer Y-axis PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
601	Mixer nozzle - Z-axis PMC error	An error occurred in the Z-axis of the Mixer. Press the [Abort] button as can not continue.
	Mixer Z-axis PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
602	Mixer 1 - Jammed	Mixer nozzle 1 has jammed. Press the [Abort] button as can not continue.
	Mixer1 Jamming	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
603	Mixer selection sensor error	The mixer selection sensor failed to turn ON. Press the [Abort] button as can not continue.
	Mixer selection sensor error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
604	Mixer 2 - Jammed	Mixer nozzle 2 has jammed. Press the [Abort] button as can not continue.
	Mixer2 Jamming	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
605	Mixing 1 insufficient rotation speed	Rotation speed of mixer motor 1 is insufficient. Press the [Abort] button as can not continue.
	Mixer1 insufficient rotation	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
606	Mixing 2 insufficient rotation speed	Rotation speed of mixer motor 2 is insufficient. Press the [Abort] button as can not continue.
	Mixer2 insufficient rotation	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
607	Mixer nozzle - Y-axis origin error	Y-axis origin detection for mixer did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.
	Mixer Y-axis origin error	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
608	Mixer nozzle - Z-axis origin error	Z-axis origin detection for mixer did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.
	Mixer Z-axis origin error	<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
609	Mixer nozzle - Z-axis step-out	The Z-axis of mixer step out detected. Press the [Abort] button as can not continue.
	Mixer Z-axis step-out	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
613	Mixing 1 rotation PMC error	An error occurred in the rotating motor of the Mixer 1. Press the [Abort] button as can not continue.
	Mixer1 PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
614	Mixing 2 rotation PMC error	An error occurred in the rotating motor of the Mixer 2. Press the [Abort] button as can not continue.
	Mixer2 PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
648	Samp. nozzle - Syringe PMC error	An error occurred in the syringe of the sample nozzle. Press the [Abort] button as can not continue.
	Samp Syringe PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
649	Samp. nozzle - Z-axis PMC error	An error occurred in the Z-axis of the sample nozzle. Press the [Abort] button as can not continue.
	Samp Z-axis PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
650	Samp. nozzle - $\theta$ -axis PMC error	An error occurred in the $\theta$ -axis of the sample nozzle. Press the [Abort] button as can not continue.
	Samp T-axis PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
651	Samp. nozzle - Liquid level sensor error	Abnormality was detected in the liquid level sensor of the sample nozzle. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Samp Liquid level sensor error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
658	Samp. OFC - Wash solution dispensing shortage	Wash solution could not be detected in the sample OF cell. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available. If you suspect that the prime was insufficient, stop the process and prime again.
	Samp OFC Wash sol. disp shortage	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
659	Samp. nozzle - Jammed	The sample nozzle has jammed. Press the [Close] button and wait until the results of the sample being analyzed are available. Pressing the [Abort] button will stop the measurement.
	Samp Jamming	<Cancelling Procedure> [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
660	Samp. OFC - PW dispensing shortage	Purified water could not be detected in the sample OF cell. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available. If you suspect that the prime was insufficient, stop the process and prime again.
	Samp OFC PW disp shortage	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
663	Samp. nozzle - Z-axis step-out	The Z-axis of sample nozzle step out detected. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Samp Z-axis step-out	
664	Samp. nozzle - Z-axis origin sensor error	Z-axis origin detection for sample nozzle did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Samp Z-axis origin error	
665	Samp. nozzle - $\theta$ -axis origin error	$\theta$-axis origin detection for sample nozzle did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Samp T-axis origin error	
666	Samp. nozzle - P-axis origin error	P-axis origin detection for sample nozzle did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Samp P-axis origin error	
671	Samp. nozzle - P-axis step-out	The P-axis of sample nozzle step out detected. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Samp P-axis step-out	
700	Cell washing nozzle - Z-axis PMC error	An error occurred in the Z-axis of the cell washing nozzle. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Cell wash Z-axis PMC error	

Error No.	Screen Message Printed Message	Error details
701	Cell washing mechanism - Jammed	The cell washing mechanism has jammed. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Cell wash Jamming	
702	Cell washing nozzle - Z-axis origin error	Z-axis origin detection for cell washing nozzle did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Cell wash origin error	
703	Cell washing nozzle - Z-axis step-out	The Z-axis of cell wash nozzle step out detected. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Cell wash Z-axis step-out	
704	Cell washing nozzle - Liquid overflow	Liquid overflow was detected during cell washing. It is possible that the waste liquid tank connection pipe is bent or clogged, preventing aspiration. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Cell wash Liquid overflow	
800	PW shortage	Refill with purified water and then press the [Continue] button.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
801	Wash solution shortage	Refill with wash solution and then press the [Continue] button.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
802	Drain tank - Full	Empty the waste tank and then press the [Continue] button.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
804	Reag. refrigerator - Shutter operation error	The shutter of the reagent refrigerator failed to operate properly. If an error occurs after pressing the [Continue] button, press the [Abort] button.
	Refrigerator Shutter error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
805	Exhaust FAN alarm (UPPER)	The exhaust fan has been detected as stopped.(UPPER) Press the [Abort] button as can not continue.
	Exhaust FAN alarm (UPPER)	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
806	Exhaust FAN alarm (LOWER)	The exhaust fan has been detected as stopped.(LOWER) Press the [Abort] button as can not continue.
	Exhaust FAN alarm (LOWER)	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
807	Exhaust FAN alarm (UPPER/LOWER)	The exhaust fan has been detected as stopped.(BOTH) Press the [Abort] button as can not continue.
	Exhaust FAN alarm(BOTH)	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
808	Exhaust FAN alarm (Reag. refrigerator)	The exhaust fan has been detected as stopped.(PELTIER) Press the [Abort] button as can not continue.
	Exhaust FAN alarm (PELTIER)	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
810	Reag. refrigerator - Lid open	The lid of the reagent refrigerator is open. Close the lid of reagent refrigerator before pressing the [Retry] button.
		<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
811	Protective cover open	Close the protective cover before pressing the [Retry] button.
		<Cancelling Procedure> [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
815	PW Shortage (WARNING)	Sample dispensing has been paused due to insufficient liquid level in the purified water tank. Tank replacement or refilling of purified water is not possible during operation. You will be notified again when it is safe to replace the tank,so please press the [Continue] button to close the warning message.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	PW Shortage (WARNING)	
816	Wash solution Shortage (WARNING)	Sample dispensing has been paused due to insufficient liquid level in the wash solution tank. Tank replacement or refilling of purified water is not possible during operation. You will be notified again when it is safe to replace the tank,so please press the [Continue] button to close the warning message.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Wash sol. Shortage (WARNING)	
817	Drain tank - Full (WARNING)	Sample dispensing has been paused due to the waste tank being full. Tank cannot be replaced during operation. You will be notified again when it is safe to replace the tank,so please press the [Continue] button to close the warning message.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Drain tank Full (WARNING)	
820	There are 11 or more unusable cells	There are 11 or more unusable cells. Pressing the [Continue] button will resume dispensing the sample, but replace with new cells as this will reduce processing capacity.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Unavailable cells	



Error No.	Screen Message Printed Message	Error details
830	PW buffer tank - PW shortage	Purified water was not supplied to the buffer tank inside the instrument. There may be a problem with the purified water supply pump or piping system. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	PW buffer tank shortage	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
831	PW buffer tank - Sensor error	The liquid level sensor in the buffer tank is abnormal. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	PW buffer tank Sensor error	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
900	Reaction table - Origin error	The origin detection for reaction table did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.
	Reaction table origin error	<Cancelling Procedure> If analysis is underway, it will be terminated as well.
902	Reaction table - $\theta$ -axis PMC error	An error occurred in the $\theta$ -axis of the reaction table. Press the [Abort] button as can not continue.
	Reaction table PMC error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
903	Residual liquid in cell (cell soak)	Residual liquid was detected in the cell during the cell soaking preservation. The cell washing nozzle may not be aspirated properly. If the same error occurs after pressing the [Continue] button, press the [Close] button and wait until the results of the sample being analyzed are available.
	Residual liquid in cell	<Cancelling Procedure> [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.

Error No.	Screen Message Printed Message	Error details
904	Reaction table - Temp. range error	An abnormal temperature was detected on the reaction table. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reaction table Temp range error	
920	Reaction table - Temp. setting error	Reaction table temperature setting failed. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reaction table Temp set error	
921	Reag. table - Temp. setting error	Reagent refrigerator table temperature setting failed. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag table Temp set error	
950	Reag. refrigerator table - Origin error	The Origin detection for reagent refrigerator table did not work properly. If the error occurred even after pressing the [Retry] button, press the [Abort] button.   &lt;Cancelling Procedure&gt; [Retry] Resumes processing. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Refrigerator table origin error	
952	Reag. refrigerator - $\theta$ -axis PMC error	An error occurred in the $\theta$-axis of the reagent refrigerator. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Refrigerator table PMC error	
954	Reag. refrigerator - Temp. range error	An abnormal temperature was detected on the reagent refrigerator. Press the [Abort] button as can not continue.   &lt;Cancelling Procedure&gt; [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Refrigerator Temp range error	
955	Reag. barcode reader error	The reagent barcode could not be read. Check that the reagent barcode is not peeled off, dirty, or damaged before pressing the [continue] button.   &lt;Cancelling Procedure&gt; [Continue] Continue with the next process. [Close] Operation will be interrupted, but any ongoing analysis will continue. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
	Reag barcode read error	

Error No.	Screen Message Printed Message	Error details
970	Reag. table - Temp. acquisition error	Failed to get the temperature of the reagent refrigerator. Press the [Abort] button as can not continue.
	Reag temp acquisition error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
971	Reaction table - Temp. acquisition error	Failed to get the temperature of the reaction table. Press the [Abort] button as can not continue.
	Reaction temp acquisition error	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
972	Room temp. acquisition error	Failed to get the room temperature. Operation can continue, but the recording of room temperature will be interrupted.
	Room temp acquisition error	<Cancelling Procedure> [Continue] Continue with the next process. [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
997	Cycle time over	The cycle time has expired. Press the [Abort] button as can not continue.
	Cycle time over	<Cancelling Procedure> [Abort] Terminates processing. If analysis is underway, it will be terminated as well.
999	Internal communication error	An error occurred in the communication within the instrument. For safety reasons, the power will automatically shut down after 5 seconds.
	Internal communication error	

## 11.2. Error (Analysis Progress Error)

If an error occurs during analysis progress, an error message is displayed for the relevant sample on the [Analysis status] screen.

**Analysis status** eiken  
2026/02/03 13:42

Time left: 10 min

Rack	Sample Code	Item	Processing Status
010-05	00005	FCa	45.6 ug/g
010-05	00005	FIT	303 ng/mL
010-04	00004	FCa	Sample shortage
010-04	00004	FIT	1 ng/mL
010-03	00003	FCa	2.3 ug/g
010-03	00003	FIT	39 ng/mL
010-02	00002	FCa	Sample shortage
010-02	00002	FIT	179 ng/mL
010-01	00001	FCa	11.2 ug/g
010-01	00001	FIT	119 ng/mL

**Reagent/install**

<b>P-1</b>  <b>FIT</b> Lot 501 Test 246 Limit 2026/10/31	<b>P-2</b>  <b>FCa</b> Lot 501 Test 134 Limit 2026/10/31	<b>Smp dilu</b>  100% 0%
<b>P-3</b> 	<b>P-4</b> 	

QC settings  
 Dilut. Retest  
 Device settings  
 Data process  
 Rack info  
 Quick help

Example of progress error

When an error occurs during analysis progress, the error message is displayed with a red background in the {Processing status} column on the [Analysis status] screen.

- * When an analysis progress error occurs, the [Error] screen is not displayed, and the analysis continues automatically.

## ■ Progress error list

Error name	Progress error message (upper line)	Error details
	Print message (lower line)	
Cell blank error	-	The cell blank measurement is abnormal.
	Cell blank error	
No tube	-	No samples have been placed in the rack. ■ An error will only be detected if "Align sample numbers" is set to "Disable" in "Test mode".
	No Tube	
Sample barcode read error	-	The sample barcode could not be read. Check for barcode contamination or damage.
	BC Read err	
No sample	No sample	The liquid level of the sample could not be detected. Check the sample volume.
	No Sample	
Insufficient sample volume	Sample Shortage	The sample volume was insufficient and could not be dispensed. Check the sample volume.
	Sample Shortage	
Sample Air aspiration Error	Samp. Air Asp. Error	Sample was aspirated with no liquid. Check for air bubbles in the Sample.
	Samp. Air Asp. Err	
Sample Dispence Error	Samp. Dsip err	An error occurred during sample dispensing.
	Samp. Dsip err	
No Reagent 1	-	The reagent 1 has run out. Please add more reagent.
	No Reag1	
Ragent 1 Dispence Error	-	An error occurred during the dispensing of Reagent 1.
	Reag1 Disp err	
Ragent 1 Air aspiration Error	-	Reagent R1 was aspirated with no liquid. Check for air bubbles in the reagent bottle.
	Reag1 Air Asp. Err	
No Reagent 2	No Reag2	The reagent 2 has run out. Please add more reagent.
	No Reag2	

Error name	Progress error message (upper line)	Error details
	Print message (lower line)	
Reagent 2 Air aspiration Error	Reag2 Air Asp. err	Reagent R2 was aspirated with no liquid. Check for air bubbles in the reagent bottle.
	Reag2 Air Asp. err	
Reagent 2 Dispence Error	Reag2 Disp err	An error occurred during the dispensing of Reagent 2.
	Reag2 Disp err	
Puncture Error	-	The stool sample collection container was not successfully punctured. Perform the analysis again.
	Puncture err	
Mixing1 Error	Mixing1 Error	An error occurred during the rotation of stirring 1.
	Mixing1 Error	
Mixing2 Error	Mixing2 Error	An error occurred during the rotation of stirring 2.
	Mixing2 Error	
Wash Error	-	Liquid overflow was detected during cell cleaning.
	Wash Error	
Reagent Blank Error	Reag. Blank err	The absorbance at the T1 cycle was below the A1 check lower limit.
	Reag. Blank err	
No Calibration Curve	No Cal. Curve	A calibration curve is not registered for the reagents used in the measurement.
	No Cal. Curve	
Calibration curve Error	-	When creating the calibration curve, the STD measurement values at each point were lower than the previous DA values.
	Cal. Curve Error	
None Result	-	The re-test results for the dilution test are abnormal. ■ This will only be displayed if you select "Yes" for initial simultaneous analysis during dilution retesting.
	None Result	
Order Error	-	The order you requested from the host did not match.
	Order Error	
No Order	-	The host did not receive the order you requested.
	No Order	

## 12. Technical Explanation Related to EMC

This system complies with EMC (Electromagnetic Compatibility) standards required for the safe use of electrical equipment for measurement, control, laboratory use, and in vitro diagnostic medical devices, namely IEC 61326-1:2020 and IEC 61326-2-6:2020.

If connections other than those specified are used, electromagnetic emissions may increase or electromagnetic immunity may decrease. Therefore, special precautions regarding EMC are required, and the System must be installed and used in accordance with the EMC information provided below.

This system is designed for use in a professional healthcare facility environment. Use in a home healthcare environment may cause malfunction.

If this system is used in a dry environment, especially where chemical fibers (synthetic fiber clothing, carpets, etc.) are present, harmful electrostatic discharge may cause incorrect measurement results. Because electromagnetic radiation sources may interfere with proper operation, the System should not be used near strong or unshielded intentional electromagnetic radiation sources.

Guidance and manufacturer's declaration – electromagnetic emissions		
This product is intended for use in the electromagnetic environments described below. The customer or user should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions	Group 1	This system uses RF energy only for internal functions. Therefore, its RF emissions are very low and are unlikely to cause interference with nearby electronic equipment.
RF emissions	Class A	This instrument is suitable for use in all facilities other than residential establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity			
This product is intended for use in the electromagnetic environments described below. The customer or user should ensure that it is used in such an environment.			
Immunity test	IEC61326-2-6 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge test IEC 61000-4-2	±6 kV contact ±8 kV contact ±2 kV in air ±4 kV in air ±8 kV in air ±15 kV in air	±6 kV contact ±8 kV contact ±2 kV in air ±4 kV in air ±8 kV in air ±15 kV in air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of typical commercial or hospital environments.
Radiated RF IEC 61000-4-3  Conductive RF IEC 61000-4-6	3 V/m (80 MHz to 6 GHz)  3 V (150 kHz to 80 MHz)	3 V/m  3 V	Portable and mobile RF communications equipment should be used no closer to any part of this system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=2\sqrt{P}$ (80 Mhz to 6 GHz) (P is maximum output power [W]) The electromagnetic field strength from fixed RF transmitters, as determined by an electromagnetic site survey ^{*1} , should be less than the compliance level in each frequency range ^{*2} . There may be potential interference in the vicinity of equipment bearing the following symbol. 
*1: For example, the electromagnetic field strength from fixed transmitters such as radio (mobile/cellular and cordless) telephone base stations, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be accurately predicted theoretically. To assess the electromagnetic environment caused by fixed RF transmitters, it is advisable to consider an on-site electromagnetic survey. If the electromagnetic field strength measured at the location where this product is used exceeds the applicable RF compliance level, this product should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as changing the orientation or location of this product.   *2: Across the entire frequency range from 150 kHz to 80 MHz, the electromagnetic field strength should be less than 3 V/m.			
Electrical fast transient/burst  IEC 61000-4-4	±1 kV power supply lines ±1 kV input/output lines	±1 kV power supply lines ±1 kV input/output lines	The power supply quality should be that of a typical commercial or hospital environment.



Guidance and manufacturer's declaration – electromagnetic immunity			
This product is intended for use in the electromagnetic environments described below. The customer or user should ensure that it is used in such an environment.			
Surge IEC 61000-4-5	±0.5 kV line-to-line ±1 kV line-to-ground	±0.5 kV line-to-line ±1 kV line-to-ground	The power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-4	0% for 0.5 cycle 0% for 1 cycle 70% for 25/30 cycles 0% for 250/300 cycles	0% for 0.5 cycle 0% for 1 cycle 70% for 25/30 cycles 0% for 250/300 cycles	The power supply quality should be that of a typical commercial or hospital environment.  If continuous operation of this product during power interruptions is required, it is recommended that the product be powered from an uninterruptible power supply.

■ Performance level during electromagnetic immunity testing

- Temporary screen flicker or disappearance during electromagnetic immunity exposure is acceptable (it does not affect test results).
- Temporary screen disappearance due to extremely large electrostatic discharges, momentary power interruptions, or power loss resulting in power-off is acceptable.



## 13. Information on Trademarks and Software

### <Trademarks>

- Microsoft and Windows are registered trademarks of Microsoft Corporation in the United States and other countries.
- “QR Code” is a registered trademark of Denso Wave Incorporated.
- All other company names and product names mentioned herein are trademarks or registered trademarks of their respective owners.

### <Software License Agreement >

This product comes with Microsoft Windows 10 IoT Enterprise pre-installed, and users must agree to the Microsoft license terms.

Before using this product, please read the Microsoft license terms enclosed with it and ensure that you comply with them.



## 14. Glossary

Term	Meaning
<b>DA value</b>	Absorbance difference. Calculated as the amount of change in absorbance. For example, $DA1 = A3 - A1$ [ABS] $DA2 = A2 - A0$ [ABS]
<b>DIL (Dil)</b>	Retest diluent
<b>PRC method</b>	Method that compares the DA2 values of STD-6 (the highest concentration of an STD sample series) and a patient sample.
<b>QC (sample)</b>	Control sample. Also referred to as reference material or reference sample.
<b>QC value check</b>	Check based on the "control limit values" set on the [QC settings] screen. Specification: The minimum control limit value is less than 1: abnormal The maximum control limit value is +1 or greater: abnormal
<b>RBC method</b>	Method that compares the absorbance at the RBC point (in the initial stage of a reaction) of the highest concentration of an STD sample series (STD-6) and a patient sample.
<b>STD (sample)</b>	The calibrator sample. Also referred to as standard material or standard sample.
<b>Back-fit</b>	Value obtained by fitting absorbance to the calibration curve.
<b>Absorbance</b>	A0, A1, A2, A3 Logarithm of ratio of strength of incident light striking sample (I ₀ ) and strength of transmitted light (I) (i.e. I ₀ /I)
<b>Dilution retest mode</b>	Tests the sample once again after the sample is diluted (10x, 20x, 100x, 200x, 400x). However, it is not punctured.
<b>Retest mode</b>	Retests sample depending on test results. However, it is not punctured. One of the measurement modes.
<b>Analysis mode</b>	Measures a sample for the first time. One of the measurement modes.
<b>Re-measurement mode</b>	Measures the sample again. One of the measurement modes. Remeasured samples are handled in the same manner as the samples of the initial analysis.
<b>Jamming</b>	An error where something is touching the sample nozzle or mixer.
<b>Measurement value</b>	Concentration values of haemoglobin and calprotectin. The measurement value (concentration value) is calculated from the DA value and the calibration curve.
<b>Time course</b>	Results (graph) of measuring/recording changes in absorbance as time passes.
<b>Prozone</b>	Phenomenon where there are excessive antibodies or antigens, and observable reactions 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.





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