

# HM-JACKarc II Instruction for Use EN

Contains the instruction for use of HM-JACKarc  ${\rm I\!I}$  , HM-JACK Reaction Cell and Sample Cup

Ver.03

**Canon Medical Diagnostics Corporation** 

# **Change History**

Edition	Date (YYYY/MM/DD)	Revision Contents
01	2022/04/04	Newly established.
02	2024/07/04	2.5.1 Symbol list: Added explanation of WEEE to *1
03	2025/02/01	2.5.1: Added UKCA mark and UK Responsible Person.
		4.1.9, 4.1.11: Added Certification mark to the product
		information for HM-JACK Reaction Cell and Sample
		Cup.
		Back cover: Added the UK Responsible Person information.
		Corporate name change:
		(Old) Minaris Medical co., Ltd.
		(New) Canon Medical Diagnostics Corporation

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# **Chapter 1. Introduction**

Thank you for choosing our "HM-JACKarc II" In vitro diagnostics medical device (hereinafter this device).

This device is a fully automated immunoassay analyzer based on the principle of particle agglutination reaction. Quantitative measurement of specific components in stool samples by optically detecting changes in turbidity associated with particle agglutination. Intended to be used by professional users.

This instruction for use describes how to handle HM-JACKarc II and its accessories, HM-JACK Reaction Cell, HM-JACK Sample Cup, and Wash Liquid (Auto Detergent H).

HM-JACK Reaction Cell (hereinafter referred to as reaction cell) is a disposable cuvette for reacting reagents and samples.

HM-JACK Sample Cup (hereinafter referred to as sample cup) is a disposable container for putting samples in for measurement.

Additionally, Wash Liquid (hereinafter referred to as detergent) is a washing liquid for cleaning the probe of HM-JACKarc II.

Before start using the device, please read this Instruction for Use (hereinafter this instruction) thoroughly, and not perform analysis operation and/or handle specimens and other materials until you fully understand its content.

Each Chapter explains the matters that must be observed in order to prevent from harm to users and other people and damage to property. If it is used improperly, it may cause damage or physical damage.

Keep this instruction near this device. If you are unsure of the analysis operation method, read this instruction thoroughly before proceeding with any operation or analysis. Furthermore, please keep this instruction in a safe place.

# 1.1 Warranty

Check with your local distributor for the warranty period of this device. If the device fails within this warranty period, we will repair or replace it. Please note that this warranty does not apply in the following cases:

- Malfunction or damage due to natural disasters such as lighting strikes, earthquakes, storms and floods
- Malfunction or damage due to fire, riot, crime, war and other accidents or flooding caused by force majeure
- Malfunction or damage due to carelessness or misuse
- · Malfunction or damage due to maintenance work by worker who is not designated by us
- Malfunction or damage due to the use of consumables or replacement parts other than those specified by us
- Malfunction or incorrect operation due to disassembly or modification that we do not permit
- Malfunction due to usage not described in this instruction
- Corrosion or deterioration of the device due to installation in an environment other than that described in this instruction
- · Environmental (temperature, humidity, magnetic field etc.) changes from when this device is installed
- · Loss of saved data due to inadequate or improper maintenance of this device
- · Malfunction due to software usage that we are not aware of
- Data corruption and defects due to device malfunction
- We do not guarantee if the measurement data is deleted by mistake.
- Damage to the computer and software used by the device due to a power outage or fluctuations in power supply
- · Consumables and malfunction outside the limited usage period

We are not liable for any consequential damages such as disadvantages or business losses incurred by the customer from the device malfunction caused by misuse of this device or the measurement data obtained by misuse. We provide maintenance and repair services after the warranty period has expired. please contact your local distributor. The service life of this device is 7 years. Please avoid using it for more than 7 years. However, since there are differences depending on the usage conditions, priority is given to this when determining individually.

# 1.2 How to use this instruction for use

This instruction describes how to use the device safely. The contents include maintenance guide and troubleshooting so this is the reference to explain basic operations for all customers. This customer includes all of the person who use a part of device functions and clinical technicians.

# 1.2.1 Target readers

This instruction targets the persons who have basic knowledge of clinical testing measurement principles and techniques, had our trainings for operation of target products, or appropriately trained by trainer who had taken our training already.

# 1.2.2 Device installation

This instruction includes description of installation environment and hardware for the devices but is not the installation instruction. All of this device are installed by our certified stuffs. Therefore it does not provide the information of how to install the device. If you would like to change something for installation, check with your local distributor.

## **1.2.3** Customers using this device for the first time

Please read through this instruction before operating this device even if you took the training approved by us.

### 1.2.4 Notes on device software and this instruction

- The copyright of the application software of this device and this instruction belongs to Canon Medical Diagnostics Corporation (Hereinafter our company).
- The contents of this instruction and software are subject to change without notice.
- It is prohibited to copy a part or all of this instruction without permission.
- We do not guarantee the data lost due to accidental deletion of measurement data or failure of this device.
- The contents of this instruction have been created and described with the utmost care, but if you find any suspicious points, errors, or omissions, please contact your local distributor.

# 1.3 Symbol marks and notations used in this document

Describes the symbol marks and notations used in this instruction.

## 1.3.1 Terms used in this instruction

each company.

Terms	Description
IST	Integrating Sphere Turbidity

■ Unit notation In this manual, the unit is expressed in SI (International System of Units).

■ Trademark HM-JACKarc II is trademark or registered trademark of Canon Medical Diagnostics Corporation Other company names/product names mentioned are registered trademarks or trademarks of

### 1.3.2 Symbol marks used in this instruction

### Description of alert symbols



The alert symbol on the left is used in this instruction to indicate potential hazard. This symbol represents the biohazard. Please handle with great care.

The alert symbol on the left is used in this instruction to indicate potential dangers. This symbol represents unspecified general risks, warnings and cautions. The precautions stated after this symbol should be notified for safety reason so please be sure to read it.

### Explanation of signal word

Three types of signal words are used in this instruction. These signal words are used separately as described below to indicate the degree (magnitude) of personal injury and property damage which could occur.

This signal is used in situations in which incorrect handling could result in death or serious injury to the user and device breakage (inoperable)
This signal is used in situations in which incorrect handling could result in minor injury to the user, physical damage, degradation of system performance, or risks of displaying incorrect data.

NOTE	Explanation of function, notification in operation, supplementary explanations
NOTE	in operation, etc.

#### Classification and categories of damage and injury severity

The degrees of damage and injury used above are classified as follows:

Severe injury	: Loss of vision, wounds, burns (high or low temperature), electric shock, bone fracture, poisoning, infection etc. Resulting in permanent after effects, or requiring medical care involving hospitalization or prolonged outpatient treatment.
Minor injury	: Injury other than the above, not requiring medical care involving hospitalization or prolonged outpatient treatment.

**Property damage** : Extended damage to buildings, assets, equipment, etc. in clinical/analytical laboratories of hospitals or medical institutions etc.

# Chapter 2. Precaution for Use, Installation Environment and Specifications

Before using this device, need to understand how to operate safely. This chapter describes the following precautions.

# 2.1 How to use the device safely

Use this device according to the method specified. If used this device in a manner not specified, it may impair the protection provided by this device. Therefore, read through precautions in this chapter before using this device.

We are not responsible for any damages or injuries resulting from operating the device without following these precautions. This device should only be used by those who were trained by use or who were received the appropriate guidance from those who have been trained. Additionally, this device is intended to be used under the supervision of medical doctors or clinical laboratory technicians to provide doctors with measurement data necessary for diagnosis.

This instruction contains warnings about dangers to the extent that we can foresee, but please be careful about other dangers as well. If you have any problems or questions about the device, please contact our designated service counter.

### 2.1.1 Prevention from ignition and damages

Observe the following precautions to prevent from damages and ignition to the device.

# 

- Use the device correctly according to the installation environment and installation conditions described in this instruction.
- Installation and adjustment of this device is performed only by our certified workers.
- If you would like to change installation condition, contact your local distributor.
- If the device malfunctions, stop the device immediately and contact your local distributor.
- Never use flammable or explosive gases near this device because it is not explosion proof.

# 2.1.2 Precaution of this device operation

When using the device, follow the procedure described in this instruction. Inappropriate operation or contacting with driving units results in the device malfunction.

- Damage to the power cord may cause fire, electric shock, or electric leakage. Please observe the followings.
  - Do not twist.
  - Do not pinch between products, walls, etc.
  - Do not bend forcibly.
  - Do not put heavy things on the device.
  - Do not bundle.
  - Do not process.
  - Keep away from heating appliances (including the device main unit).
  - Do not pull (When unplugging the power plug, be sure to hold the power plug without pulling the cord).
  - Do not use the code of this device for any other purposes.
  - Do not do anything else that could damage the power cord.
- If dust collects on the power plug, it may cause a fire, so check it regularly to remove the dust.
- Make sure that the power plug is firmly inserted all the way into the outlet. Poor contact will generate heat and cause burns or fire.
- When not in use, turn off the power supply and disconnect the power cable. Also, do not leave the device with the power plug inserted.
- Do not allow the power cord and power plug to get wet. It may cause electric shock or electric leakage.
- Do not touch the power plug with wet hands. It may cause electric shock.
- When the power is turned on with the plug of the power cord (by plugging and unplugging the outlet), the plug may generate heat. Be sure to use the power switch (or the breaker of the power supply).
- When unplugging the power cord from the outlet, hold the plug without pulling on the cord.
- If the device is used in a dry environment, harmful electrical discharges can cause incorrect measurement results, especially if there are chemical fibers (synthetic clothing, carpet, etc.). Please use in an environment where electrostatic discharge does not occur.
- Use the device under the conditions specified in this instruction.
- Do not allow the device to get wet. Also do not place it in a place where it may get wet. If the device gets wet, unplug the device's main power plug before touching it.
- Use only for the purposes described in this instruction.
- Do not use if the device does not operate normally or is damaged.
  - Example 1) Damaged power cord or its plug.
    - 2) Damage caused by dropping the device.
    - 3) Damage caused by dropping the device into water or getting the device wet.
- Do not block the vents of this device and not place the device on a soft surface that could possibly block the vents.
- Be careful not to let lint, hair, fluff, etc. get into the vents of this device.
- Do not place anything on the device.
- Do not drop or insert anything into the openings, pipes or joints of the device unless explicitly stated in this document.
- Do not get on this device.



• Be sure to close the outer cover or inner cover during measurement as it is extremely dangerous to open it while the device is operating.

# 2.1.3 Precautions regarding MC Collection Picker, sample cup, reaction cell, etc.

<ul> <li>Please give full consideration to prevent infection.</li> <li>General specimens, used Reaction cells, and sample cups, may be contaminated with pathogens. Always take great care in handling.</li> <li>Please wear medical rubber gloves when handling.</li> <li>Please read the package insert carefully and understand the contents regarding the handling of MC Collection Picker and reagents.</li> </ul>
<ul> <li>Use protective equipment during operation.</li> <li>When using this device, use protective equipment (medical rubber gloves, a mask, protective goggles, etc.) to prevent infection.</li> </ul>
<ul> <li>Dispose of waste properly.</li> <li>For used medical waste such as MC Collection Picker, sample cups, and reaction cells, be careful not to damage the surrounding environment and health, and ask a professional contractor to dispose of it.</li> </ul>
<ul> <li>Do not stain the barcode attached to the MC Collection Picker.</li> <li>The barcode (specimen ID) affixed to the MC Collection Picker is read during measurement. Information important for measurement is registered in the sample ID. Do not stain or peel off the barcode.</li> </ul>
<ul> <li>O Do not use anything other than the MC Collection Picker, sample cup, and reaction cell dedicated to this device.</li> </ul>

## 2.1.4 Precaution for detergent

If the detergent adheres to the human body, it may damage the skin or cause blindness. Wear appropriate protective googles and gloves if it may adhere. If you have sensitive skin, please wear appropriate protective clothing and equipment.

Do not use any other detergent other than the dedicated detergent for this device.

# 2.1.5 Precaution for electromagnetic compatibility

This device complies with the mission and immunity requirements specified in the EMC standard JIS C1806-2-6, and is designed and tested in accordance with CISPR11 Class A.

Depending on the adjacent device, the noise from that device may affect the measurement results and operation of this device, and the noise from this device may affect the performance of the adjacent device. In addition, it may cause radio interference in the home environment etc., in which case it is necessary to take measures to reduce the interference. Evaluate the electromagnetic environment and take countermeasures as necessary prior to the operation of the device.

## **2.1.6** Precaution for electromagnetic waves

Please observe the following precautions to protect this device from electromagnetic waves.



- $\, \odot \,$  Do not install this device near equipment that emits large electromagnetic waves.
- $\, \odot \,$  Do not intentionally bring mobile phones, cordless phones, transceivers, etc., close to this device.

# 2.1.7 Replacement and maintenance of parts

Parts replacement and maintenance will be performed based on the followings.

Items	Recommended term	Person in charge
Periodical maintenance	Every ~one year	Our certified worker
Inlet filter replacement	Every ~6 months	Our certified worker and customer
Sample pipette replacement	Every ~one year	Our certified worker and customer
Lamp replacement	Every ~one year	Our certified worker
Pump tube replacement	Every ~two years	Our certified worker
Water supply pump replacement	Replace if needed	Our certified worker
Reagent pipette replacement	Replace if needed	Our certified worker
Stirring spatula replacement	Replace if needed	Our certified worker
Cell hand replacement	Replace if needed	Our certified worker

 Replace parts before usage regardless of the above replacement period if it is severely damaged or dirty.

## 2.1.8 Precautions for cleaning the device cover and rack

If the device cover becomes dirty, wipe it off with a well-wrung cloth or a dry cloth in order to use the device for a long period of time. If the rack becomes dirty, wear medical rubber gloves and clean it with rubbing alcohol.

# 2.1.9 Dispose of the device

Special processing is required to dispose of this device. Our certified workers will dispose of this device.

# 2.2 Precaution for installation environment

# 2.2.1 Installation environment

Please observe the following precautions to operate this device safely and accurately.

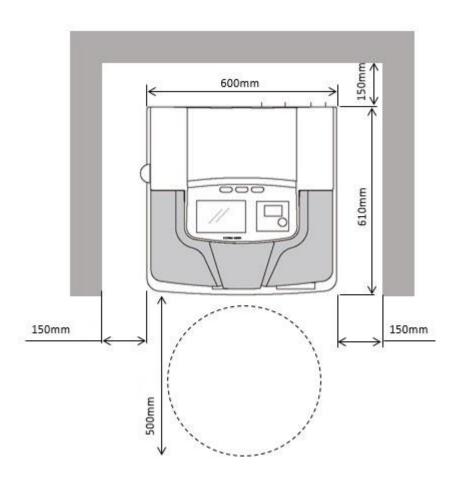
# 

- **O** Please secure the following installation environment.
  - Use indoor only.
  - Place the device which does not expose to direct sunlight or overly bright lighting.
  - A place with little dust (Pollution degree 2 as defined by IEC and UL standards)
  - Flat place with little slope (Slope 1/200 or less)
  - A place with little vibration
  - A place where does not exceed an altitude of 2000m.
  - A place without corrosive gas.
  - The air conditioning wind should not hit directly. (Where there is concern about reagent concentration).
- Condition relates to electricity and noise
  - Power supply voltage AC220–240V, 50/60Hz
  - Power consumption 300VA or less
- Temperature and humidity conditions during use
  - Operation temperature 20–30°C
  - Operation humidity 45–85%RH (Do not condense.)
- Temperature and humidity conditions of storage place
  - Storage temperature 5–35°C
  - Storage humidity 75% or less (Do not condense.)

## 2.2.2 Requirements of installation space

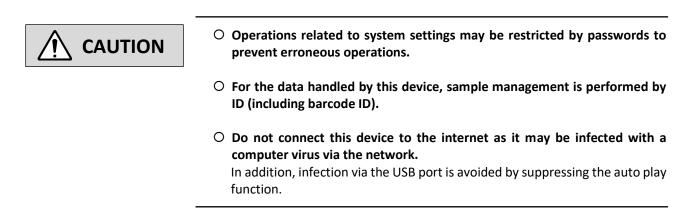
Please secure the space to install this device.

\*The space to place is 15 cm or more, and to operation is 50 cm or more.



# 2.3 Security

Precautions for security



# 2.4 Main specification of system

# 2.4.1 Device specification

Device specification are as follows.

Items	Specification
Analysis method	Latex agglutination method
Measurement principles	Integrating sphere turbidity method
Processing speed	200 specimens/hour
Sample volume	10–60 $\mu$ L(Sample quantitative pump)
Reagent volume	Latex: 20–300 μL Buffer solution: 20–300 μL
Total volume for reaction	300 μL
The number of specimen installation	80 specimens (10 specimens/rack x 8 racks)
Sample container	EXTEL HEMO • AUTO MC Collection Picker
Sample pipette	EXTEL HEMO·AUTO MC collection picker direct insertion method (With stirring function)
Reagent container	20 mL container
Reagent pipette	Buffer fluid extrusion nozzle method
Reaction container (Reaction cell)	Made of acrylic disposable
Reaction table	The number of reaction containers installation: 40 units
Reaction time	Up to 5.6 minutes
Reaction container supply	Automatic feed and discharge
The number of reaction container stored	80 cells (40 cells/cassette x 2 cassette)
Reaction temperature	Room temperature
Source of light	xenon lamp 5V 9W
Detector	Silicon photodiode
Concentration calculation method	7-point calibration curve, Cubic equation
Calibration curve	Master curve method, 2-point calibration curve correction
Repeatability	CV 5% or less
Display device	Backlit color LCD (touch panel)
Interface (external output)	For communication (D-Sub 25 pin) 1 port/USB 1 port
Wash pump	diaphragm pump
Dimension (mm)	600 mm(W)×500 mm(H)×610 mm(D)
Weight	56 kg
Power supply	AC220–240V 50/60Hz
Power consumption	300VA or less
Excessive voltage category	Excessive voltage category II
Temperature range used	20–30°C
Humidity range used	45–85% (No condensation)
Storage temperature range	5–35°C

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Items	Specification
Storage humidity range	75% or less (No condensation)
Altitude	2000 m or less
Degree of pollution	Class 2
Noise level	85db or less
Printer type	Thermal printer
Paper	Thermosensitive paper TR-58
Handy barcode scanner	Corresponding code : CODE39, ITF, industrial 2 of 5, COOP2 of 5, NW- 7, CODE128, JAN

## 2.4.2 Consumables list

Product code	Product name
053150	HM-JACK Reaction cell
053151	HM-JACK Sample cup
052404	Auto Detergent H
057848	Printer paper A
037332	Inlet filter

Please contact your local distributor to order the products.

# 2.4.3 Racks list

Rack can be identified with the color and labels as follows.

Rack for calibrator White rack with red labels (STD)	
Rack for control White rack with yellow labels (CONT)	
Rack for MC Collection Picker Blue rack :	
Rack for adaptors with sample cups Green rack(option) [NOTE] This rack is used to measure samples from sample Cups. Set the Adaptors (white blocks) on the rack and place sample cups with samples onto the adaptors.	HILITIC CONTRACTOR
<ul> <li>*The adaptors should be placed with cups with samples.</li> <li>(Refer to the righ figure)</li> <li>① OK Adaptor, sample cup: attached</li> <li>② OK Adaptor, sample cup: not attached</li> <li>③ NG Adaptor: attached, Sample cup: not attached</li> </ul>	1 2 3 OK OK NG

# 2.5 **Description of labels**

# 2.5.1 Symbol list

Symbol	Description of symbol	Symbol	Description of symbol
	Manufacturer	[]i	Consult instructions for use
EC REP	Authorized representative in the European Community	$\triangle$	Warning / Caution
~~~	Date of manufacture	IVD	In vitro diagnostic medical device
$\Sigma$	Use-by date	Œ	CE mark
LOT	Batch code	X	WEEE (Waste Electrical and Electronics Equipment) *1
REF	Catalogue number		Protective conductor terminal
SN	Serial number	I	On (power supply)
Ţ	Fragile, handle with care	0	Off (power supply)
	Keep away from sunlight and heat		Causes severe skin burns and eye damage.
Ť	Keep dry		Suspected of causing cancer.
X	Temperature limit	CONT	Contents
	Biological risks	P	For professional use only
(2)	Do not re-use	UK CA	UKCA mark
UKRP	UK Responsible Person		

#### \*1:

Only for European Union and EEA (Norway, Iceland and Liechtenstein)



These symbols indicate that this product is not to be disposed of with your household waste, according to the WEEE Directive (2012/19/EU), the Battery Regulation((EU) 2023/1542) and/or national legislations implementing those Directive and Regulation.

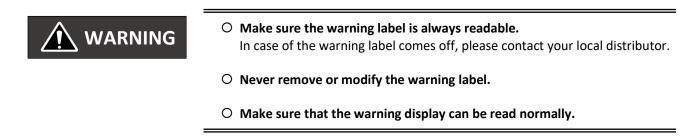
If a chemical symbol is printed beneath the symbol shown above, in accordance with the Battery Regulation, this indicates that a heavy metal (Pb = Lead) is present in this battery at a concentration above an applicable threshold specified in the Battery Regulation.

This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE) and batteries and accumulators. Improper handling of this type of waste could have a possible impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. Your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources.

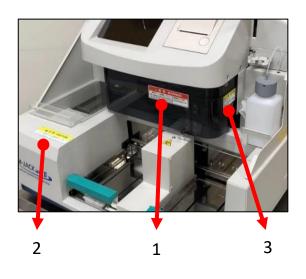
In the EU, there are separate collection and recycling schemes for batteries. To find out more about recycling schemes for batteries available in your area, please contact the local service provider.

# 2.5.2 Labels display

Warning labels are affixed to the parts of the device where to handle with care. Here are the notes on the warning label attached below. The notes on the warning label attached are described below. Please follow the precautions.

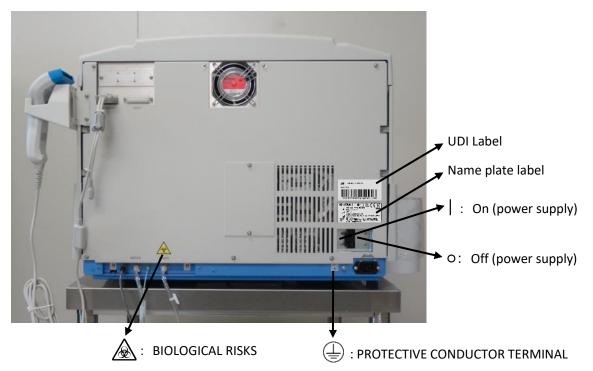


### Front side of device

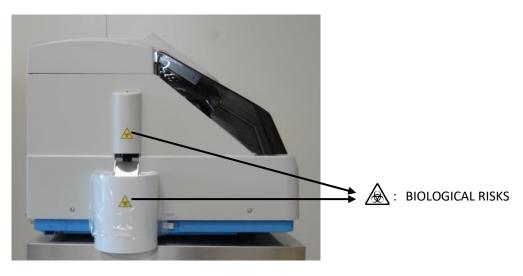


No.	Warning label	Description
1	Keep hands away from SHARP NEEDLES during operation	Keep hands away from SHARP NEEDLES during operation
2	CAUTION Close All Covers before START Keep all materials away from operating area	Close All Covers before START Keep all materials away from operating area
3	CAUTION Remove the REAGENT CAP from bottle before START	Remove the REAGENT CAP from bottle before START

#### Rear side



#### Left side





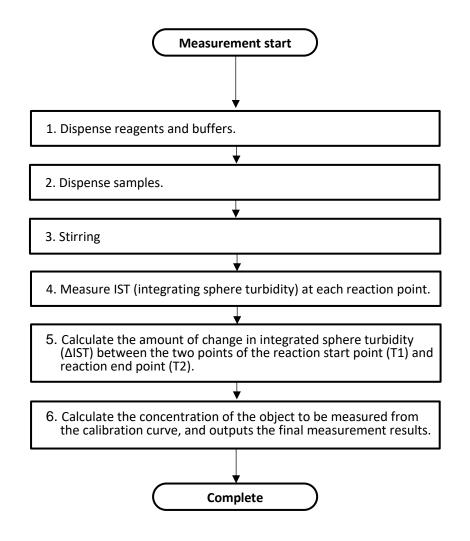
#### O Always wear medical rubber gloves.

- Be careful not to touch the wash tube or waste tube with your bare hands.When disposing of used cells in the cell dust box, be careful not to touch
  - them with your bare hands.

# **Chapter 3. Device Outline**

# 3.1 Measurement principles

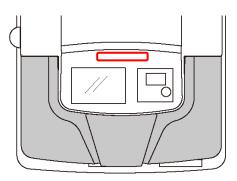
The reagent pipette sucks the reagent from the reagent bottle and dispenses (discharges) it to the reaction cell installed on the reaction table together with the buffer solution filled in the dispensing line. Next, the sample pipette sucks the sample from the sample rack and dispenses (discharges) it to the reaction cell where the reagent and buffer were previously dispensed. In the next cycle, stir the sample in the reaction cell where the reagent, buffer, and sample are dispensed with a stirring spatula. In the stirred reaction cell, the reaction progresses as the reaction table rotates. Photometry is performed at each reaction point and data on integrating sphere turbidity (IST) is acquired. Calculate the amount of change in integrated sphere turbidity ( $\Delta$ IST = IST T2 – IST T1) between the two points of the reaction start point (T1) and reaction end point (T2), and calculate the concentration of the object to be measured from the calibration curve, and outputs the final measurement results.



# 3.2 Display LED of device

### Condition displaying LED

Displaying part (
) on the upper part of operation area lights and blinks according to the device conditions.



#### [Displaying color and displaying condition]

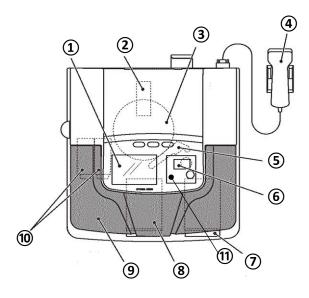
Event	Green	Red	Yellow	Others
At power on				Off
Start measuring, during	Light			
measurement				
During sampling stop			Light	
(Sampling stop at no reagent)				
Resume sampling	Light			
Measurement complete	Blink			<ul> <li>Off</li> </ul>
Error occurrence		Light		
(Unable to continue due to		/Blink		
mechanical reasons)				
Warning error occurrence			Light	
(No reagent etc.)			/Blink	
Home position start	Light			
Washing start	Light			
Cell set start	Light			
Start check	Light			
Standby mode				Green→Blue→Cyan→White blink repeatedly

# 3.3 Configuration of this device

The names of parts/accessories of this device are as follows.

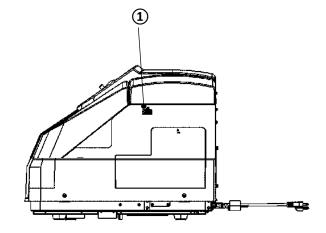
# 3.3.1 Parts name

∎ Тор



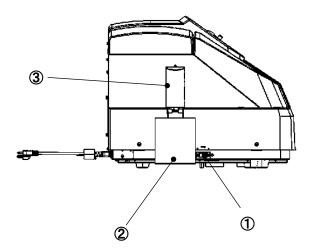
Number	Name	Contents
1	Display	Display operation screens.
2	Integrating sphere turbidity meter	Measure turbidity.
3	Reaction table (Reaction cell)	40 reaction cells installed on the reaction table.
4	Bar code scanner	Input bar code.
5	Injection arm	Arm with integrated stirring spatula, sample pipette, and reagent pipette.
6	Printer	Print measurement results etc.
7	Rack installation line	Install the rack you want to measure.
8	Rack unloading line	Unloading the rack which measurement completed.
9	Outer cover	Device outer cover
10	Cell cassette	40 units reaction cells x 2 (L, R)
(11)	Inner cover	Device inner cover in order not to contact with pipette directly.

### Right side



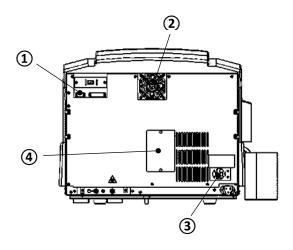
Number	Name	Contents
1	USB port	USB memory can be used.

### ■ Left side



Number	Name	Contents
1	Power supply switch	Power ON/OFF of device power supply.
2	Cell dust box	Discard and collect used reaction cells.
3	Cell hand cover	Cover to prevent direct contact with the cell hand.

#### Rear



Number	Name	Contents
1	Bar code scanner connector	Connect bar code scanner.
2	Cooling fan	Cool in the device.
3	Power supply breaker	Turn off the power supply of the device.
4	Lamp replacement panel	Dedicated port for replacing the light source lamp. *Service person uses.

# **Chapter 4. Basic Operation Flow**

Describe overall flow of the basic operation flow.

Measurement operation start

	_
<b>1. Power on the power supply of the device.</b> Turn on the power switch	( <u>Chapter 4.1.1</u> – <u>Chapter 4.1.2</u> )
<b>2. Prepare tanks.</b> Prepare detergent tank/waste tank to set them.	( <u>Chapter 4.1.3</u> – <u>Chapter 4.1.4</u> )
<b>3. Prepare buffer and reagent.</b> Set buffer and reagent on the device to check the remaining volume.	( <u>Chapter 4.1.5</u> – <u>Chapter 4.1.7)</u>
<b>4. Washing</b> Touch the wash icon to run a wash.	( <u>Chapter 4.1.8</u> )
5. Prepare cell cassette Prepare cell cassette to set in the device. Confirm (Set) the position of the start to remove it.	( <u>Chapter 4.1.9)</u>
6. Register Calibrator Card/Master Curve Card. Input Calibrator Card /Master Curve Card to barcode.	( <u>Chapter 4.1.10)</u>
<b>7. Set calibrator and control rack to measure.</b> Set a sample cup in the rack. Load racks to the device to measure.	( <u>Chapter 4.1.10</u> – <u>Chapter 4.1.12</u>
8. Set rack tray to start measuring. Set MC Collection Picker in the rack for measurement to set the rack on the rack tray. Set the rack tray in the device to start measurement.	( <u>Chapter 4.1.13</u> )
<b>9. Confirm measurement results.</b> Confirm the results which are printed or displayed the measurement results on the screen.	( <u>Chapter 4.3)</u>
<b>10. Implement routine maintenance every day.</b> Perform cleaning following routine maintenance procedure.	( <u>Chapter 6.3)</u>
<b>11. Power off the power supply of the device.</b> Turn off the power switch on the left side of device.	( <u>Chapter 4.4)</u>
Measurement operation complete	

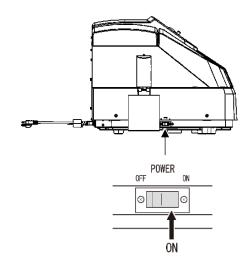
25

# 4.1 Preparation and execution of measurement

Explain preparation and execution of measurement which used this device.

### 4.1.1 Initialize the device

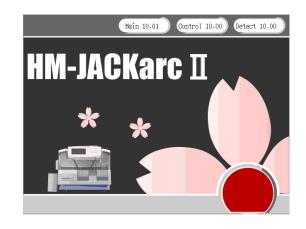
Turn on the power switch on the left side of main unit.



<ul> <li>Check the connection of device.         <ul> <li>Power cord is connected to the device.</li> <li>Power cord is connected to the power supply outlet.</li> </ul> </li> <li>There is a risk of fire or electric shock due to overheating if the power cord and ground connection are not properly connected.</li> </ul>
• Power ON the device about 1 hour before the start of measurement for warming up.
<ul> <li>Make sure the inner cover is attached before measurement.</li> <li>Be careful not to touch the moving parts during the measurement.</li> </ul>
$ \odot $ Inner cover closes automatically. Be careful not to get your hands caught.
$\odot$ Be careful not to get your hands caught when closing the outer cover.

## 4.1.2 Confirm the operation screens

This screen is displayed after the power is turned ON. Tap the screen to move to the main menu screen.



# 

#### ○ External memory device (USB device)

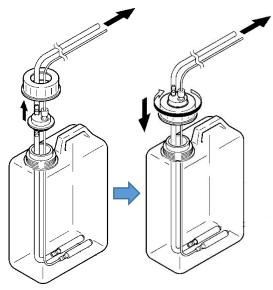
Please perform virus check in advance, although you can use your own USB memory to save the measurement results.

 $\ensuremath{\bigcirc}$  Please be sure to read the notes of each screen explanation.

# 4.1.3 Prepare detergent in detergent tank

Prepare detergent in the detergent tank and install detergent tank cap.

\*For preparation method, refer to the package insert for Wash Liquid (Auto Detergent H).





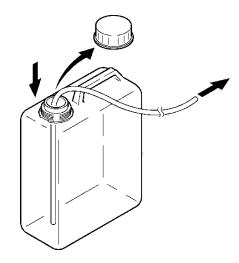
O Use pure water or ion-exchanged water when preparing the detergent. Do not use products that have been passed for a long period of time from preparation, that are contaminated with foreign substances or with chemicals, or tap water.

\* If the detergent is not appropriate, correct analysis results will not be obtained.

# Wear medical rubber gloves when injecting detergent into the tank. Do not touch the part that enters into the detergent tube or detergent tank with your bare hands.

# 4.1.4 Prepare the waste tank

Insert the waste tube to the waste tank.



<ul> <li>Empty the waste tank before starting measurement.</li> <li>The device does not stop when the waste tank is full.</li> <li>Before starting the measurement be sure to empty the waste liquid tank.</li> </ul>
$\ensuremath{\bigcirc}$ Treat the waste as medical waste and ask a professional contractor to dispose of it.
<ul> <li>Wear medical rubber gloves when disposing the waste.</li> <li>Be careful not to touch the waste tube or the part that enters the waste tank with your bare hands.</li> </ul>

## 4.1.5 Prepare the buffer

### 1) Inverse and mix the buffer bottle.

Inverse and mix the buffer bottle gently after letting the buffer to be room temperature.

### 2) Set the buffer bottle.

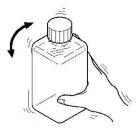
Open the buffer bottle cap, and set it the installation place ( part).

### 3) Insert the suction nozzle.

Insert the suction nozzle into the buffer bottle.

### 4) Set the amount of buffer solution.

- 1 Tap [Analysis] on the Main Menu screen.
- (2) Tap the "buffer" frame to register the liquid volume. (Enter the amount of buffer solution (initial value 250mL).)
- \* Refer to "5.3.1.1 Amount of reagent setting procedure (when reagent level detection is invalid)"







## 

- $\, \odot \,$  Be sure to read the package insert for buffer before handling it.
- Do not use buffer that has passed its expiration date, for a long time since the cap was opened, that is mixed with foreign substances, or contaminated with other chemicals.

If the buffer solution is not appropriate, correct analysis results will not be obtained.

- Do not change the lot of buffer solution during the measurement. Correct measurement results cannot be obtained if the lot of buffer solution is changed during measurement or if buffer solutions of different lots are mixed and used.
- O Prepare a sufficient amount of buffer solution for the number of measurements.

This device requires about 190  $\mu$ L of buffer solution per sample.

- Mixing the buffer solution should be done gently.
   If air is mixed in the buffer solution, correct measurement results will not be obtained.
- $\, \odot \,$  Be careful not to let the removed buffer bottle cap get inside the device.
- When a new buffer solution is set or replaced, touch the [wash] button on the Main Menu screen to perform the cleaning operation.
   Removes air bubbles inside the tube by performing a cleaning operation.

## 4.1.6 Prepare the reagent

#### 1) Mix the reagent by repeatedly inverting the bottle gently.

Let the reagent to be room temperature, and then invert gently and mix it well.

#### 2) Set the reagent bottle.

1 Open the reagent bottle cap and set it to the bottle holder.

(2) Close the reagent evaporation prevention lid.









## 

- $\, \odot \,$  Read the package insert for the reagent before handling the reagent.
- O Do not use reagents that have passed the expiration date, that have passed a long time since the cap was opened, that contain foreign substances, or that are contaminated with other chemicals.
   If the reagents are not appropriate, correct measurement results will not be

obtained.

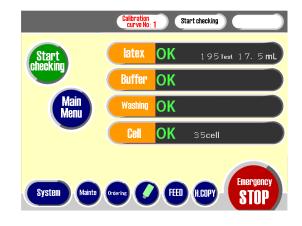
- Do not change the lot of reagents during the measurement.
   Correct measurement results cannot be obtained if the reagent lot is changed or reagents from different lots are mixed during measurement.
- If the lot of reagents used is changed, check that the correct measured values are obtained with the quality control sample, etc.
- $\, \odot \,$  Do not add the reagents.
- O **Prepare a sufficient amount of reagent for the number of measurements.** (Usage per sample: 90µL)
- **Mix the reagent by repeatedly inverting the bottle gently.** Correct measurement results cannot be obtained if air is mixed in the reagent.
- **O** Be careful not to let the reagent bottle cap get inside the device.
- Be careful not to spill the reagent when installing the reagent bottle to the reagent bottle holder.
- After installing the reagent bottle, close the reagent evaporation prevention lid to prevent evaporation.

# 4.1.7 Check the volume of reagent solution (when reagent level detection is enabled)

[Refer to <u>"5.3.1.1 Amount of reagent setting procedure"</u> if reagent level detection is disabled.]

- 1) Tap [Check] on the Main Menu screen.
- 2) Tap [Start Checking] on the Check screen.

\*The amount of reagent solution, buffer solution, cleaning solution, and the status of the remaining cells can be checked.



NOTE

• The number of times that can be measured is displayed by [Start Checking] or detecting the liquid level during measurement.

## 4.1.8 Wash

#### 1) Tap [Wash] on the Main Menu screen.

#### (1) Washing starts.

(2) A buzzer sounds when cleaning complete.



## 4.1.9 Prepare the reaction cell

\*Prepare the following products.

HM-JACK Reaction Cell				
A disposable cuvette for	Transferration of the second second second			
Certification mark	CER	WE (C) Wei-Old Trans ( r Ge 1-2 Jan 2017 - C) - A ( r Jan 2017 - C) 2 ( 日本) - ( F) - ( r Jan 2017 - C) 2 ( 日本) - ( F) - ( r Jan 2017 - C) 2 ( 日本) - ( F) - ( r Jan 2017 - C) 2 ( 日本) - ( F) -		
Product code	053150			
Package configuration	40 cells/cassette x 25	Restance of the second se		
Storage	Store in a building avoiding from light, heat and humidity.			
Expiration date	Use by the expiration date indicated on the product box label.			

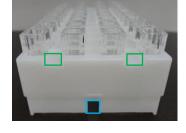
#### 4.1.9.1 How to set the reaction cell

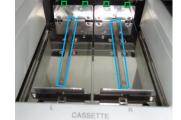
Take the cell cassette out of the bag and set two sets of cell cassettes on the cell cassette table. These steps are required every time when the cells on the cell cassette are used up.

#### 1) Set the groove on the bottom of the cell cassette on the rail of the cell cassette table.

- (1) Hold the cell cassette handle ( $\Box$  part).
- 2 Align the center rail ( part) of the cell cassette table with the groove ( part) on the bottom of the cell cassette, and set it so that it slides in.







(3) Set the cell cassette on the L and R rails of the cell cassette table respectively.

#### 2) Insert the cell cassette.

Gently insert the cell cassette until it hits the back of the cell cassette table.

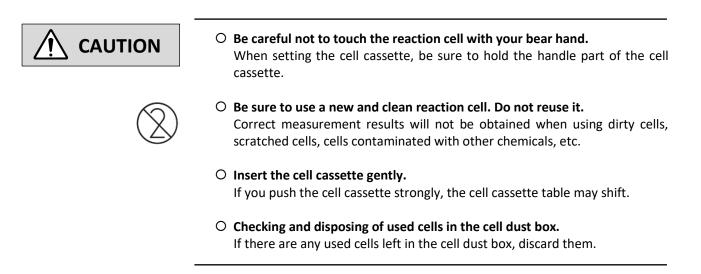
(Make sure that the two protrusions ( $\Box$  part) on the back of the cell cassette table match the guide grooves ( $\Box$  part) on the cell cassette.)



#### 3) Hold the handle part of the cell cassette.

Hold the handle of the cell cassette downward until it stops gently. (Check if the cell cassette is not floated.)





### 4.1.9.2 Setting the start position of the reaction cell

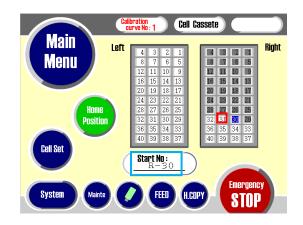
Set (Confirm) the cell start position of the set cell cassette.

#### 1) Display the setting screen of the reaction cell extraction start position.

Tap [Cell] – [Cell Cassette] from the Main Menu screen. (Cell Cassette screen is displayed.)

#### 2) Display the start No.

Tap the position frame (□ part) of the cell cassette. (No. □) is displayed in the "Start No." display window.



## 4.1.10 Bar code input for Calibrator Card/Master Curve Card

[If there is no change in the reagent lot, refer to the procedure in  $\frac{"4.1.12 \text{ Preparation and measurement of control"}}{" . ]$ 

When the lot of reagents changes (when calibration curve correction is required), enter the barcodes of "Calibrator Card" and "Master Curve Card" from the barcode scanner.

#### 1) Display the Cal curve screen.

Tap [Cal curve] on the Main Menu screen.

#### 2) Display the cal curve barcode screen.

- ① Select No. to register in [No.1/2 switching].
- 2 Tap [Barcode].



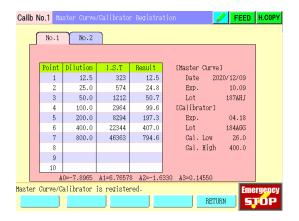
#### 3) Read the barcode.

- 1 Press the barcode scanner button. (ON)
- (2) Read all the barcodes on the Master Curve Card attached to the reagent in order from the top.
   (Expiration date, reagent lot number, and calibration curve parameters from 1 to 7 are entered in order.)
- Read all the barcodes on the Calibrator Card attached to the calibrator in order from the top.
   (Expiration date, reagent lot number, Cal. Low concentration, and Cal. High concentration are entered respectively.)
- (4) When the barcode is read correctly, an electronic sound will sound.
- (5) Press the bar code scanner button. (OFF)

#### 4) Complete the bar code input.

Tap [RETURN] to complete bar code input.





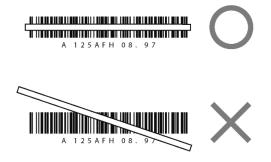


- O Be sure to read the Master Curve Card (bar code) attached to the reagent.
- Check the expiration date of the reagent on the Master Curve Card or the calibration curve screen.
- Confirm that the entered concentration value and IST value are displayed on the screen.

#### 4.1.10.1 How to use the bar code scanner

Keep the following in mind when scanning barcodes with a barcode scanner.

- 1) Let the bar code scanner touch the bar code surface lightly.
- 2) Press and release the barcode scanner switch, and when you hear a beep sound, reading is complete.





- $\, \odot \,$  For a detailed explanation of the barcode scanner, see the instruction for use.
- **O** If the red light of the barcode crosses diagonally, it cannot be read correctly.
- Do not look directly at the barcode reader.
   When you press the button, it glows for a certain period of time until you press the button again.

## 4.1.11 Calibrator preparation and measurement

[If there is no change in the reagent lot, refer to the procedure in "4.1.12 Preparation and measurement of control"]

If the lot of the reagent changes (when the calibration curve needs to be corrected), measure the calibrator and correct the calibration curve.

#### 1) Prepare calibrator

- Prepare two types of calibrators with different concentrations.
   Please check the package insert of the calibrator for the preparation method.
- (2) Dispense the prepared calibrator into the sample cup\* in the required volume.

\*Prepare the following products.

HM-JACK Sample Cup					
A disposable container to	input the sample for measurement.				
Certification mark		A A A A A A A A A A A A A A A A A A A			
Product code	053151				
Package configuration	500 pcs	Me JACK Sample Gup			
Storage	Store in a building avoiding from light, heat, and humidity.	Lacks. If			
Expiration date	Use by the expiration date indicated on the product box label.	3			

#### 2) Set the calibrator in the dedicated rack

Place the calibrator dispensed sample cups in the positions S1 and S2 of the calibrator measurement rack in ascending order of concentration.

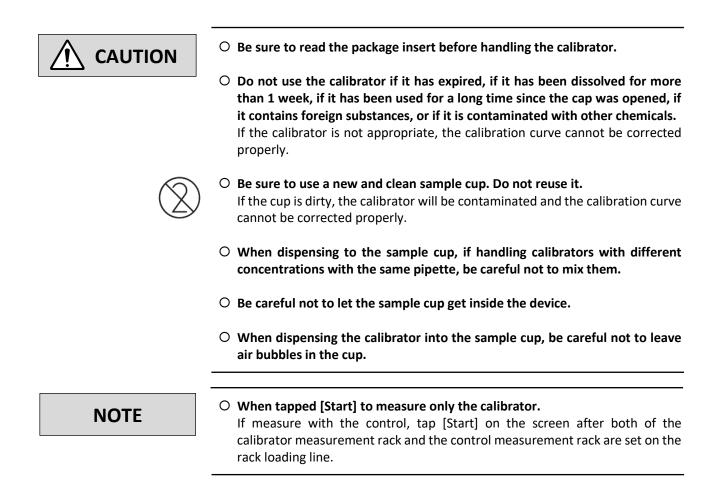


#### 3) Start measurement

[To request the measurement of the calibrator manually, refer to <u>"5.3.1.2 Procedure to request calibrator</u>"]

- Set the calibrator measurement rack on the rack loading line of the equipment.
   [refer to <u>"4.1.13 Preparation and measurement of general samples"</u>]
- (2) Tap [Analysis] on the Main Menu screen.

3 Tap [Start].



## 4.1.12 Preparation and measurement of control

#### 1) Preparation of control

- Prepare two types of controls with different concentrations.
   Please refer to the package insert of the control for the preparation method.
- ② Dispense the prepared control into the sample cup in the required volume.

#### 2) Set the control in the dedicated rack.

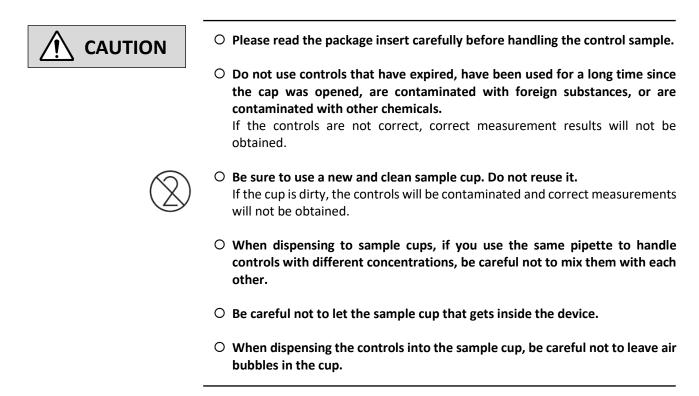
Place the sample cups with the controls dispensed in the CL1 and CL2 positions of the control measurement rack in ascending order of concentration.



#### 3) Start measuring

[To manually request the measurement of the control, refer to <u>"5.3.1.3 Procedure to request control"</u>]

- Set the control measurement rack on the device rack loading line.
   [Refer to "4.1.13 Preparation and measurement of general samples"]
- (2) Tap [Analysis] on the Main Menu screen.
- 3 Tap [Start].



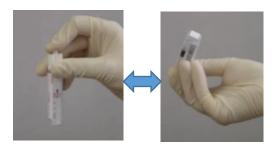
## 4.1.13 Preparation and measurement of general samples

#### 1) Mix with inverting the MC Collection Picker.

- (1) Gently tilt the MC Collection Picker up and down so that it does not foam, and mix it well by tipping it over.
- (2) After tipping and mixing, turn the cap of the MC Collection Picker down and move the air bubbles in the container to the upper side (opposite the cap).

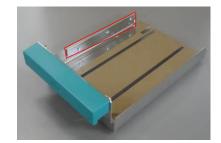
#### 2) Set the MC Collection Picker in the dedicated rack.

- Place the MC Collection Picker on the MC Collection Picker measurement rack with the cap part down.
   (Make sure that the barcode of the MC Collection Picker faces the side where the rack barcode is attached. As shown in the photo on the right, you can set samples 1, 2, .... and sample 10 from the left.)
- Place the rack for MC Collection Picker measurement on the handle side of the rack tray, align the sample rack (□ part) with the rack tray (□ part), and slide it to set. (As for one-day method, 8 racks (80 samples) can be set at one time.)







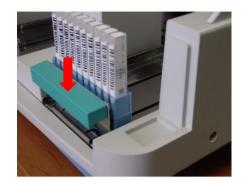




#### 3) Set the MC Collection Picker measurement rack in the device

 Place the tip of the rack tray on the rack loading line on the right side of the device and slide it. (Place it so that the bottom on the handle side is on the white stopper (
 part).





 Push down to fit the bottom completely in the tray (
 part). (Rack tray is held by the white stopper.)

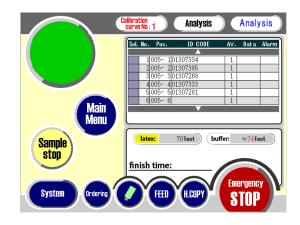
#### 4) Start measuring

[To request sample measurement manually, refer to <u>"5.3.1.4 Procedure to request samples from MC Collection</u> Picker"]

(1) Tap [Analysis] on the Main Menu screen.

#### 2 Tap [Start].

(The Analysis screen is displayed, the measurement starts, and the following table contents are displayed.)



Display	Contents	
Sel.	(Unused)	
No.	Sample No., 1 ~ 320	
Pos.	Position No.	
	Calibrator 1 = STD1	
	Calibrator 2 = STD2	
	Control L = CTLL	
	Control H = CTLH	
	General sample = rrr-pp	
	pp: position in rack No. 1 ~ 10	
	rrr: rack No. 001 ~ 999 (Rack barcode)	
ID CODE	16 digits	
	At sample barcode is valid, the sample barcode.	
	At sample barcode is invalid, the user ID.	
Av.	Repeat No.	
	Calibrator 1,2 = Calibration average unit number (Set by item parameters: $1 \sim 3$ ).	
	Control L = Control L repeat times (Set by item parameters: $1 \sim 3$ )	
	Control H = Control H repeat times (Set by item parameters: $1 \sim 3$ )	
	General samples (One day method) = 1	
	General sample (2 days method) = 1 (First day) , 2 (Second day)	
Data	Results	
Alarm	C:Barcode error	
	Q: Request confirmation error	
	N : Automatic measurement => Specimen Sensor OFF Manual request measurement =>	
	Specimen sensor OFF upon request	
	F: Specimen sensor ON without manual request measurement	
	T: Transportation error	

O Correct measurement values may not be obtained if air bubbles in the	MC
collection picker are on the lower side (cap side) or on the way.	

 If the MC Collection Picker overseal is dirty, the correct measurement values may not be obtained.
 Measure after removing the overseal

Measure after removing the overseal.

- Be careful not to peel off the label of the MC Collection Picker, and insert it firmly under the sample rack.
- $\ensuremath{\bigcirc}$  Make sure that the rack barcode and sample barcode are not dirty or scratched.
- When attaching a barcode on a MC collection picker, be sure to correctly attach the barcode with a clear and appropriate ratio of bars printed on it.
   If the barcode is not correct, it may not be read correctly.
- If the sample used as a specimen contains a large amount of solid matter, it may cause troubles such as clogging of the pipette or it may not be possible to obtain correct data.

NOTE

CAUTION

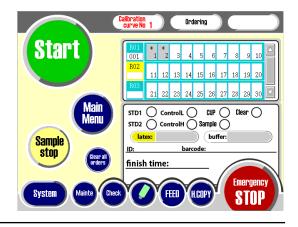
• O During the measurement, the measurement result is printed by the printer every time one sample is analyzed.

## 4.2 Measurement complete

When sample measurement is completed, the end operation is automatically started.

- 1) Eject the used reaction cell, and then stop the device.
- (2) At the same time as the device stops, an electronic sound will sound for 10 seconds.

(The position number after the measurement ends turns to gray.)



NOTE

#### Scheduled measurement complete time (finish time)

At the time of manual measurement, calculate and display the end time based on the number of sample registrations at the start of measurement.
At the time of automatic measurement, calculate and display the end time after completing the sampling.

## 4.2.1 Procedure after measurement

- (1) When measurement is completed, discard used cells in the cell dust box and all the samples (MC Collection Picker and sample cup) on the rack.
- (2) Remove the bottles of reagents and buffer solution from the device, and store them in the refrigerator.
- ③ Set a bottle of pure water in the buffer solution installation position and insert the suction nozzle into the bottle.
- (4) Tap "Wash" on the Main Menu screen. (Replace the buffer solution in the pipe with water.)



#### ○ Always wear medical rubber gloves.

When disposing of used cells in the cell dust box or samples on the rack (MC collection picker or sample cup), be careful not to touch them with your bare hands.

- $\ensuremath{\bigcirc}$  Treat each waste as medical waste and ask a professional contractor to dispose of it.
- For storage of reagents and buffers, follow the instructions in the reagent and buffer package insert.

## 4.3 Displaying and printing measurement results

Tap [Result] on the Main Menu screen to display, print, and send the results to the host computer, and calculates statistics.

#### 1) Display Result screen

Tap [Result] to display Result screen. The Result screen has the following 5 menus.

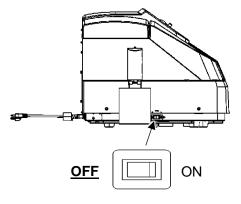
Menu	Contents
File	Display the file list of measurement results
Output	Output measurement results
Calc	Recalculation by changing the calibration
	curve and IST calculation mode
Avail	Select valid (unmarked)/invalid (x) and
	output the measurement result
RETURN	Exit of measurement result screen

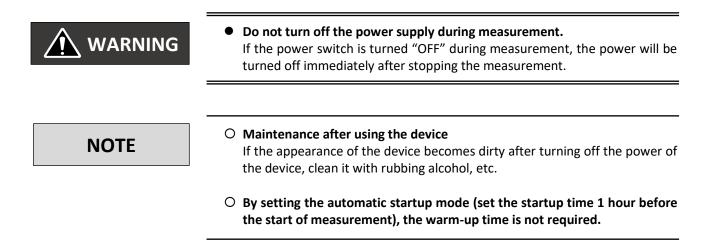
File Name : 2012091549 Num. : 30 Avail Sel. No. Pos. User ID Barcode Av. Data Mark									
vail	Sel.	No	Pos.	User ID	Barcode	Av.	Data		Mark
					<u> </u>				
		1	010- 1	000001	117000507728	1	>400.0	3+	B
		2	010- 2	000001	135000416375	2	181.5	2+	B
		3	010- 3	000002	134000356714	1	75.4	+	B
		4	010- 4	000002	135000416307	2	34.2	+-	B
		5	010-5	000003	134000356551	1	15.1	-	B
		6	010- 6	000003	134000321928	2	<7.0	-	B
		7	010-7	000004	3125067890123456	1	<7.0	-	B
		8	010- 8	000004	117000507728	2	<7.0	-	
		9	010- 9	000005	00007051	1	<7.0	-	
		10	010-10	000005	134000322098	2	<7.0	-	
					$\sim$				

## 4.4 Operation after measurement complete

- 1) Tap [Shut down] on the Main Menu screen.
- 1) Set the automatic start date and time.
- (2) Tap [Sleep Mode NOW].

\*If not set the automatic startup mode, set the power switch on the left side of the device to "OFF".

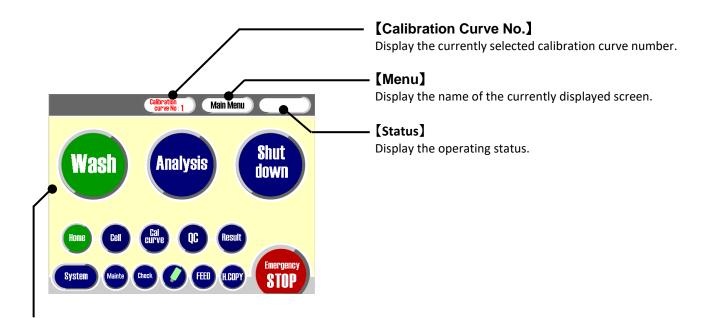




## **Chapter 5.** Screen Details

## 5.1 Main Menu screen

Tap the startup screen to display the Main Menu screen.



#### [Main Menu]

Main Menu	Function	Screen Operation Method
【Wash】	Perform washing operation.	-
[Analysis]	Register the sample request, set the reagent solution amount, and start measurement.	( <u>Chapter 5.3.1</u> )
【Shut down】	After setting the automatic start date and time, it automatically stops.	( <u>Chapter 5.3.2</u> )
【Home】	Return all units to home position.	-
【Cell】	Perform cell setting on the reaction table.	( <u>Chapter 5.3.3</u> )
【Cal curve】	Display/select calibration curve information and input calibration curve parameters.	( <u>Chapter 5.3.4</u> )
[QC]	Perform quality control.	( <u>Chapter 5.3.5</u> )
[Result]	Display the latest and past measurement results.	( <u>Chapter 5.3.6</u> )
[System]	Set various parameters.	( <u>Chapter 5.3.7</u> )
[Mainte]	Set various parameters.	( <u>Chapter 5.3.8</u> )
【Check】	Display reagent solution amount, buffer solution amount, tank liquid amount, number of remaining cells.	-
<b>USB</b>	Display the installation status of the USB memory and remove it.	-
[Feed]	Feed the printer paper.	-
【H.COPY】	Print the displayed screen.	( <u>Chapter 5.3.9</u> )
[Emergency Stop]	Emergency stop.	( <u>Chapter 5.3.10</u> )

\*The colors of the table heading are the button color of the Main Menu screen.

## 5.2 Submenu

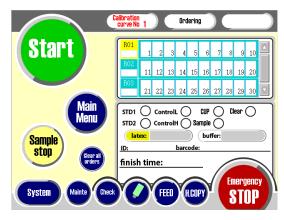
Various submenus and their functions

Main Menu	Submenu		Submenu Function
【Analysis】	Ordering	-	Register requests and set the amount of reagent solution.
		Start	Move to the Measurement monitor screen and start measurement.
		Main Menu	Move to the Main Menu screen.
		Sample Stop	Temporarily stop sampling operation.
		Clear all orders	Delete all measurement requests.
	Measurement monitor		Display the measurement result during
	Measurement monitor	—	measurement.
		Sample Stop	Temporarily stop sampling operation.
		Main Menu	Move to the Main Menu screen.
【Cell】	All change	_	Unconditionally replace all cells.
	Selective Change	—	Replace cells whose cell status is not OK.
			*However, even if it is OK when the sensor is
			enabled, replace it if it does not detect.
	All OK	-	Forcibly put all reaction cells in a cell-existing & unused state.
	Cell Cassette		Move to Cell Cassette screen.
		Main Menu	Move to Main Menu screen.
		Home Position	Return all units to home position.
		Cell Set	Set the position to take out the cell cassette
		Cell Set	(reaction cell).
[Cal curve]	Master		Functions for service personnel.
	Curve		Display calibration curve.
	Barcode	_	Input barcode for calibration curve parameter.
	Curve1⇔2	_	Switching calibration curve.
			*Selected calibration curve is used for
			measurement.
[QC]	Control X bar chart	_	Display measurement results with quality control or
			accuracy control.
			• Display X-R control chart of control sample.
	Histogram	-	• Display histogram of measurement results.
[Result]	File	-	Move to the result file and display the measurement
			result file list.
	Output	_	Output selection
			• Print: Display the print screen of the measurement
			result
			<ul> <li>HOST: Display the screen for sending the</li> </ul>
			measurement results to the host computer.
	Calc	-	Recalculation by changing the calibration curve and
			IST calculation mode.
	Avail		Select valid (unmarked)/invalid (x) results
[Mainte]	Unit Control		Functions for service personnel
	DETECT TEST	—	
	Error history	_	
	Maintenance	—	Menu used during maintenance
【Check】	Start checking	-	After standby operation, various information is
			acquired and displayed
	Main Menu	—	Move to the Main Menu screen

## 5.3 Screen Operation Method

## 5.3.1 Analysis screen

Tap [Analysis] on the Main Menu screen to display sample request screen, then display request information, sample amount, buffer amount, ID and finish time.



## 5.3.1.1 Amount of reagent setting procedure (when reagent level detection is invalid)

If you replace the reagent bottle with a new one, or if it is different from the reagent bottle used in the previous analysis, follow the procedure below to manually set the amount of reagent.

#### 1) Display numeric keypad input screen

Tap the latex remaining amount display (□ part) to display the numeric keypad screen for reagent amount registration.

\*Set the buffer solution ( part) in the same procedure.

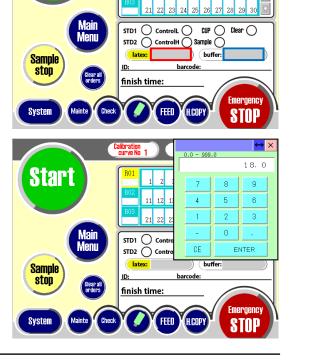
#### 2) Input amount of reagent

Use numeric keypad to input reagent amount. \* Input reagent amount (initial value 18 mL).

#### 3) Register reagent amount

Tap [ENTER] to register.

(When amount of reagent is registered, display the number of samples that can be registered where calculated from the registered reagent amount.)



Ordering

11 12 13 14 15 16 17 18

### NOTE

**O** Please register reagent amount before registering samples.

If the number of samples that can be registered (the amount of registered reagents) is exceeded, a message will be displayed.

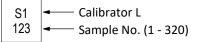
Stari

### 5.3.1.2 Procedure to request calibrator (If measurement mode is manual)

The procedure for registering a request to measure the calibrator is as follows.

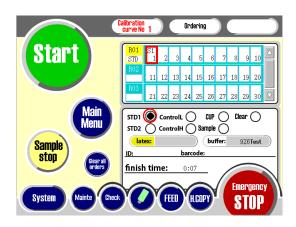
#### 1) Register Calibrator L

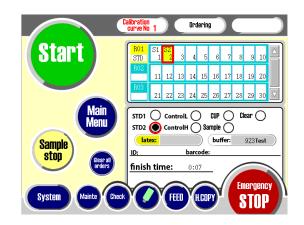
- 1 Tap (o part) of STD1 to be O.
- (2) Tap the position frame (No. □) to register the request of Calibrator L.
- ③ Display request details in the position frame.



#### 2) Register Calibrator H

- 1 Tap (o part) of STD2 to be O.
- (2) Tap the position frame (No. □) to register the request of Calibrator H.
- ③ Display request details in the position frame.





NOTE

#### $\odot\,$ Tap [Start] to measure only the calibrator.

\*If measures with control, tap [Start] on the screen after both of calibrator and control requests are registered.

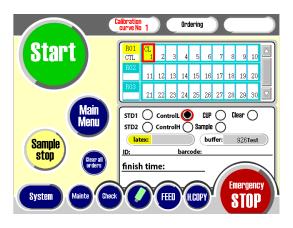
#### 5.3.1.3 Procedure to request control (if measurement mode is manual)

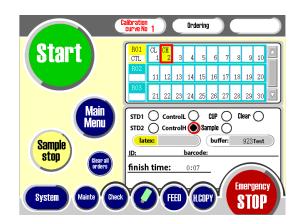
The procedure for registering a request to measure the control solution is as follows.

#### 1) Register Control L

- 1 Tap (o part) of ControlL to be O.
- (2) Tap the position frame (No. □) to register the request of Control L.
- ③ Display request details in the position frame.

CL	Control L
123	<ul> <li>Sample No. (1 - 320)</li> </ul>





	<ul> <li>If changed the number of repetitions of the control in the item parameter settings, register the request of control again.</li> </ul>
NOTE	<ul> <li>Tap [Start] to measure only the control solution.</li> <li>If measures with calibrator, tap [Start] on the screen after both of calibrator</li> </ul>

and control requests are registered.

#### 2) Register Control H

- ① Tap (○ part) of Control H to be ●
- (2) Tap the position frame (No. □) to register the request of Control H.
- ③ Display request details in the position frame.

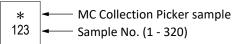
СН	Control H
123	Sample No. (1 - 320)

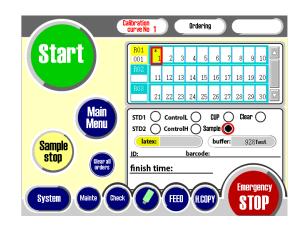
## **5.3.1.4** Procedure to request samples from MC Collection Picker (if measurement mode is manual)

The procedure for registering a request to measure the samples from MC Collection Picker is as follows.

#### 1) Register sample

- 1 Tap (o part) of Sample to be O.
- (2) Tap the position frame (No.  $\Box$ ) to register sample.
- (3) Display request details in the position frame.





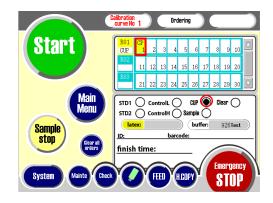
#### 5.3.1.5 Procedure to request samples from cup (if measurement mode is manual)

The procedure for registering a request to measure the samples from sample cup is as follows.

#### 1) Register sample

- 1 Tap (o part) of CUP to be O.
- (2) Tap the position frame (No.  $\Box$ ) to register sample.
- ③ Display request details in the position frame.





#### 5.3.1.6 Addition of samples during measurement (if measurement mode is automatic)

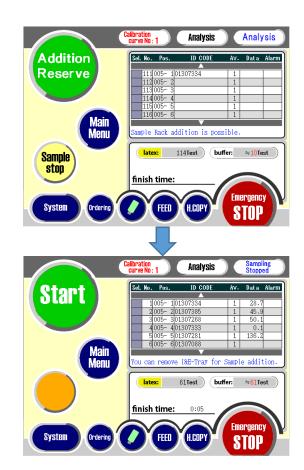
This device does not measure as an emergency sample.

However, if sampling of the installed rack is completed and "Sample Rack addition is possible" is displayed in the operation message field, the rack can be additionally registered.

#### 1) Tap [Addition Reserve]



(Restart measurement)



	$\bigcirc$ Check the following points when starting the measurement.
	<ul> <li>The required amount of detergent, reagents and samples for measurement must be prepared.</li> <li>The cover must be closed.</li> <li>The detergent tube and waste tube on the back of the main unit must be connected correctly.</li> </ul>
NOTE	O If the sample registration is manual, register the sample on the Analysis screen and then tap [Start].

## 5.3.1.7 Request method by sample ID (bar code) registration (If measurement mode is manual)

Sample request is possible by sample ID (barcode) registration.

- 1) Tap barcode (□ part) column.
- 2) Tap position frame (No. 🔲) to start registration.
- 3) Scan the barcode of the sample (MC Collection Picker)

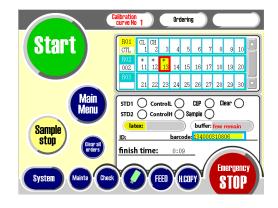
Scan the sample barcode with a barcode scanner. (Registered as a sample " \* " along with barcode registration/display.)

#### 4) Register the next sample

Then scan the next sample barcode. (Registered in the position frame next to the registration start.)

#### 5) End of procedure

Tap the barcode column (becomes white) again.



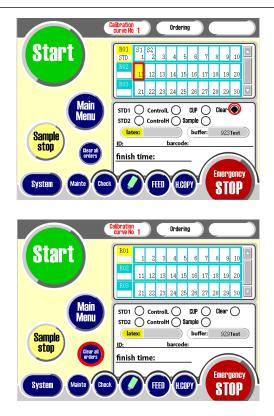
	0	If the positions where the sample is registered and the MC Collection picker is set in the rack are different, cannot obtain correct measurement results. Be sure to check the position before measuring.
NOTE	0	Sample ID (bar code) cannot be registered during measurement operation.
	0	Unable to register in a position where the sample ID has already been registered.
	0	If the barcode cannot be registered, the electronic sound will be short and will sound twice.

#### 5.3.1.8 Clear of each registered contents

- 1 Tap (o part) of Clear to be •.
- (2) Tap the position frame (No. □) to clear the register.

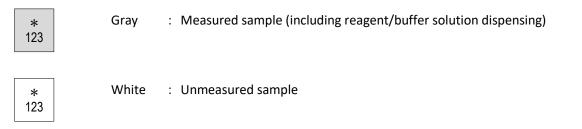
#### 5.3.1.9 Batch clear of registered contents

- 1 Tap [Clear all orders] (o part).
- (2) The message box is displayed to tap [Yes].



### 5.3.1.10 Color display of position frame

Each position frame is displayed to the following colors according to each sample measurement status.





Magenta : Sample in transportation line when transportation error

## 5.3.2 Shut down screen

#### 1) Display the date and time setting screen

Tap [Shut down] on the Main Menu screen. (The screen for setting the date and time when to boot the device next time after stopping the operation of the device.)



#### 2) Set the startup date and time

Set the date and time and tap [Sleep Mode NOW]. (The device automatically stops.)



O **It takes about one hour to warm up from the device starts up.** Set the automatic start date and time approximately 1 hour before the measurement start time.

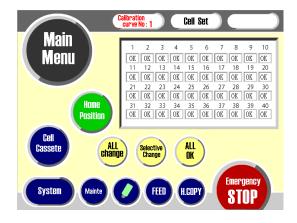
## 5.3.3 Cell screen

#### 5.3.3.1 Display reaction cell status

Tap [Cell] on the Main Menu screen to display the status of the reaction cell on the reaction table.

The status of the reaction cells at positions 1 to 40 of the reaction table is displayed by dividing them into the following 5 types.

Status of Cells	Display
With cells (Unused)	ОК
With cells (During measurement)	MS
Cell replacement error or suspend	NG
Cell unconfirmed	??
Without cell	(Blank)



#### 5.3.3.2 Setting reaction cells

Reaction cells can be set in the reaction table with the [All Changes], [Selective Change] and [All OK] buttons.

There are following three types of reaction cell settings.

Display	Contents
All Changes	Replace all reaction cells.
Selective Change	Replace used cells or unavailable reaction cells.
All OK	Forcibly put all reaction cells in a state with cells (unused).

## 5.3.4 Cal curve screen

Create and display a calibration curve, and select a calibration curve for measurement.

#### 1) Display Cal curve screen

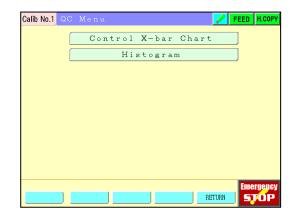
Tap [Cal Curve] on the Main Menu screen. (Display Calibration Curve screen.)

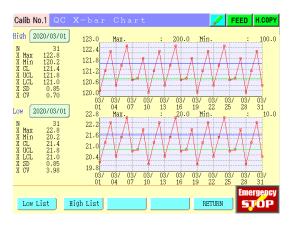
Ma	ster C	urve regis	tered 2020	/11/30 11:	53
٢	Point	Dilution	I.S.T	Besult	[Master Curve]
	1	6.3	178	6.3	Date 2020/11/30
	2	12.5	340	12.6	Exp. 06.18
	3	25.0	789	25.4	Lot 137AGF
	4	50.0	2127	49.0	[Calibrator]
	5	100.0	6702	99.0	Exp.
	6	200.0	18146	205.9	Lot
	7	400.0	35956	394.3	Cal. Low 25.0
	8				Cal. High 400.0
	9				
	10				
	A	0=-5.9235	A1=5.4447	1 A2=-1.3	930 A3=0.13354

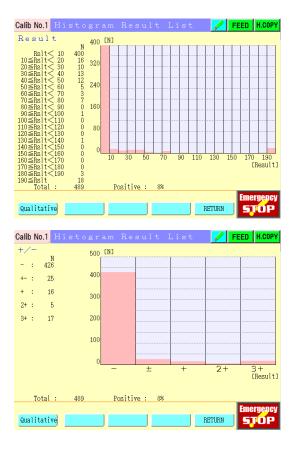
Menu	Contents
Master	Display master calibration curve, create calibration curve by multi-
	point measurement of standard sample, display and correction of
	calibration curve correction data
Curve	Display calibration curve
Barcode	Input barcode for calibration curve parameter
Curve 1⇔2	Switching calibration curve

## 5.3.5 QC screen

Tap [QC] on the Main Menu screen to display QC screen.







## 5.3.5.2 Histogram screen

5.3.5.1 Control X bar chart screen

The fluctuation transition of the control can be checked.

Display histogram of sample by "Concentration Value" or "Qualitative Judgment".

## 5.3.6 Result screen

Result Screen displays measurement results of the latest and the past.

#### 1) Display Result screen

Tap [Result] on the Main Menu screen.

Displaying contents are as follows.

Display	Contents
Sel.	Check column
No.	Sample No.(1 $\sim$ 320) on the day of measurement
Pos.	Display rack No. and position No.
User ID	Display of user ID set in user parameters
Barcode	The sample barcode is displayed when it is valid.
Av.	Repetition No. of calibrator and control.
Data	Measurement results (ng/ml)
+/-	Determination of results
Mark	Flag or error code

	File I Sel.		: 201209 Pos.	liser ID	Num. : 30 Barcode	ÅΥ.	Data		Mark
			100.	0001 10			butu		
		1	010- 1	000001	117000507728	1	>400.0	3+	В
		2	010-2	000001	135000416375	2	181.5	2+	B
		3	010-3	000002	134000356714	1	75.4	+	B
		4	010- 4	000002	135000416307	2	34.2	+-	В
		5	010-5	000003	134000356551	1	15.1	-	B
		6	010- 6	000003	134000321928	2	<7.0	-	B
		7	010-7	000004	3125067890123456	1	<7.0	-	В
		8	010- 8	000004	117000507728	2	<7.0	-	
		9	010- 9	000005	00007051	- 1	<7.0	-	
		10	010-10	000005	134000322098	2	<7.0	-	
					$\sim$				
								Em	ergei
Fi	le	)	Output	Cal	c Avail	1	RETURN	5	ŢΟ

#### 2) Display reaction data

Tap the raw ( $\Box$  part) of the sample to display the reaction data of the measurement.

#### Calib No.1 Re 24000 [I.S.T] :2020/12/09 15:51:51 Date User ID :000005-1 Barcode :00007051 21000 SampleNo.: 9 Pos.:010- 9 Cell No.: 6 △I.S.T.: 8873 1800 0.5 [- ] -Conc Point 1500 Point 11 12 13 14 15 16 17 18 19 20 IST 1838 1200 5271 600' 900 17 19 [Point] Rg.L.Surface:1225 1241 Lot Info 1P ST

### 5.3.6.1 If display the Result screen of past files

1) Tap [File]

#### 2) Tap the line to display Result screen

(Result screen displays.)

Sel.	No.	File Name		Sel.	No.	File Name	
		1				1	
	21	2012021420			31	2012031407	
	22	2012021454			32	2012031429	_
	23	2012021509			33	2012031446	
	24	2012021700		ø	34	2012031647	
	25	2012030938		ø	35	2012091512	
	26	2012030953		ø	36	2012091549	
	27	2012031102					
	28	2012031129					
	29	2012031302					
	30	2012031325					
			-	/			

#### 5.3.6.2 Print measurement results

- 1) Tap [Output]
- 2) Tap [Print]

Calil	b No.1	Res	ult					FEED H.COPY
	File	Name	: 200702	1748	Num.: 2			
Ava	ail Sel.	No .	Pos.	User ID	Barcode	Á۷.	Data	Mark
					$\sim$			
		41	003- 1	000031	04987727	1	0.0	
		42	003- 2	000032	52942170	1	0.1	
_					$\sim$			
_								_
			Print	HOS	т ]		RETURN	Emergency STOP

## 3) Select the number to print.

Tap the position frame [Sel.] to print measurement results to display [ $\checkmark$ ]. Or tap [All].

lib No.1	Res	ult (	Print	:)			FEED H.	C
File 1	Name	: 201209	1549	Num.: 30				
rail Sel.	No.	Pos.	User ID	Barcode	Av.	Data	Marl	ĸ
	1	010- 1	000001	117000507728	1	>400.0	3+ B	-
ø	2	010- 2	000001	135000416375	2	181.5	2+ B	-
	3	010- 3	000002	134000356714	1	75.4	+ B	-
ø	4	010- 4	000002	135000416307	2	34.2	+- B	-
ø	5	010- 5	000003	134000356551	1	15.1	- B	-
	6	010- 6	000003	134000321928	2	<7.0	- B	-
Ý	7	010- 7	000004	3125067890123456	1	<7.0	- B	-
	8	010- 8	000004	117000507728	2	<7.0		-
Ý	9	010- 9	000005	00007051	1	<7.0		-
	10	010-10	000005	134000322098	2	<7.0		-
				$\sim$				
s column	of ES	el.] or	[All] to	choose, [Execute]	to pr	rint.	Emerg	eI
All			1	Execute		RETURN	51	1

#### 4) Tap [Execute].

Printing starts.

 \*\*\*\*\*\*\* Analytical Result \*\*\*\*\*\*\*

 DATE:2010/09/21 11:21:45

 Cut off (ng/mL) 1: 30.0 2: 30.0

 Pos.
 I.S.T. ng/mL [+-] Mark

 002-1
 80
 0.5[-] --- 

 Barcode=[00017900
 ]

 002-2
 61
 0.3[-] --- 

 Barcode=[00017555
 ]

 002-3
 52
 0.2[-] ---- 

 Barcode=[00017921
 ]

 002-4
 59
 0.3[-] ---- 

 Barcode=[00017858
 ]

#### 5.3.6.3 Sending results to host computer

Tap [HOST] to send the measurement result data to the connected host computer.

- 1) Tap [Output].
- 2) Tap [HOST].

#### 3) Select the number of results to send.

Tap the position frame [Sel.] of results to send to the host computer to display [ $\checkmark$ ]. Or touch [All].

#### 4) Tap [Execute].

Send to host computer.

### 5.3.6.4 Calculate CV for concentration

Calculate the CV of the measured concentration.

- 1) Tap [Calc].
- 2) Tap [CV].

#### 3) Select the number of the result to calculate.

Tap the position frame [Sel.] of results to send to the host computer to display [ $\checkmark$ ]. Or tap [All].

- 4) Tap [Execute].
- 5) Tap [Print] to print.

lib N	lo.1	Res	ult					FEED	H.C
	ا ما آ	Jama	· 210520	1136	Num.: 3				
					Barcode	٨v.	Data		Mark
			2.501				Latu		
		31	003-1	000001	05265368	1	0.1	-	
		32		000002	53156025	1	0.0	-	
		33	003- 3	000003	00040247	1	0.0	-	
					[				
					$\sim$				
								-	
									erge
Fi	le		Output	Cal	c Avail		RETURN	5	ŢΟ
IL N	la 1	D	1 + /	HOST)				FEED	H.C
	10.1	nes	urt(	повт			-	FEED	14.0
	Filel	Name	: 210520	1136	Num.: 3				
					Barcode	Å٧.	Data		Mark
	ø	31	003- 1	000001	05265368	1	0.1	-	
		32	003- 2	000002	53156025	1	0.0	-	
		33	003-3	000003	00040247	1	0.0	-	

	1	31	005-1	1000001	05762262	1 1	0.1	-	
		32	003-2	000002	53156025	1	0.0	-	
		33	003- 3	000003	00040247	1	0.0	-	
Pres	ss column	of ES	el.] or	[All] to	choose, [Execute]	to s	end.	E	nergenc
	¥11				Execute		RETURN		TOP

	File M	lame	: 210520	1136	Num.: 3			
wail	Sel.	No.	Pos.	User ID	Barcode	Å٧.	Data	Mark
	ø	31	003- 1	000001	05265368	1	0.1	
		32	003-2	000002	53156025	1	0.0	
		33	003- 3	000003	00040247	1	0.0	
					$\sim$			
000.0	olumn	of IS	allor	rall1 to	choose, [Execute]	to pr	int	Emergen

## 5.3.7 System Menu screen

These menu are for service personnel to set each parameter. \*If you want to change, contact your local distributor.

Calib No.1	System	Menu		FEED H.COPY
		Item	Parameter	
		User	Parameter	
		Commu	ınication	
	Date/Time			
		Systen	n Save∕Load	
HM-J Ma	ACKarc <b>II</b> in:10.00T1	Control:10	.00 Detect:10.00	Temp: 1.00
			MakerClear I	RETURN Emergency

## 5.3.8 Maintenance Menu screen

These menu are for service personnel to set each parameter display and setting that are measurement condition. \*If you want to change, contact your local distributor.

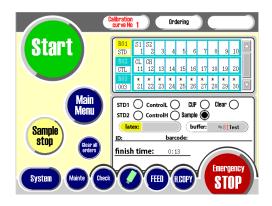
Calib No.1 Mai	ntenance Menu	FEED H.COPY
	Unit Control	
	DETECT TEST	
	Error History	
	Maintenance	
		RETURN Emergency

## 5.3.9 H.COPY screen

#### 1) Tap [H.COPY].

Print out the hardcopy of current screen.

\*Cannot be used during measurement operation.



## 5.3.10 Recovery operation from Emergency STOP

If this device stopped by tapping [Emergency STOP], operate as follows to recover the device.

- ① After tapping [Emergency STOP], confirm that each unit has stopped.
- (2) If there are obstacles within the range of movement of the unit, remove them.
- ③ Tap the [Home] button to return to origin.

NOTE

O If cannot recover from the error even with the above operation, please contact your local distributor.

## **Chapter 6. Maintenance**

This chapter provides the necessary information of maintenance work.

## 6.1 Tools and parts required for maintenance work

For the device maintenance, the following tools and consumables are required.

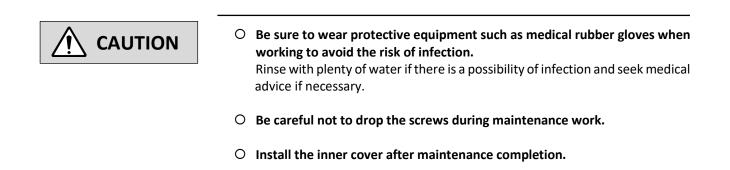
■ Tool		
Tool	Description	
Driver (+) driver (No.1)	Removing/installing fixing screw on the device cover. Removing/installing the parts.	
Cotton swab	Wiping parts	
Gauze, dry cloth, etc.	Wiping parts	
USB memory	Read/write various parameters. Update etc.	
Air spray	Patch's removal of dust on the products.	
Rubbing alcohol	At necessary (Cleaning)	
Detergent diluent (Haiter etc.)	At necessary (Cleaning Tank)	

Consumable etc.

Product name	Implemented	Contains of Maintenance Contents.
Inlet filter	At necessary	Replace the filter.
Printer paper A	At necessary	A set of Printer paper.

## 6.2 How to remove/install inner cover

Most of maintenance needs to remove the inner cover. Please follow the following procedure to remove the inner cover.



### 6.2.1 How to remove

1) Open the outer cover.

#### 2) Loosen the inner cover.

Loosen the two screws ( $\rightarrow$  parts). (The inner cover is hooked on the two left and right screws and fastened to the main body.)



#### 3) Remove the inner cover

Pull the inner cover slightly toward front (less than 1 cm) and pull it horizontally to remove it. \*Hold the inner cover with both hands to shift both sides at the same time.

## 6.2.2 How to install

#### 1) Install the inner cover

Hook the inner cover so that the screw goes into the notch in the inner cover.

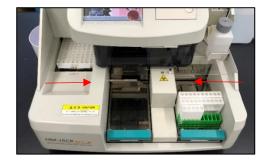
Bring it with both hands so that the other side can enter at the same time.

\*Be careful not to let the washer through the screw get between the inner cover and the main body.



#### 2) Fix the inner cover

Tighten the screw to secure the inner cover.



3) Close the outer cover.

## 6.3 Daily maintenance

# CAUTION Be sure to wear protective equipment such as medical rubber gloves when working to avoid the risk of infection. Rinse with plenty of water if there is a possibility of infection and seek medical advice if necessary. Ethanol (alcohol) is flammable. Please handle with care.

**O** Be careful not to bend each pipette and stirring spatula.

## 6.3.1 Cleaning of sample pipette, reagent pipette and stirring spatula

- 1) Remove the inner cover.
- 2) Display Maintenance screen.

Tap "Mainte" on the Main Menu screen.

#### 3) Tap "Maintenance".

Tap "Maintenance" on the Maintenance Menu screen.

#### 4) Tap [S/R Pipette, Stirring Spatula wash].

#### 5) Tap [Start].

Display "Pipette operates. OK?" in the message box.

Make sure that there is no obstacle within the movable range of the pipettes, and then tap [Yes]. (Sample/reagent pipette and stirring spatula move onto the wash station.)

#### 6) Wipe it off with gauze etc.

Wipe each pipette and stirring spatula with alcohol-soaked gauze.







#### 7) Tap [End].

Start washing operation.



- 8) End of washing and then install the inner cover.
- 9) Close the outer cover.

## 6.4 Weekly maintenance

O Do not use boiling water.
<ul> <li>Be careful when handling hot water, etc., and do not touch it directly with your bare hands.</li> </ul>
<ul> <li>Be sure to wear protective equipment such as medical rubber gloves when working to avoid the risk of infection.</li> <li>Rinse with plenty of water if there is a possibility of infection and seek medical advice if necessary.</li> </ul>
O Ethanol (alcohol) is flammable. Please handle with care.

## 6.4.1 Cleaning the retaining lever for a stool picking container

#### 1) Wipe the retain lever for a stool picking container

Wipe the front and back sides of the o part with alcoholsoaked gauze, etc.

#### 2) Wipe the piercing holes

Wipe the pierced hole ( $\bigcirc$  part) with a cotton swab soaked in alcohol.

\*If it is very dirty, please try it with hot water. (If necessary, remove the dripping prevention plate fixing screw ( $\rightarrow$  part) by hand, and remove the dripping prevention plate before starting work.

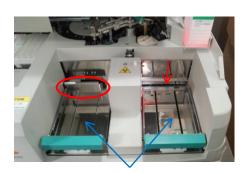
#### 6.4.2 Cleaning the rack tray and sampling line

- 1) Shut down mode or power switch OFF.
- 2) Please place the carry-out arm in the back (Opart).
- 3) Wipe out the rack tray ( $\rightarrow$  part).

Remove the left and right rack trays and wipe the surface with alcohol-soaked gauze.

\*If it is very dirty, please try with hot water as well.

4) Wipe out the sampling line (→ part) as well.





## 6.5 Monthly maintenance

O Do not use boiling water.
<ul> <li>Be careful when handling detergent, hot water, etc., and do not touch it directly with your bare hands.</li> </ul>
<ul> <li>Be sure to wear protective equipment such as medical rubber gloves when working to avoid the risk of infection.</li> <li>Rinse with plenty of water if there is a possibility of infection and seek medical advice if necessary.</li> </ul>
O Ethanol (alcohol) is flammable. Please handle with care.

## 6.5.1 Cleaning the buffer tray

#### 1) Wipe the buffer solution tray/suction nozzle temporary stand ( $\rightarrow$ part).

Wipe the buffer solution tray/suction nozzle temporary stand with alcohol-soaked gauze, etc. \*If the dirt does not come off, try with detergent or hot water as well.



## 6.5.2 Cleaning the detergent tank

#### 1) Wash the detergent tank.

Clean the detergent tank periodically with detergent diluent such as haiter.

\*Please wash thoroughly with purified water after using detergent.

## 6.5.3 Cleaning the pipette wash tank

#### 1) Remove the inner cover.

2) Display the maintenance screen.

Tap "Mainte" in the Main Menu screen.

#### 3) Tap "Maintenance".

Tap "Maintenance" in the Maintenance Menu screen.

#### 4) Tap "Washing tank wash".

#### 5) Tap [Start].

- 1 Display "Beware of the movement of the pipettes."
- (2) Make sure that there are no obstacles in the movable range of the pipettes, and then tap [Yes].
   (Sample/reagent pipette and stirring spatula move onto the reaction table.)

#### 6) Wipe the washing tank with a cotton swab.

Wipe the inside of the wash tank with a cotton swab.

Calib No.1 Main	tenance Menu	FEED H.COPY
	Unit Control	
	DETECT TEST	
	Error History	
	Maintenance	
		RETORN STOP
Calib No.1 Main	tenance(for Field Service ONL)	
	S/R pipette, Stirrer spatula wash	
	Washing tank wash	
	Sample pipette exchange	
	Beagent pipette exchange	
в	eware of the movement of the pipetto:	rs.
	Yes No	
<ul> <li>During maintenar</li> <li>Beware of the sh</li> </ul>	ned personnel can proceed this funct nee, wear protective gear to prevent marp tip of sample pipette and reagen - and remove inner cover before start	infection. t pipette.
Press [Start] to p	erform maintenance.	
		Emergency





#### 7) Tap [End] after cleaning complete.

Washing operation starts.



#### 8) Install the inner cover after washing complete.

Close the outer cover and operation is end.

## 6.6 Maintenance every three months

## 6.6.1 Cleaning cell sensor



- Never use alcohol, detergent, etc.
- Be sure to wear protective equipment such as medical rubber gloves when working to avoid the risk of infection.
   Rinse with plenty of water if there is a possibility of infection and seek medical advice if necessary.
- 1) Sleep mode or power switch OFF.
- 2) Remove the inner cover.
- 3) Move the cell hand to left side.

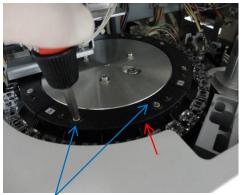
Move the cell hand from the top of the reaction table to the left side by hand.



#### 4) Remove the cell holder.

Remove the two screws ( $\rightarrow$  part) of one of the cell holders, and remove the cell holder ( $\rightarrow$  part).

\*Be careful not to drop the screws inside the device when removing.



#### 5) Move the reaction table to the cell hand position.

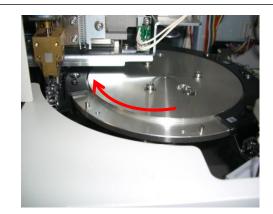
Turn the reaction table clockwise to move the removed cell holder part to the cell hand position.

#### 6) Removes dirt from the tip of the cell censor.

- (1) Wipe the tip of the cell sensor with a cotton swab soaked in water to remove dirt.
- (2) Then remove the water with a dry cotton swab. (Dry wipe)



- 7) Fix the removed cell holder with mounting screws.
- 8) Install the inner cover.
- 9) Close the outer cover.



## 6.6.2 Cleaning cell holder

## 

 Be sure to wear protective equipment such as medical rubber gloves when working to avoid the risk of infection.
 Rinse with plenty of water if there is a possibility of infection and seek medical advice if necessary.

**O** Ethanol (alcohol) is flammable. Please handle with care.

#### 1) Sleep mode or power switch OFF.

- 2) Remove the inner cover.
- 3) Move the cell hand.

Move the cell hand from the top of the reaction table to the left side by hand.

#### 4) Remove the cell holder.

Remove the cell holder by referring to "cleaning cell sensor". \*There are 4 cell holders, but please work one by one. If you remove them all at once, you may not know the location when resetting.

#### 5) Removes dust from the (whole) surface of the cell holder.

Please blow off the dust on the surface with an air spray etc.

#### 6) Remove dirt from the cell holder.

Lightly soak gauze, kimwipe, etc. with water and wipe the surface to remove dirt.

\*Make sure that lint, paper waste, etc. do not remain in the holder. Use ethanol if the stain is tough.

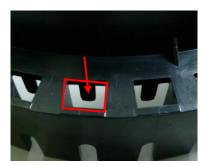
#### 7) Also clean the part of the cell holder where the cell is inserted.

Lightly soak a cotton swab with water and clean the part where the cell is inserted (inside, holding plate).

#### 8) Finally, use an air spray to remove dust and water.



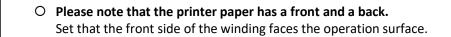




## 6.7 Replacement of consumables

## 6.7.1 Setting Printer paper A

CAUTION



• When cutting the printer paper, remove the printer paper from the paper guide and cut it.

#### 1) Open the paper cover

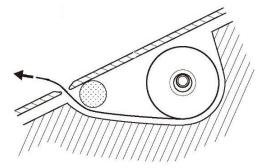
Press the button on the printer and lift the front edge of the paper cover to open it.

#### 2) Set the Printer paper A

Set the printer paper so that the tip of the printer paper protrudes slightly from the paper cover, and pull out the edge of the printer paper by about 3 cm.



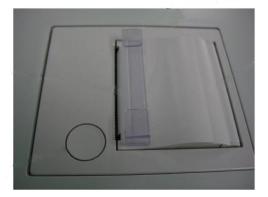




#### 3) Close the paper cover

#### 4) Insert the Printer paper A into the paper guide

Insert the drawn printer paper into the paper guide.



### 6.7.2 Replacement of Inlet filter

\*Replace about every 6 months.

## 

- When replacing the Inlet filter, wear medical rubber gloves, etc.
   Be careful not to touch the detergent solution tube with your bare hands.
- If the tube inside the detergent solution tank is contaminated by touching it with bare hands, thoroughly clean it with detergent solution before setting it in the tank.

#### 1) Pull out the Inlet filter.

Pull the old filter out of the filter holder.

#### 2) Insert the Inlet filter.

Insert the new filter firmly into the filter holder.

### 6.7.3 Replacing the sample pipette

\*Replace about every year.

• Be sure to wear protective equipment such as medical rubber gloves when working to avoid the risk of infection. The stirring spatula, sample pipette, and reagent pipette attached to the dispensing arm are structurally in direct contact with the sample (stool) and reagent, and if handled improperly, there is a risk of infection with pathogens and poisoning by the reagent, which is extremely dangerous.
<ul> <li>Power OFF of the device, unplug the power plug from the outlet, and perform the work.</li> <li>If you work with the power plug connected to the outlet, the arm may malfunction which is outrempty dependence.</li> </ul>
<ul> <li>Mhen removing the sample pipette, be careful not to pierce your hands with the momentum.</li> </ul>
<ul> <li>The installation of the sample pipette is a little tight.</li> <li>The tip of the sample pipette, stirring spatula, and reagent pipette is sharp and dangerous, so be careful not to get injured.</li> </ul>
<ul> <li>O When pulling out the sample pipette, be careful not to damage the stirring spatula and reagent pipette.</li> </ul>
$\odot$ When attaching the sample pipette, insert it firmly to the root.

1) Tap "Mainte" in the Main Menu screen.

2) Tap "Maintenance" in the Maintenance Menu screen.



#### 3) Tap "Sample pipette exchange".

#### 4) Tap "Start".

- 1 Display "Beware of the movement of the pipettes."
- Make sure that there are no obstacles in the movable range of the pipettes, and then tap [Yes].
   (Sample/reagent pipette and stirring spatula move onto the reaction table.)

#### 5) Power OFF.

Power OFF the device and unplug the power plug from the outlet.

#### 6) Remove the inner cover.

#### 7) Remove the bag nut

Remove the bag nut (O part) at the base of the sample pipette.

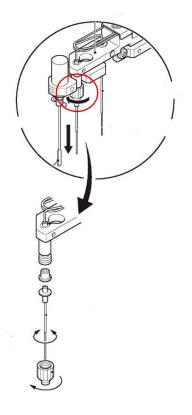
#### 8) Pull out the sample pipette

Gently pull the sample pipette downward. \*At this time, you can easily remove the sample pipette by turning it left and right.

#### 9) Install the sample pipette

Install a new sample pipette in reverse order.





## **Chapter 7. Error Message**

## 7.1 Error mark

The error mark indicates the following conditions:

Mark					
1	2	3	4		
Reaction 1	Reaction 2	Barcode	Reaction 3		
Mark1					
	-	Normal			
	S	Without samp	ole	IST of sample dispensing point exceeds set value	
	В	Reagent abno	rmality	IST of reagent dispensing point is out of the set range.	
Reaction 1	A	Reagent abnormality With reaction abnormality		The difference in IST between reaction point TA (=14 <sup>th</sup> point) and reaction point T1 (=7 <sup>th</sup> point) is out of the set range ((1)). The difference in IST between reaction point T2 (=20 <sup>th</sup> point) and reaction point TA (=14 <sup>th</sup> point) is out of the set range ((2)). The difference in inclination between ((1)) and ((2)) is out of the set range.	
	Р	Prozone		More than the set value of reaction point T1 (=7 <sup>th</sup> point).	
	р	Prozone caution		Added to the sample for the set number of consecutive times after the P mark.	

Mark2			
	-	Normal	
Reaction 2	U	Reaction upper limit error	The difference between the IST of reaction point T1 and reaction point T2 is greater than or equal to the set maximum value.
	D	Reaction lower limit error	The difference between the IST of reaction point T1 and reaction point T2 is less than or equal to the set minimum value.

Mark3			
	-	Normal	
	С	Sample barcode error	Unable to read the sample barcode.
Barcode	Q	Request check error	No request or no response.
	Н	Bar code scanner adopted	Built-in barcode reading error, but when the sample is registered with the barcode scanner.
Transportation error	Т	Transportation error	With transportation error (priority is given to barcode errors against 'C' and Q')

Mark4			
	-	Normal	
Reaction 3	т	Point IST error	When the concentration is not within the set range, the points of IST and $\Delta$ IST within the specified range are less than the set value.

## 7.2 Error code/Error message

#### ■Error code

The error code consists of 5 digits and has the following contents.



The contents of each code are shown in the table below.

#### Operation No.

No.	Contents			
01	Initialization of pulse motors			
02	Home position			
03	Stand-by motion or preparation before starting measurement			
04	Movement to the start reaction cell No. position			
05	Importing sample racks to start measurement			
06	Analysis operation			
07	Wash operation			
08	Recovery motion from sleep mode			
09	Cell set			
10	Unit control operation			
11	Test for adjustment test			
12	Analysis for calibration curve creation			
13	Transfer of PPMC configuration data			
14	Transfer of temperature control parameter			
15	Switching temperature control mode between stand-by and ready			
16	Reception of temperature control parameter			
17	Detect test processing			

## • Error Status No.

The last 3 digits of the error code are displayed with the number corresponding to the error occurrence contents.

#### • Status Display LED

Lights up according to the error content that occurred on the display at the top of the operation unit. Display color: Red (error), Yellow (warning)

#### • Error Message

Display the details of the occurred error. Selected Japanese display: Japanese, Selected English display: English

- Cause Explanation of the phenomenon/cause of the occurred error
- User Action

Explanation of the confirmation/recovery procedure for the occurred error \*When checking, wear rubber gloves and be careful of using the needle of the pipette. \*If you cannot recover with the following user actions, please contact your local distributor.

Error Status No.	Status Display LED color	Displaying Status	Error Message	Phenomena/Cause	User Actions
001	Red	Blink	Pipette rotation error	The operation of the dispensing arm rotation cannot complete within the specified time.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
002	Red	Blink	Pipet Up/Down error	The up and down movement of the dispensing arm cannot complete within the specified time.	Check the home position operation or operation on the unit control screen.
003	Red	Blink	Wash Syringe error	The operation of the washing syringe cannot complete within the specified time.	Check the washing line for clogging. Check the home position operation or operation on the unit control screen.
004	Red	Blink	Export rack movement error	The following factors can be considered. •Operation cannot complete within the specified time. •Position sensor does not turn on when ejecting. •Origin movement is not possible.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.

Error Status No.	Status Display LED color	Displaying status	Error Message	Phenomena/Cause	User Actions
005	Red	Blink	Transportation rack movement error	The following factors can be considered. •Operation cannot complete within the specified time. •Position sensor does not turn on when moving to each position. •Origin movement is not possible.	Check the following on the transport line. • If there are obstacles or not. • Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.
006	Red	Blink	Import rack movement error	<ul> <li>The following factors can be considered.</li> <li>Operation cannot complete within the specified time.</li> <li>There is no import tray at the timing of import operation.</li> <li>Origin movement is not possible.</li> </ul>	If removed import tray, then reinstall the import tray. In other cases, please check the following on the import line. • If there are obstacles or not. • Is the rack or tray dirty due to sample solution leakage? (Unslipperry) Check the home position operation or operation on the unit control screen.
007	Red	Blink	Cell Hand horizontal error	The cell hand horizontal movement could not complete within the specified time.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
008	Red	Blink	Cell Hand Up/Down error	The up and down movement of the Cell Hand cannot be completed within the specified time.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
009	Red	Blink	Right cell cassette error	The operation of the right cell cassette could not complete within the specified time.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
010	Red	Blink	Left cell cassette error	The operation of the left cell cassette could not complete within the specified time.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
011	Red	Blink	Sample syringe error	The operation of the sample syringe could not complete within the specified time.	Check the sample line for clogging. Check the home position operation or operation on the unit control screen.
012	Red	Blink	Reagent syringe error	The operation of the reagent syringe could not be completed within the specified time.	Check the reagent line for clogging. Check the home position operation or operation on the unit control screen.

Error Status No.	Status Display LED color	Displaying status	Error Message	Phenomena/Cause	User Actions
013	Red	Blink	Reaction table error	The operation of the reaction table could not complete within the specified time.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
021	Red	Blink	Reagent switching valve error (SV1)	Reagent switching valve processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
022	Red	Blink	Washing solution switching valve error (SV2)	Reagent switching valve processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
023	Red	Blink	Mixing motor error	Stirring motor processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
024	Red	Blink	R Wash station valve error (SV4)	Wash station valve processing error on the reagent side (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
025	Red	Blink	S Wash station valve error (SV3)	Wash station valve processing error on the sample side (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
026	Red	Blink	Wash station pump error (P1)	Wash station pump processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
027	Red	Blink	Waste fluid pump error (P2)	Waste fluid processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.

Error Status No.	Status Display LED color	Displaying Status	Error Message	Phenomena/Cause	User Actions
031	Red	Blink	Reagent liquid surface error	Reagent liquid surface detection processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
037	Red	Blink	Cell Hand error	Cell Hand processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
038	Red	Blink	Export rack solenoid error	Export rack solenoid processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
039	Red	Blink	Import rack stopper error	Import rack stopper processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
040	Red	Blink	Export rack stopper error	Export rack stopper processing error (program error)	Power ON again. Check the home position operation or operation on the unit control screen.
061	Red	Blink	Pipet sample position Sensor error	The dispensing arm rotated to the sample position on the rack, but the position sensor did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
062	Red	Blink	Pipet washer position Sensor error	The dispensing arm rotated to the wash station position but the position sensor did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
063	Red	Blink	Pipet reaction cell position Sensor error	The dispensing arm rotated to the reaction cell position but the position sensor did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
064	Red	Blink	Reaction table index Sensor error	The reaction table rotated to the predetermined position but position sensor did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.

Error Status No.	Status Display LED color	Displaying Status	Error Message	Phenomena/Cause	User Actions
065	Red	Blink	Error: Reaction table is empty	Reaction table cell check processing error (program error)	
066	Red	Blink	Error: There is not a buffer bottle	Buffer bottle is not set.	Set the buffer bottle properly. If the message is output even though setting properly, set the user parameter "Buffer level sensor" to "Disable".
067	Red	Blink	Error: Wash tank is Empty	Detergent tank is empty.	Fill the detergent.
069	Red	Blink	Error: Device cover is open	Device cover opened so that stop operation.	Close the device cover.
070	Red	Blink	Error: Latex cover is opened	The reagent cover has opened so that stop measurement.	Close the reagent cover after the measurement is completed.
071	Yellow	Blink	The purified water disappears. Please supply.	Pure water tank sensor detects low remaining amount.	Fill the pure water tank with pure water.
072	Yellow	Blink	Buffer level is low	The remaining amount of buffer solution has fallen below the rated value.	Prepare new buffer solution.
073	Yellow	Blink	Latex is empty	Out of reagent. (Stop sampling)	Replace the reagent and set the remaining reagent (latex).
077	Red	Blink	Cell Hand index senor error	The cell hand moved to the horizontal predetermined position, but the position sensor did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
078	Red	Blink	Left cell cassette index Sensor error	The left cell cassette moved to the specified position, but the position sensor did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
079	Red	Blink	Right cell cassette index Sensor error	The right cell cassette moved to the specified position, but the position sensor did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
080	Red	Blink	Import rack sensor error	The following factors can be considered. •Operation cannot complete within the specified time. •There is no import tray at the timing of importing operation. •Origin movement is not possible.	If removed the import tray, reset the import tray. In other cases, check the following on the import line. •With/without obstacle •Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.
081	Red	Blink	Error: Import tray has been removed.	The following factors can be considered. •Operation cannot complete within the specified time. •There is no import tray at the timing of importing operation. •Origin movement is not possible.	If removed the import tray, reset the import tray. In other cases, check the following on the import line. •With/without obstacle •Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.
082	Red	Blink	Transport rack presence Sensor error	The following factors can be considered. •Operation cannot complete within the specified time. •Position sensor does not turn on when moving to each position. •Origin movement is not possible.	Check the following on the import line. •With/without obstacle •Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.
083	Red	Blink	Transport rack stop position Sensor error	The following factors can be considered. •Operation cannot complete within the specified time. •Position sensor does not turn on when moving to each position. •Origin movement is not possible.	Check the following on the import line. •With/without obstacle •Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.
085	Red	Blink	Error: Export tray is full	The export tray is full.	Remove the sample rack which became full. Or replace it to the empty export tray.
086	Red	Blink	Export rack presence sensor error	The following factors can be considered. •Operation cannot complete within the specified time. •Position sensor does not turn on when moving to each position. •Origin movement is not possible.	Check the following on the import line. •With/without obstacle •Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
087	Red	Blink	Error: Export tray has been removed	The export tray is dislodged.	Retry to set the export tray.
088	Red	Blink	Export rack index sensor error	The following factors can be considered. •Operation cannot complete within the specified time. •Position sensor does not turn on when moving to each position. •Origin movement is not possible.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
099	Red	Blink	Error: No transportation rack movement.	Transportation rack did not move. (Unable to detect OFF of transport index sensor.)	Check the following on the import line. •With/without obstacle •Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.
100	Red	Blink	Pipet reagent position (R) Sensor error	The dispensing arm rotated to the rack reagent position but the position sensor (origin) did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
101	Red	Blink	Pipet origin sensor error	The origin sensor of the dispensing arm did not turn on.	Check the home position operation or operation on the unit control screen.
102	Red	Blink	Wash syringe origin sensor error	The origin sensor of the dispensing arm did not turn on.	Check the wash line for clogging. Check the home position operation or operation on the unit control screen.
103	Red	Blink	Export rack origin sensor error	The origin sensor of the exporting arm sensor did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
104	Red	Blink	Transportation rack origin sensor error	The origin sensor of the transportation arm sensor did not turn on.	Check the followings on the transportation line. •With/without obstacle •Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
105	Red	Blink	Import rack origin sensor error	The origin sensor of the importing arm did not turn on.	Check the followings on the importing line. •With/without obstacle •Is the rack or tray dirty due to sample solution leakage? (Unslippery) Check the home position operation or operation on the unit control screen.
106	Red	Blink	Cell Hand horizontal origin sensor error	The origin sensor of the cell hand did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
107	Red	Blink	Cell catch Up/Down origin sensor error	The up/down origin sensor of the cell hand did not turn on.	Check if there are any obstacles in operation. Check the home position operation or operation on the unit control screen.
108	Red	Blink	Right cell cassette origin sensor error	The origin sensor of the right cell cassette did not turn on.	Check if there are any obstacles in operation. Check the operation on the home position operation or the unit control screen.
109	Red	Blink	Left cell cassette origin sensor error	The origin sensor of the left cell cassette did not turn on.	Check if there are any obstacles in operation. Check the operation on the home position operation or the unit control screen.
110	Red	Blink	Sample syringe origin sensor error	The origin sensor of the sample syringe did not turn on.	Check the sample line for clogging. Check the operation on the home position operation or the unit control screen.
111	Red	Blink	Reagent syringe origin sensor error	The origin sensor of the reagent syringe did not turn on.	Check the reagent line for clogging. Check the operation on the home position operation or the unit control screen.
112	Red	Blink	Reaction table origin sensor error	The origin sensor of the reaction table did not turn on.	Check if there are any obstacles in operation. Check the operation on the home position operation or the unit control screen.
121	Red	Blink	Detection unit error	Detection processing error (program error)	Please turn on the power again. Check the operation on the home position operation or the unit control screen.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
122	Red	Blink	Temp controller error	Temperature control processing error (program error)	Please turn on the power again. Check the operation on the home position operation or the unit control screen.
123	yellow	Blink	Hand-held barcode reader error	Handy barcode processing error (program error)	Please turn on the power again. Check the operation on the home position operation or the unit control screen.
124	yellow	Blink	Rack barcode reading error	Rack barcode processing error (program error)	Please turn on the power again. Check the operation on the home position operation or the unit control screen.
125	yellow	Blink	Sample-1 barcode reading error	Sample-1 barcode processing error (program error)	Please turn on the power again. Check the operation on the home position operation or the unit control screen.
126	yellow	Blink	Sample-2 barcode reading error	Sample-2 barcode processing error (program error)	Please turn on the power again. Check the operation on the home position operation or the unit control screen.
127	Red	Blink	Control CPU finish code error	Measurement processing error (program error)	Please turn on the power again. Check the operation on the home position operation or the unit control screen.
200	Yellow	Blink	Memory has been initialized. Please set date & time.	Memory (parameter) initialized due to dead backup battery	Until the backup battery is replaced, set the date and time, load the system, and operate after turning on the power. Leave the power on after the measurement is complete.
201	Red	Blink	Error: Control CPU is unconnected	Control CPU communication processing error (program error)	Please turn on the power again. Check the operation on the home position operation or the unit control screen.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
202	yellow	Blink	No measurement is ordered	Manual sample measurement request, no registration request.	Please register the request from the start rack on the sample request screen.
203	yellow	Blink	No order for the first rack	Manual sample measurement request, no registration request in the starting rack.	Please register the request from the start rack on the sample request screen.
204	yellow	Blink	Reaching maximum racks. Please wait until end of current run to restart.	The number of racks measured in one round has exceeded the maximum. (stop sampling)	Please wait until the measurement is completed. In case of manual sample measurement request, please clear all registration request once. Set the next rack and start the measurement.
205	yellow	Blink	Reaching maximum tests. Please wait until end of current run to restart.	The number of samples measured in one round has exceeded the maximum. (stop sampling)	Please wait until the measurement is completed. In case of manual sample measurement request, please clear all registration request once. Set the next rack and start the measurement.
206	yellow	Blink	LIS communication error	Abnormal communication data sent from HOST.	It may occur in the following cases. • If the HOST goes down during communication. • When noise gets on the communication cable.
208	Red	Blink	Error: Movement time- out	The operation has exceeded the time limit.	Please retry to turn on the power again.
209	Red	Blink	Error: CONTROL CPU. not receive the command	Control CPU operation start processing error.	Please retry to turn on the power again.
210	yellow	Blink	Error: Reaction table is empty.	No cells available in the reaction table.	Make sure there are cells in the cell cassette. Please install a new cell cassette to measure.
215	yellow	Blink	Finished during the stop of the sampling.	The measurement was terminated because all the measurement results were output during the sampling stop.	Please premeasure if there are any remaining samples in the rack.
216	Red	Blink	Emergency stop	Made an emergency stop.	Eliminate the emergency stop factor and resume measurement.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
221	yellow	Blink	Reagent Blank Error (T0). Sampling stop	Detected consecutive cells without reagents. (Stop sampling.)	Check the remaining volume of reagent. Replace reagent bottle.
222	Red	Blink	Error: Detect CPU unconnected	Control CPU communication processing error.	Retry to turn on the power again. Check the operation on the home position operation or the unit control screen.
223	yellow	Blink	CUnet mail error	Communication error between CPUs	Retry to turn on the power again. Check the operation on the home position operation or the unit control screen.
225	yellow	Blink	CUnet start error	Communication error between CPUs.	Retry to turn on the power again. Check the operation on the home position operation or the unit control screen.
227	Red	Blink	Latex Temp. control error	Liquid temperature exceeded the controllable range.	Press [Operating Control] on the control screen to check the temperature display. Set the user parameter [With/without temperature control: disabled] Operation is possible.
229	yellow	Blink	Enter Calibrator Low first.	Tried to register STD-1 after STD- 2.	Register STD-2 after STD-1.
230	yellow	Blink	Too many order for Calibrator Low	STD1 is already registered in one rack.	Review the registration.
231	yellow	Blink	Too many order for Calibrator High	STD2 is already registered in one rack.	Review the registration.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
232	yellow	Blink	Choosing finished rack.	Measured samples are following from the start rack.	Restart after deletion.
234	yellow	Blink	Order attribution conflict.	Tried to register other than STD, if already registered STD-1 in one rack.	Review the registration.
235	yellow	Blink	Order attribution conflict.	Tried to register other than STD, if already registered STD-2 in one rack.	Review the registration.
236	yellow	Blink	Order attribution conflict.	Tried to register other than CTL, if already registered CTL-L in one rack.	Review the registration.
237	yellow	Blink	Order attribution conflict.	Tried to register other than CTL, if already registered CTL in one rack.	Review the registration.
238	yellow	Blink	Order attribution conflict.	Tried to register other than general sample, if already registered general sample in one rack.	Review the registration.
239	yellow	Blink	Control order conflict.	The number of control registration samples exceeded the rated value. (Default value = consecutive 10 units.)	Set not to exceed the rated value.
240	yellow	Blink	Latex is empty.	No reagent. (Stop sampling.)	Replace the reagent and set the remaining amount of reagent (latex).
241	yellow	Blink	Latex level is low.	Remaining amount of reagent is below the rated value.	Prepare new reagent.
242	yellow	Blink	Buffer is empty	The buffer is empty. (Stop sampling.)	Replace the buffer solution and set the remaining amount of buffer solution.
243	yellow	Blink	Buffer level is low.	Remaining amount of reagent is below the rated value.	Prepare new buffer solution.
244	yellow	Blink	Latex/Buffer is empty.	Latex/Buffer is empty.	Replace the Latex/Buffer solution and set the remaining amount of reagent (latex) and buffer.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
245	yellow	Blink	Latex/Buffer level is low.	Remaining amount of Latex/Buffer solution is below rated value.	Prepare new Latex/Buffer solution.
247	yellow	Blink	Buffer level is low. Set the remaining volume.	Set the remaining volume since detected the Buffer level is low.	Prepare new Buffer solution.
251	yellow	Blink	Choosing finished rack.	Cannot be registered in a rack that has been measured or is being measured.	Register in unmeasured rack.
253	yellow	Blink	Choosing finished rack.	There are samples other than general samples or measured samples within the ID registration range.	Review the ID registration range or delete the corresponding sample.
254	yellow	Blink	Order attribution conflict	If a cup sample is already registered in one rack, an attempt was made to register a sample other than the cup sample.	Review registration.
255	yellow	Blink	Cup order conflict	The number of cup sample has exceeded the rated value. (Default value = consecutive 20 units.)	Set not to exceed the rated value.
260	Red	Blink	Detection data error	Photometric data (transmitted/scattered light data) is below the rated value.	Perform [Rotation measurement] on the DETECT TEST screen and check the transmitted/scattered light data.
261	Red	Blink	Non Detection data	The photometric data could not be captured in a measurement sequence.	Perform [Rotation measurement] on the DETECT TEST screen and check the transmitted/scattered light data.
300	yellow	Blink	Barcode command is not defined.	Program error or sample barcode reader error.	Measurement is possible with the user parameters [rack barcode] and [sample barcode] disabled.
301	yellow	Blink	Barcode command format error	Program error or sample barcode reader error.	Measurement is possible with the user parameters [rack barcode] and [sample barcode] disabled.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
302	yellow	Blink	Barcode command error	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
303	yellow	Blink	Barcode[m]error	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
304	yellow	Blink	Barcode command error	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
305	yellow	Blink	Barcode long command	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
306	yellow	Blink	Barcode short command	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
307	yellow	Blink	Barcode[n]!=0,1	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
308	yellow	Blink	Barcode[n]error	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
309	yellow	Blink	Barcode[nnn]error	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
310	yellow	Blink	Barcode[hhh]not Hex	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
311	yellow	Blink	Barcode[hh]=FF	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
312	yellow	Blink	Barcode[hhh], [aaa] Over	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
313	yellow	Blink	Barcode[aaa]error	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
314	yellow	Blink	Barcode EEP_ROM broken	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
315	yellow	Blink	Barcode initialize memory error	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
317	yellow	Blink	Barcode [¥¥] next not [!] and [?]	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
318	yellow	Blink	Barcode [!] is over	Program error or sample barcode reader error	Measurement is possible with disabled user parameters [rack barcode] and [sample barcode].
322	yellow	Blink	ID CODE is wrong	ID CODE is wrong (Non-alphanumeric)	Check the barcode for non-alphanumeric characters.
331	yellow	Blink	Barcode read time out	No response from the barcode within the specified time.	Check the followings • No scratch on the barcode? • Is there enough margin at the top and bottom? (Communication parameter [Quiet zone Magnification mode]) • Is the barcode type appropriate? (Communication parameter [Type 1-4]) • Are barcode characters 16 or less? Disable the user parameters [Rack Barcode] and [Sample Barcode]. Measurement is possible with manual mode.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
332	yellow	Blink	No sample barcode reading	Unable to read sample barcode	Check the followings • No scratch on the barcode? • Is there enough margin at the top and bottom? (Communication parameter [Quiet zone Magnification mode]) • Is the barcode type appropriate? (Communication parameter [Type 1-4]) • Are barcode characters 16 or less? Disable the user parameters [Rack Barcode] and [Sample Barcode]. Measurement is possible with manual mode.
333	yellow	Blink	Sample barcode information error	There is an error in the content of the read barcode error.	Check the followings • No scratch on the barcode? • Is there enough margin at the top and bottom? (Communication parameter [Quiet zone Magnification mode]) • Is the barcode type appropriate? (Communication parameter [Type 1-4]) • Are barcode characters 16 or less? Disable the user parameters [Rack Barcode] and [Sample Barcode]. Measurement is possible with manual mode.
335	yellow	Blink	No rack barcode reading	Cannot read sample barcode	Check the followings • No scratch on the barcode? • Is there enough margin at the top and bottom? (Communication parameter [Quiet zone Magnification mode]) • Is the barcode type appropriate? (Communication parameter [Type 1-4]) • Are barcode characters 16 or less? Disable the user parameters [Rack Barcode] and [Sample Barcode]. Measurement is possible with manual mode.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
336	yellow	Blink	Rack barcode information error	There is an error in the content of the read barcode error.	Check the followings • No scratch on the barcode? • Is there enough margin at the top and bottom? (Communication parameter [Quiet zone Magnification mode]) • Is the barcode type appropriate? (Communication parameter [Type 1-4]) • Are barcode characters 16 or less? Disable the user parameters [Rack Barcode] and [Sample Barcode]. Measurement is possible with manual mode. (The number of barcode characters are 4 or less.)
340	yellow	Blink	Please set an import tray	The import tray is dislodged.	Retry to set the import tray.
341	yellow	Blink	Please set an Export tray	The export tray is dislodged.	Retry to set the export tray.
343	yellow	Blink	Export tray is full. Please remove racks.	The export tray is full.	Remove the sample rack which became full. Or replace it to the empty export tray.
344	Red	Blink	Error: Import tray was removed. Sampling stop.	The import tray was dislodged during sampling.	Remove the rack on the transport line by operating the home position. Retry to set the import tray.
347	Red	Blink	Cover is open. Sampling stop.	The device cover opened, so stop sampling.	Close the device cover and restart.
350	yellow	Blink	Master Curve registration has been already finished.	The master curve data has already been read.	Select [Back] – [Barcode] to read it again.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
351	yellow	Blink	Master Curve Lot/Exp.	There is an error in the lot number	Check the master curve if there are no faint,
			data error	or deadline data format.	not dirty on barcodes, etc.
					Please input by hand after downloading.
352	yellow	Blink	Master Curve conc./ IST	There are errors in concentration	Check the master curve if there are no faint,
			data error	and IST format.	not dirty on barcodes, etc.
					Please input on the master editing screen by hand.
353	yellow	Blink	Calibrator registration has been already	The normal concentration data has already been read.	Check the master curve if there are no faint, not dirty on barcodes, etc.
			finished.		
					Enter the master editing screen by hand.
354	yellow	Blink	Calibration Lot/Exp.	There are errors in lot number, time	Check the master curve if there are no faint,
			data error	limit data format.	not dirty on barcodes, etc.
					Enter the master editing screen by hand.
355	yellow	Blink	Calibration Conc./IST	There are errors in normal	Check the master curve if there are no faint,
			data error	concentration and format.	not dirty on barcodes, etc.
					Enter the master editing screen by hand.
356	yellow	Blink	Master Curve/Calibrator	There are errors in master curve or	Check the master curve if there are no faint,
			data error.	normal concentration and format.	not dirty on barcodes, etc.
					Enter the master editing screen by hand.
358	yellow	Blink	Calibration Data Edit is	Master calculation is not done at	Calculate the master.
			not completed.	the time of correction.	
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Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
359	yellow	Blink	Master/Calib parameter error	Revision point or repetition count is zero.	Check the item parameter. Enter [Average number of calibrations] [Standard number of revision point].
360	yellow	Blink	Calibration Curve calculation error (No correction IST.)	Unable to calculate calibration curve since there is no revision IST.	Enter revision IST.
361	yellow	Blink	Calibration Curve calculation error (Insufficient number of IST.)	The calibration curve cannot be calculated because the number of valid IST is lacking. Valid IST: over 1.0, Units: 4 or more	Enter 4 or more valid IST.
362	yellow	Blink	Calibration Curve calculation error (wrong IST -1)	The calibration curve cannot be calculated because the IST value is abnormal.	Revise the normal IST manually.
363	yellow	Blink	Calibration Curve calculation error (wrong IST -2)	The calibration curve cannot be calculated because the IST value is abnormal.	Enter normal IST manually to revise.
370	yellow	Blink	Printer error	The following factors can be considered. • Run out of papers • Cover open • Printer mechanical error	Check if out of paper and open/close the cover.
380	yellow	Blink	USB memory error (directory)	The following factors can be considered. • Memory display capacity is full. • With security function.	Check the available memory of the USB memory. Use USB memory without security function.
381	yellow	Blink	USB memory error (open file)	The following factors can be considered. • Memory capacity is full. • With utility function.	Check the available memory of the USB memory. Use USB memory without security function.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
382	yellow	Blink	USB memory error (save file)	The following factors can be considered. • Memory capacity is full. • With security function.	Check the available memory of the USB memory. Use USB memory without security function.
383	yellow	Blink	USB memory error (open file)	The following factors can be considered. • Memory capacity is full. • With security function.	Check the available memory of the USB memory. Use USB memory without security function.
384	yellow	Blink	System parameter in the USB memory is not compatible.	The following factors can be considered. • Memory capacity is full. • With security function.	Check the available memory of the USB memory. Use USB memory without security function.
385	yellow	Blink	The number of folders exceeded the limit (USB)	The following factors can be considered. • Memory capacity is full. • With security function.	Check the available memory of the USB memory. Use USB memory without security function.
386	yellow	Blink	The number of files exceeded the limit (USB)	The following factors can be considered. • Memory capacity is full. • With utility function.	Check the available memory of the USB memory. Use USB memory without security function.
387	yellow	Blink	The attribution of the file cannot be found in the USB memory.	The following factors can be considered. • Memory capacity is full. • With security function.	Check the available memory of the USB memory. Use USB memory without security function.

Error Status No.	Status Display LED color	Displaying condition	Error Message	Phenomena/Cause	User Actions
388	yellow	Blink	No data can be found in the result file in the USB memory.	The following factors can be considered. • Memory capacity is full. • With security function.	Check the available memory of the USB memory. Use USB memory without security function.
396	yellow	Blink	System is in process.	Under operation.	Carry out after operation complete.
397	Red	Blink	System is in process.	Tried to carry out unregistered operation.	Turn the power ON again. Check the home position operation or operation on the unit control screen.

## **Chapter 8. Trouble Shooting**

## 8.1 Power off at an emergency

If a device abnormality (vibration, abnormal noise, heat generation, smoke, ignition, offensive odor, etc.) occurs, immediately pull out the power cord on the back of the device or the power plug on the outlet side.





#### Do not use the device.

If any device abnormality (vibration, abnormal noise, heat generation, smoke, ignition, offensive odor, etc.) occurs, turn off the power and contact us. Do not use with the power cord or power strip unplugged until our confirmation is complete.

#### [Note]

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- (5) Please report any serious incident associated with the product to the below address and the competent authority of the member state.

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