Automated Biochemical Analyzer

SpotChem D-Concept 2e

SD-4840 | Operating Manual

arkray,inc.

1 Premise

✣ Thank you for purchasing our measurement unit for the automated biochemical analyzer, the SpotChem D-Concept 2e SD-4840.

This manual contains important information on the functions of the SpotChem D-Concept 2e SD-4840.
This manual is issued by ARKRAY, Inc.
Read carefully prior to starting up the instrument.
It is recommended to retain this manual for future use.

■ Intended Purpose

This instrument is intended for the quantitative and automated measurement of several physiological markers in whole blood, serum and plasma. This instrument is intended for use with SPOTCHEM D reagents/electrolyte plates. For information about the analyte, the function and the target disease/condition as well as the intended use population, please refer to the reagent instructions for use. For in vitro diagnostic use and professional use only.

This product conforms to the EMC Standard EN IEC 61326-2-6:2021.
Class of emission: CISPR 11 Class A
This instrument is an IVD medical instrument.

CE

✣ This product conforms to Regulation (EU) 2017/746.

This instrument has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the instrument is operated in a commercial environment. This instrument generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the operating manual, may cause harmful interference to radio communications.
Operation of this instrument in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

- Hospitals are suitable for using this instrument, except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- The product may cause radio interference when used in home healthcare environments. In such cases, appropriate measures should be taken to lessen the interference.
- If the instrument receives electromagnetic disturbance during measurement, following phenomenon may occur.
  - Incorrect measurement result
  - User injury
  - Equipment malfunction
- Warning: Use of this instrument adjacent to or stacked with other equipment should be avoided, because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

✣
- The cables that are likely to affect compliance of the instrument with the requirements of emissions and immunity are listed below with required specifications.
  RS 232C cable: RS 232C, Double shield cross cable
  LAN cable: Ethernet cable 100BASE TX / 10BASE TX, Cat5e, not longer than 3 m
- Warning: Use of accessories, transducers, and cables other than those specified or provided by manufacturer of this instrument could result in increased electromagnetic emissions*1 or decreased electromagnetic immunity*2 of this instrument and result in improper operation.

  *1 Phenomenon by which electromagnetic energy emanates from a source.

  *2 Ability of instrument to perform without degradation in the presence of an electromagnetic disturbance.
- Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 1 m (40 inches) to any part of the SpotChem D-Concept 2e SD-4840, including cables specified by the manufacturer. Otherwise, degradation of the performance of this instrument could result.
- The emissions characteristics of this instrument make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this instrument might not offer adequate protection to radio frequency communication services.
  The users might need to take mitigation measures, such as relocating or re-orienting the instrument.
- This radio instrument uses 2.4 GHz band for Wi-Fi and Bluetooth connections.
  The full text of the EU declaration of conformity is available at the following internet address:
  https://arkray.eu/doc/sd-48xx/

2 Introduction

Read this instrument operating manual thoroughly before using the instrument. This instrument operating manual gives an overview of the instrument and the proper procedures for operation and maintenance.
Follow the instructions in this instrument operating manual in order not to defeat the purpose of the protective features of the instrument. Also, keep this instrument operating manual in an easily accessible place near the instrument.

If you have had or could have had any serious incident related to the device, please report it directly to the manufacturer or through the authorised representative and to your local regulatory authority.

For the purchase of reagents, consumables or other optional items, refer to the after-sales parts and consumables list that comes with the instrument, or contact your distributor.

- **TAKE THE UTMOST CARE WHEN HANDLING BLOOD. This system uses blood as sample. Blood may be contaminated by pathogenic microbes that can cause infectious diseases. Improper handling of blood may cause infection to the user or other individuals by pathogenic microbes.**
- **This instrument is to be operated by qualified persons only. A qualified person is one having adequate knowledge of clinical testing and the disposal of infectious waste.**
  Thoroughly read this instrument operating manual before use. Anyone who operates the instrument for the first time must be assisted by a trained person.
- **Never touch the tip case, disposal case, reagent table, plate table or other parts where sample may adhere with unprotected hands. During cleaning or maintenance of the reagent table, wear protective gloves to prevent exposure to pathogenic microbes.**
- **Discard used samples, tips, reagents, cuvettes, reference solutions, units and instruments in accordance with local regulations for biohazardous waste.**

This product contains natural rubber. Natural rubber may rarely cause allergic reactions such as itching, redness, hives, swelling, fever, breathing difficulties, asthma-like symptoms, decreased blood pressure, or shock.

*** If any of these symptoms occurs, please discontinue use immediately and consult a doctor.**

NOTE:

- **This instrument is precision equipment. Be careful when handling it and do not subject it to strong shocks or vibration.**
- **This system has a function to store measurement results as well as account information. Please contact your local distributor when disposing of the system.**

When cleaning or decontaminating the instrument by methods other than those specified by ARKRAY, confirm in advance that such methods do not cause damage to the instrument.

SpotChem D-Concept 2e SD-4840 provides the application manual in addition to this instrument operating manual. Before using the instrument, read through the application manual.

The latest versions of the instrument operating manual and the application manual are uploaded on the web. You can download them from the following URLs or 2D codes for use.

Instrument operating manual
https://www.arkray.eu/document_centre/

Application manual
https://www.arkray.co.jp/manual/app/sd-4830/index.html

- It is strictly prohibited to copy any part of this instrument operating manual without the expressed consent of ARKRAY, Inc.
- The information in this instrument operating manual is subject to change without notice.
- ARKRAY, Inc. has made every effort to prepare this instrument operating manual as best possible. Should you discover anything strange, incorrect or missing, contact your distributor.

3 Symbols

The following symbols are used in this instrument operating manual and labels on this instrument to call your attention to specific items.

■ For Your Safety

Follow the instructions given here to prevent exposure to pathogenic microbes.

Follow the instructions given here to prevent injury and property damage.

■ For Optimal Performance

IMPORTANT:
Follow the instructions given here to obtain accurate measurement results.

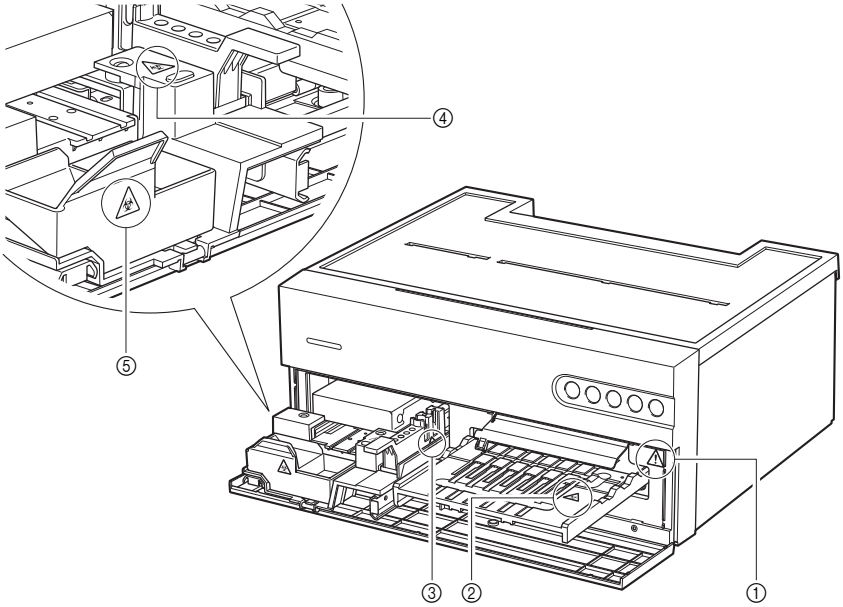
NOTE:
Information useful for preventing damage to the instrument or parts and other important information you should keep in mind.

REFERENCE:
Additional explanations that help you make the best use of the instrument and information on related functions.

4 Warning and Caution Labels

This instrument has several warning and caution labels on the areas that have potential dangers. Please learn potential dangers warned by each label and observe the precautions described below.

■ Front Side



①Inside of the unit

Do not touch the inside of the unit or insert foreign bodies into the inside of the unit. This may damage the unit and result in personal injury. When maintaining the unit, be sure to turn off the power and follow the maintenance procedure.

②Reagent table

Do not touch the reagent table with unprotected hands. During cleaning or maintenance of the reagent table, wear protective gloves to prevent exposure to pathogenic microbes.

③ Plate table

Do not touch the plate table with unprotected hands. When cleaning or maintaining the unit, or setting the electrolyte plate, wear protective gloves to prevent exposure to pathogenic microbes.

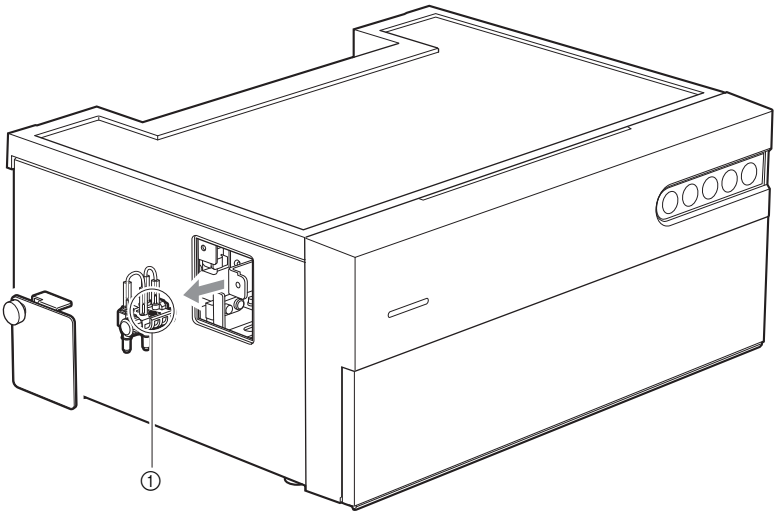
④Tip case

Do not touch the tip case with unprotected hands. When cleaning or maintaining the unit, or setting a sample or tip, wear protective gloves to prevent exposure to pathogenic microbes.

⑤Disposal case

The disposal case contains tips with sample adhering. When disposing of the tips or cleaning the disposal case, wear protective gloves to prevent exposure to pathogenic microbes.

■ Inside of the Unit



①Nozzle maintenance holder

Do not touch the nozzle maintenance holder with unprotected hands. During cleaning or maintenance of the nozzle maintenance holder, wear protective gloves to prevent exposure to pathogenic microbes.

5 Table of Contents

Chapter 1 Before Use

This chapter describes basic information about taking measurements and the operation of the instrument components.

1-1 Overview

1-1-1 Features

- **Operation via mobile devices**

The operation application on your mobile device allows for instrument operation, measurement result checking, quality control, etc. For more details, see the Application Manual.

- **Automatic sample application**

Samples are automatically deposited and dispensed by the unit. User pipetting operations are not required and samples can be dispensed without fluctuations, thereby yielding stable measurement results.

- **Lot calibration**

Calibrations can be performed reading the 2D code (Reagent Info.) supplied with a reagent. Simply scan the 2D code with the operation application on the mobile device or the handheld barcode reader, and the reagent lot-to-lot difference and variation per day are automatically calibrated.

1-1-2 Specifications

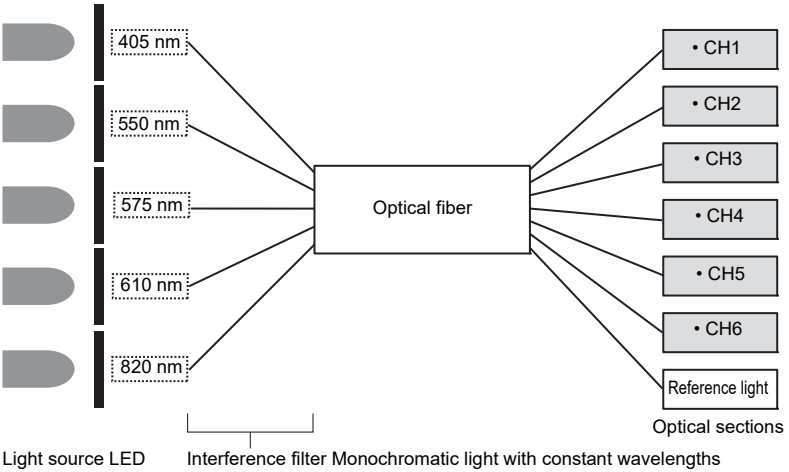
Name	SpotChem D-Concept 2e (SD-4840)
Configuration	Instrument, accessories
Measurement objects	Serum, Plasma, Whole blood
Reagent	SPOTCHEM D single reagent SPOTCHEM D multiple reagent SPOTCHEM D electrolyte plate
Measurement parameter	Listed in package insert of reagent
Measurement range	Listed in package insert of reagent
Measurement principle	Single/Multiple Reagent: Endpoint method and reaction rate method using dual wavelength reflectance photometry Electrolyte plate: Potentiometric method using ion-selective electrode (ISE)
Measurement wavelength	405 nm, 550 nm, 575 nm, 610 nm, 820 nm
Number of reagents measurable at once	6 single reagents 1 multiple reagent 1 electrolyte plate
Measurement time	Biochemical measurement: Reagent reaction time + approximately 2 minutes 30 seconds Electrolyte measurement: Approximately 4 minutes
Sample consumption	Biochemical measurement: Approximately 6 µL per item Electrolyte measurement: Approximately 22 µL
Required sample volume	When using a cuvette: 30 µL + sample consumption volume per measurement
Sample container	SPOTCHEM D cuvette (for D-Concept only)
Number of measurable samples	1 sample
Startup time	Approximately 8 minutes (at a room temperature of 25 °C)
Printer	58 mm-wide printing paper printer
Data storage capacity	Data of 300 measurements
External output	Conforming to RS-232C Communication system: Unidirectional and bidirectional systems Communication speed: 2400/4800/9600/19200 bps Ethernet Communication standard: 10BASE-T/100BASE-TX USB (Type-A) For USB memory stick
Charging port	USB (Type-C) DC 5 V/2 A or less
Measurement environment	Temperature: 10 to 30 °C Humidity: 20 to 80% RH (no condensation)
Storage environment	Temperature: 1 to 35 °C Humidity: 20 to 80% RH (no condensation)

Environment during transport	Temperature: -10 to 60 °C Humidity: 20 to 80% RH (no condensation)
Dimensions	360 (W) × 290 (D) × 160 (H) mm
Weight	Approximately 10 kg
Supply voltage	AC 100 to 240 V, ±10%, 50/60 Hz
Power input	200 VA or less
Location of use	Indoor use only
Altitude	3000 m
Pollution degree	2
Over voltage category	II
Expected life	5 years (according to company data)

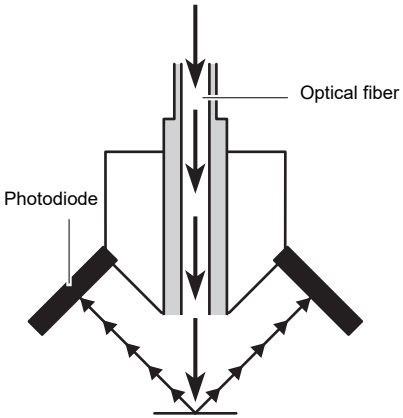
1-1-3 Measurement Principle

■ Single/Multiple Reagent

Light from the light source LED passes through the interference filter and becomes monochromatic light with constant wavelengths. There are five wavelengths in total and the optimal wavelength is chosen based on the measurement parameter. Monochromatic light is separated into seven wavelengths by optical fiber, with one wavelength transmitted to the optical section of the reference light and the other six wavelengths transmitted to the optical section of each measurement CH.



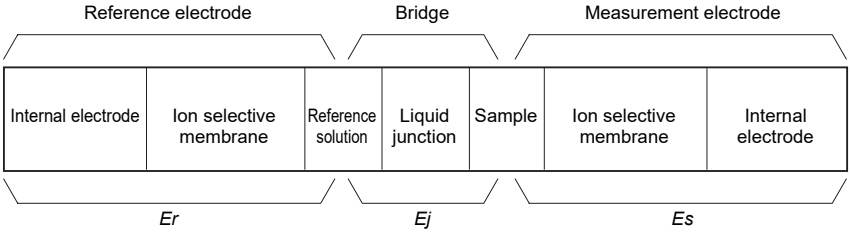
At the optical sections of each measurement CH, the monochromatic light output from the optical fiber shines on the reagent pad to which a sample is dispensed and reacted and the reflected light is read by two photodiodes. The read reflected light is numerically converted by the A/D converter and used for computations.



■ Electrolyte plate

Electrolyte measurement enables measurement of various types of ion concentrations in the sample with the potentiometric method using ion-selective electrodes (ISEs) as the basic principle.

The ISEs used for electrolyte measurement have the following configuration.



The reference electrode and measurement electrode use an ISE with exactly the same structure.

The reference solution is measured with the reference electrode and the reference electrode potential ***Er*** can be obtained. Meanwhile, the target ion in the sample is measured with the measurement electrode and the measurement electrode potential ***Es*** can be obtained.

A liquid junction is provided between the reference solution and sample, thereby the measurement electrode ***E*** between the reference electrode and measurement electrode can be obtained.

The Nernst's equation can be expressed between the potential generated by the ISE and the ionic activity (ion concentration) and the ion concentration can be obtained by measuring the potential difference ***E***.

$$E = Es - Er + Ej$$

$$E = \frac{2.303 \cdot RT}{zF} (log(as) - log(ar)) + Ej$$

$$E = \frac{2.303 \cdot RT}{zF} \cdot log(as) + Eo$$

Where ***Es***: Potential generated by ionic activity in the sample

Er: Potential generated by ionic activity in the reference solution (constant)

Ej: Liquid junction potential (constant)

Eo: $Ej - \frac{2.303 \cdot RT}{zF} \cdot log(as)$ (constant)

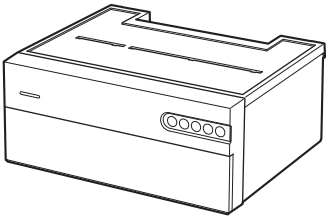
a_s: Ionic activity in the sample

a_r: Ionic activity in the reference solution (constant)

1-2 Unpacking

The following items are included with this instrument. Check that all of these items are included. If any items are missing or defective, contact your distributor.

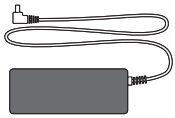
1-2-1 Instrument



Items included	Description	Quantity
Instrument	SpotChem D-Concept 2e	1

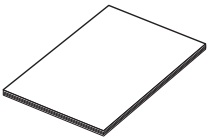
1-2-2 Accessories

✣

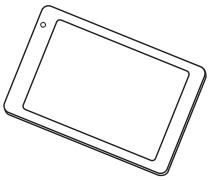


① AC adapter

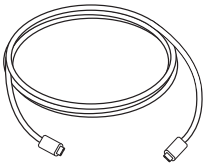
② Power cord



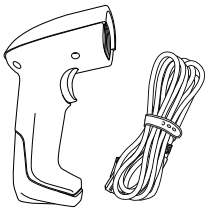
③ Operating manual



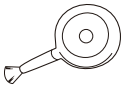
④ Mobile device



⑤ USB Type-C cable

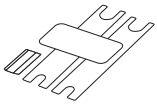


⑥ Handheld barcode reader (HCR)



⑦ Blower brush

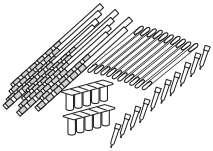
⑧ Nozzle set



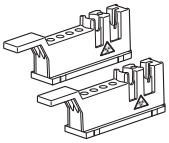
⑨ Wrench set for replacing nozzle

⑩ Cleaning wire

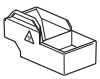
⑪ Nozzle tube



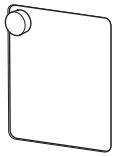
⑫ Cleaning kit



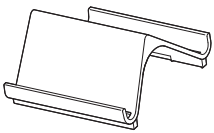
⑬ Tip case



⑭ Disposal case



⑮ Maintenance cover

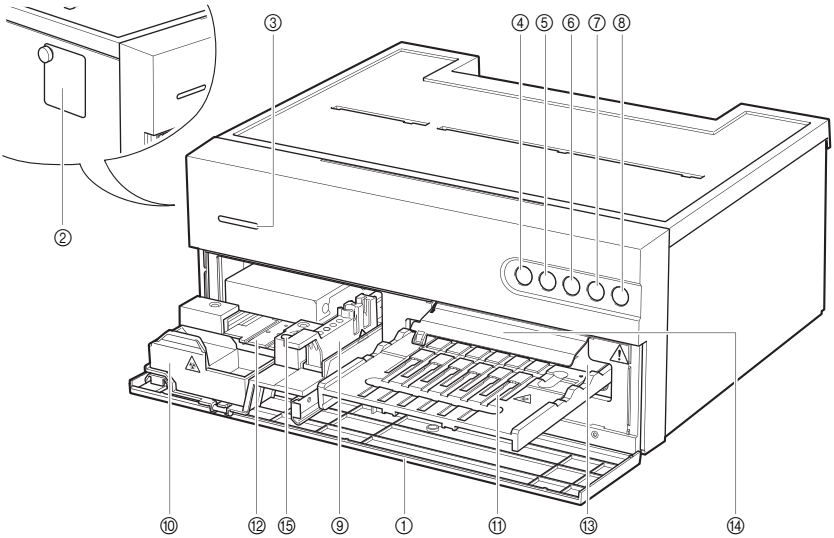


⑯ Mobile device stand

Item No.	Items included	Description	Quantity
①	AC adapter		1
②	Power cord	Rating: 125 V 13 A (A Type Plug) and 250 V 10 A (C Type Plug) Please use the appropriate power cord for your region's power voltage.	2
③	Operating manual		1
④	Mobile device		1
⑤	USB Type-C cable		1
⑥	Handheld barcode reader (HCR)	HCR, HCR cable	1
⑦	Blower brush		1
⑧	Nozzle set	2 nozzle with O-ring	1
⑨	Wrench set for replacing nozzle	2 wrenches, 1 adapter	1
⑩	Cleaning wire	For cleaning nozzle	1
⑪	Nozzle tube	1 replacement nozzle tube	1
⑫	Cleaning kit	10 cotton swabs, 2 sets of 5 containers, 10 pieces of cleaning paper, 10 tips	1
⑬	Tip case		2
⑭	Disposal case		1
⑮	Maintenance cover		1
⑯	Mobile device stand	Please place the stand near the instrument or on the top of the instrument.	1

1-3 Part Names and Functions

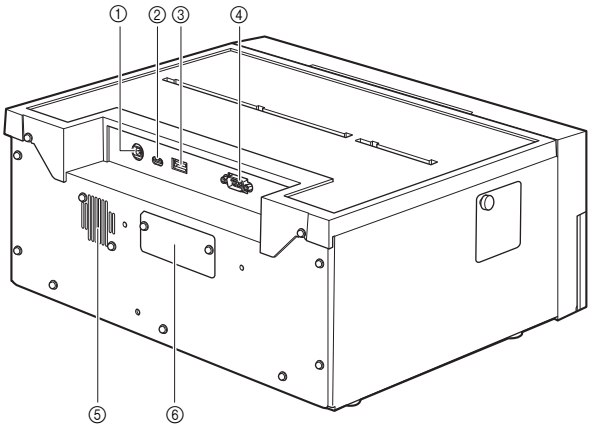
1-3-1 Front Side of Instrument



No.	Name	Function
①	Front cover	Prevents incoming ambient light. Opens when the reagent table and plate table extend toward you.
②	Maintenance cover	Can be opened to clean or replace the nozzle.
③	Status indication LED	Indicates the operation status of the instrument. In addition to the fixed indication color, any arbitrary color can be set. For more details, see the Application Manual. During startup: Lights alternately in white and the set color In standby: Lights in the set color In operation: Lights alternately in green and the set color Abnormal status 1: Lights alternately in red and the set color (error or trouble) Abnormal status 2: Lights alternately in yellow and the set color (warning)
④	Wi-Fi connection status LED	Not connected: Off Abnormal communication: Short-cycle blinking (Unable to communicate with the mobile device) Not connected: Long-cycle blinking (Unable to communicate with the mobile device application) Connected: On

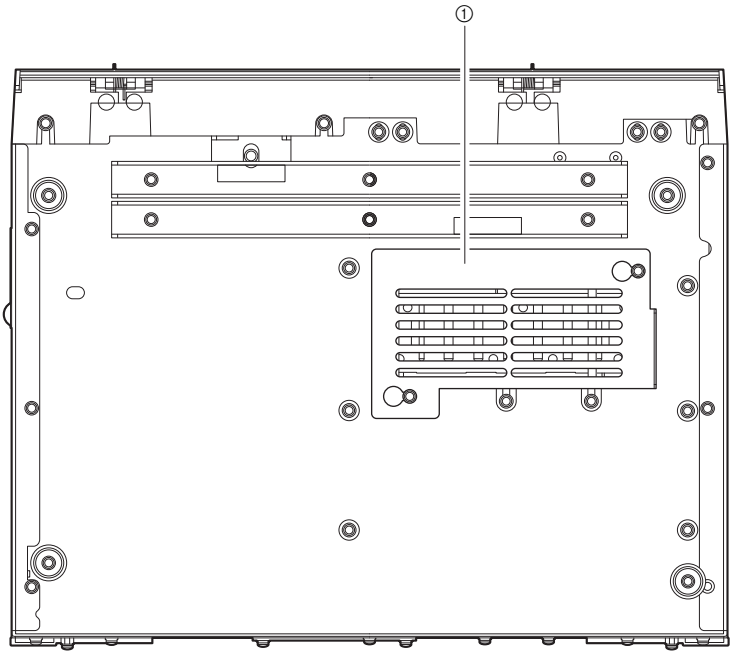
No.	Name	Function
⑤	Printer connection status LED	Not connected: Off Abnormal status: Blinking Connected: On
⑥	Start button	Press this button to start measurement.
⑦	Stop button	Press this button to cancel measurement.
⑧	Power button	Used to start and shut down the instrument.
⑨	Tip case	Used to set the measurement tips and cuvette.
⑩	Disposal case	Used tips are put.
⑪	Reagent table	Used to set a single/multiple reagent.
⑫	Plate table	Used to set the electrolyte plate.
⑬	White/black plate	Reflectance plate used as the baseline for reflectance measurement. Used to measure a single/multiple reagent.
⑭	White/black plate cover	Protects the white/black plate.
⑮	Rubber plate	Used for pressure test of the nozzle piping. Also cleans the nozzle tip.

1-3-2 Rear Side of Instrument



No.	Name	Function
①	Power input terminal	Connects the supplied AC adapter.
②	USB Type-C	Used for charging the mobile device.
③	USB Type-A	Connects the handheld barcode reader or a USB memory stick.
④	RS-232C	Used for connecting an external device.
⑤	Exhaust port	Expels warm air from inside the unit to prevent overheating.
⑥	LAN	Used for connecting an external device. (Option)

1-3-3 Bottom of Instrument

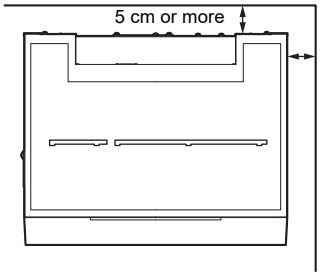


No.	Name	Function
①	Optical section cover	Open this cover for cleaning the optical window.

1-4 Installation

1-4-1 Precautions for Installation

- **Install the instrument under the supervision of a serviceperson.**
- **For safety reasons, always transport the instrument with both hands holding the bottom of the instrument. When setting down the instrument, be careful not to get your hands trapped underneath it.**
- **Install the instrument on a level, vibration-free sturdy platform. Operation of the instrument in an unstable place may cause personal injury, malfunction, or instrument trouble. Do not install the instrument where it may fall or topple over.**
- **Do not disassemble the instrument unless required for installation. Do not modify the instrument. Doing so may cause damage to the instrument, fire, or personal injury.**
- **The following space is required for installation of the instrument.**



- **Insufficient space may cause overheating of the instrument or undesirable load on cable connections, thus resulting in fire. Also, inaccurate results may be obtained if the front cover cannot be opened.**
- **After installation, ensure that the power cord can be unplugged immediately in case of an emergency.**
- **Use the included power cord and AC adapter.**
- **The instrument should desirably be connected to an independent power outlet.**
- **Always connect the instrument to a receptacle with ground terminal. If the receptacle available at the installation site does not have ground terminal, contact your distributor.**

IMPORTANT:

To obtain accurate measurement results, install the instrument in the following environment:

- **Low temperature fluctuation, adjustable from 10 to 30 °C.**
- **Humidity can be controlled between 20 to 80%.**
- **No condensation occurs inside the instrument.**
- **There is no splash of water or other liquid.**
- **There is no source of corrosive gas or electric noise.**
- **There is no place for storing chemicals.**
- **The instrument is not directly exposed to sunlight or wind.**
- **Altitude of 3000 m or lower**

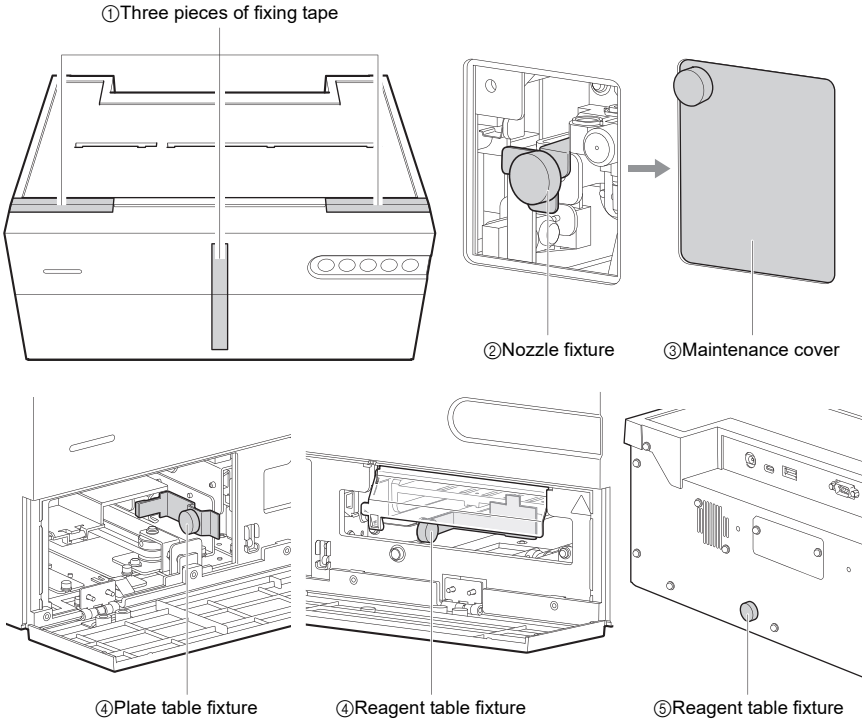
1-4-2 Precautions for Moving the Instrument

- **Do not move the instrument with any object placed on top.**
- **Move the instrument with the front cover closed. Moving the instrument with the front cover open may cause damage to the instrument.**
- **Hold the bottom of the instrument with both hands and be careful not to apply any shock or vibration to the instrument while moving it. Failing to do so may damage the instrument.**

Be sure that no reagent, tip or sample is left in the instrument before moving it. Moving the instrument with reagent, tip or sample left in it may result in diffusion of pathogenic microbes in the instrument.

1-4-3 Before Installing the Instrument

Before installing the instrument, remove any fixtures on the parts of the instrument.



✣

❶ Remove the three pieces of fixing tape on the front cover.

❷ Remove the thumb screws securing the nozzle unit.

❸ Push in the nozzle unit and attach the maintenance cover.

❹ Open the front cover by hand and remove the thumb screws securing the plate table and reagent table.

❺ Remove the thumb screw securing the reagent table on the back of the instrument.

*When transporting the instrument again, attach the removed fixtures and then pack the instrument.

1-4-4 Connecting Peripheral Devices (When Necessary)

Connect a handheld barcode reader (USB Type-A), USB memory stick (USB Type-A), charging cable (USB Type C), and RS-232C cross cable, as necessary.

- **Use the cable specified by ARKRAY when connecting the instrument to a hospital system. Using any cable other than the specified one may cause electric shock and fire. For details, contact your distributor.**
- **Use the supplied USB Type-C cable for connecting the mobile device, and do not connect any cable other than the one supplied.**

* Either the handheld barcode reader (USB Type-A) or USB memory stick (USB Type-A) can be connected for use.

■ Establishing LAN Connection

Install an Ethernet board (option) to the instrument.

For connection, use the LAN cable specified by ARKRAY.

For details, contact your distributor.

* For connection to a hospital system, use either RS-232C port or Ethernet port.

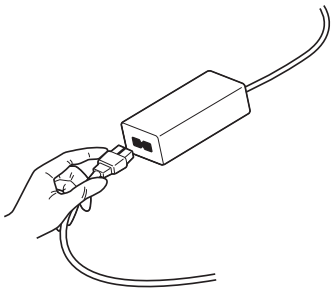
1-4-5 Connecting the Power Cord

Use the included power cord and AC adapter to prevent electrical shock and fires. Always connect the instrument to a receptacle with ground terminal in order to prevent electrical shock. If the receptacle available at the installation site does not have ground terminal, contact your distributor.

❶ Connect the AC adapter and the power cord.

❷ Connect the AC adapter to the power input terminal.

❸ Connect the power cord plug to the power outlet.



1-4-6 Turning the Power On

NOTE:
Check the following before pressing the ⏻ button.
- **Check that the maintenance cover is attached. If the maintenance cover is not attached, an E-104 error occurs.**
- **Check that the area in front of the front cover is clear. The front cover of the instrument may open during the startup process and any objects placed in front of the front cover may interfere with operations.**

❶ Start the operation application on the mobile device.

* For more details, see the Application Manual.

* The instrument starts up even when the operation application has not started or wireless connection has not been established. In such cases, the instrument can be used in the simple mode.

❷ Press the ⏻ button on the instrument.

❸ The status indication LED lights alternately in white and the set color, and the initialization of driving mechanisms, warm-up, etc., are performed. For details on the instrument statuses, check the mobile device screen.

❹ When the color of the status indication LED lights in the set color only, the warm-up is completed.

1-4-7 Wireless Connection Setting (When Necessary)

If no setting has been made for wireless connection, set up the connection in accordance with the Application Manual.
Once set, it is unnecessary to set it again, unless you need to change the setting.

1-5 Measurement Precautions

This section describes the measurement precautions. Before using this instrument for the first time, be sure to read all the precautions listed here.

1-5-1 Precautions for Operation

- **This instrument is to be operated by qualified persons only. A qualified person is one having adequate knowledge of clinical testing and the disposal of infectious waste. Thoroughly read this instrument operating manual before use. Anyone who operates the instrument for the first time must be assisted by a trained person.**
- **Never touch the nozzle, tubing or other parts where sample may adhere with unprotected hands. During cleaning or maintenance of the reagent table, wear protective gloves to prevent exposure to pathogenic microbes.**
- **Discard used samples, tips, reagents, cuvettes, reference solutions, units and instruments in accordance with local regulations for biohazardous waste.**

- **Read "1-4-1 Precautions for Installation" (page 1-12) and ensure that the instrument is installed in a proper environment before turning on the power.**
- **Do not place a collection cup or any other vessel containing a sample or other liquid on the unit. The sample or other liquid can get inside the instrument and damage the instrument.**
- **Do not move the instrument during measurement. Any vibration during measurement may cause a malfunction and prevent accurate measurement.**
- **Do not touch the instrument while measurement is in progress.**
- **Do not place anything in front of the front cover as this may prevent the cover from opening and damage the instrument.**
- **Be sure to clean and wash the specified components of the instrument to maintain measurement quality. For more details, see "3-2 Maintenance" (page 3-2).**
- **If you detect an abnormal odor or noise, immediately unplug the power cord. Continuing operation in such conditions may result in fire or damage to the instrument and consequently lead to personal injury.**
- **If the instrument malfunctions, contact your distributor for repair. Unauthorized servicing or modification can damage the instrument and consequently lead to personal injury.**

1-5-2 Precautions for Handling Samples

- **TAKE THE UTMOST CARE WHEN HANDLING BLOOD. This system uses blood as sample. Blood may be contaminated by pathogenic microbes that can cause infectious diseases. Improper handling of blood may cause infection to the user or other individuals by pathogenic microbes.**
- **Discard used samples, tips, reagents, cuvettes and parts in accordance with local regulations for biohazardous waste.**

- **See the package insert.**

The handling of samples differs for each reagent used for measurement. Be sure to follow the package insert supplied with the reagent.

1-5-3 Precautions for Handling Reagents

- **Use the reagent designed for this instrument.**

Use a SPOTCHEM D single/multiple reagent or electrolyte plate. Read the package insert supplied with the reagent.

- **Allow the reagent to return to the measurement environmental temperature before use.**

Before measurement, remove the reagent from the refrigerator and allow it to reach the environmental temperature for measurement (10 to 30 °C). Measurement of the reagent without allowing the reagent to return to the environmental temperature for measurement may lead to incorrect measurement results.

- **Check the reagent before measurement.**

Do not use expired reagents. Also, do not use reagents whose reagent pads are discolored even before the expiration date because this may lead to incorrect measurement results.

- **Do not touch the reagent pad.**

Do not touch the reagent pad of the single/multiple reagent. Touching the reagent pad with unprotected hands may leave sebum on the reagent pad and consequently lead to incorrect measurement results.

- **Do not reuse a reagent.**

Do not reuse a single/multiple reagent or electrolyte plate. Otherwise, inaccurate results may be obtained.

1-5-4 Precautions for Handling Tips

- **Use the tip designed for this instrument.**

Using an undesignated tip may prevent accurate measurement and cause damage to the instrument.

- **Do not touch the tip end with unprotected hands.**

Do not touch the tip end with unprotected hands. The tip end may become dirty and consequently lead to incorrect measurement results.

- **Do not reuse the tip.**

Tip is for single-use only. The tip has a water repellent finish that may come off when washed and consequently lead to incorrect measurement results.

1-6 Operation Application

The operation application installed on the mobile device mainly allows you to perform the following operations and settings. The operation application can connect up to 8 instruments simultaneously. For more details, see the Application Manual.

- **Parameter settings**
- **Reading 2D code with the mobile device's built-in camera (reagent lot information, ID inputs, etc.)**
- **Measurement start/stop**
- **Viewing/printing measurement results**
- **Checking the instrument status (wireless connection status/standby/measuring status)**
- **Quality control**
- **Operator management**
- **Checking abnormality information**
- **Wireless connection setting**
- **Updating the application**

REFERENCE:

The instrument will start up and perform measurement even when the operation application has not started or wireless connection has not been established. In such cases the instrument can be used in the simple mode.

For details on the simple mode, see "2-1-3 Simple Mode" (page 2-3).

Chapter 2 Measurement

This chapter describes the methods for normal measurement and calibration.

2-1 Before Measurement

This section explains what you need to know before you begin measurements with this instrument.

2-1-1 Lot Calibration

2D code (Reagent Info.) is printed on the product box of a single/multiple reagent and electrolyte plate. When you use a reagent of a new lot, scan the 2D code with the mobile device or the handheld barcode reader connected to the instrument to input the reagent lot information and automatically calibrate the lot-to-lot difference and variation per day.

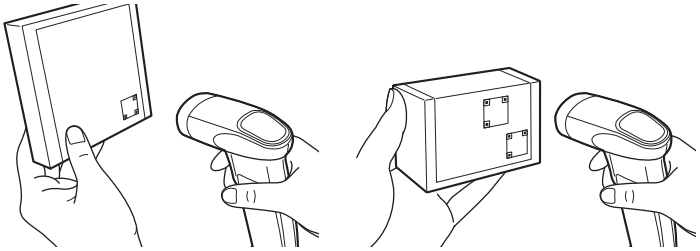
IMPORTANT:

- **When using a reagent of a new lot, read the 2D code (Reagent Info.) before measurements.**
- **Two 2D codes (Reagent Info.) are printed on the product box of an electrolyte plate. Be sure to read the one marked "For SD-4810/SD-4840".**

❶ Check that the instrument is in standby.

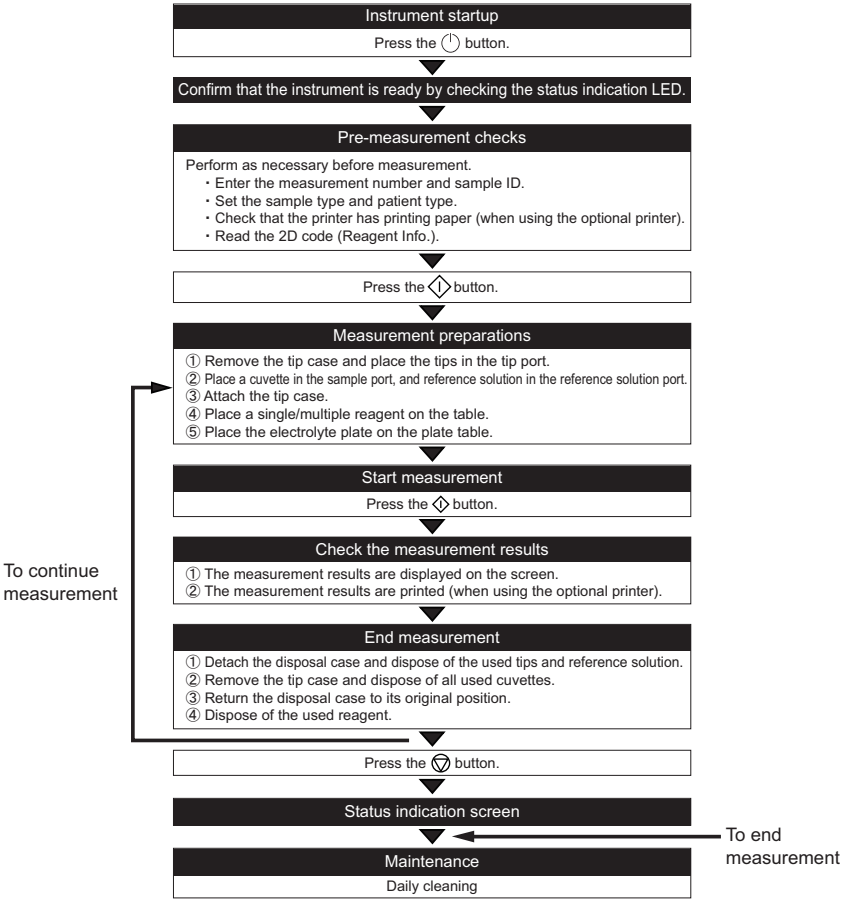
❷ Scan the 2D code with the operation application or the handheld barcode reader.

❸ After the 2D code has been read, the input information is temporarily displayed. Then, the status indication screen is displayed.



2-1-2 Measurement Procedures

The measurement procedures are shown in the following flowchart.



*For the procedures using the operation application, see the Application Manual.

2-1-3 Simple Mode

This instrument can perform measurements in simple mode (simple measurement function) even when the operation application is not available.

● Conditions to enter simple mode

Measurement is performed in simple mode in the following cases.

- No connection is established with the operation application.
- A setting code for simple mode has been read by the handheld barcode reader.
- Although the operation application is connected, the instrument has not been selected (e.g HOME is currently selected on the operation application).

● Available parameters

In simple mode, the following parameters can be set by reading the setting code with a handheld barcode reader.

- Operator ID
- Sample ID
- Patient type
- Sample type

● Measurement results

- A flag is added to the measurement results to indicate that the measurement was performed in simple mode. (2-4-1 Measurement Results)
- The QC lockout function is not available in simple mode. (3-3 Quality Control (QC))

● Security

- If the operation application is not used, measurements are performed with the operator management function disabled. Therefore, in simple mode, a flag is added to the measurement results to indicate that the measurement was performed with the operator management disabled. (2-4-1 Measurement Results)

2-2 Measurement Preparations

This section explains the preparations required prior to measurement.

2-2-1 Instrument Checks

This explains the items to be checked after the instrument has started.

■ Check the Printing Paper (When Using the Optional Printer)

Check that there is sufficient printing paper in the printer. If both ends of the paper have a red line, replace the printing paper.

2-2-2 Preparing the Sample

Place the sample into the cuvette (sample container) for measurement. Use the correct cuvette for the sample to be tested. Please note that the measurement items are subject to additions or changes in the future. Please read the package insert supplied with each reagent for information on handling the sample.

Wear protective gloves to prevent exposure to pathogenic microbes. Do not hold the cap of a cuvette containing a sample. The cuvette may fall and the sample inside may leak out. Always carry sample in a cuvette by the body.

IMPORTANT:
Remove any bubbles or film from the liquid surface of the sample. Otherwise, inaccurate results may be obtained.

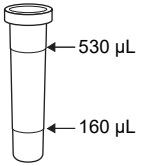
Reagent type	Cuvette to use	Sample type	Required sample volume
Single reagent Multiple reagent	Cuvette with gray cap	Serum or plasma	6 µL × number of measurement items + 30 µL
Electrolyte plate	Cuvette with green cap	Whole blood	530 µL
	Cuvette with gray cap	Serum or plasma	52 µL

NOTE:
The required sample volume when simultaneously measuring a single/multiple reagent and an electrolyte plate is 6 µL × number of measurement items + 22 µL + 30 µL
6 µL × number of measurement items: Sample consumption for single/multiple reagent
22 µL: Sample consumption for electrolyte plate
30 µL: Minimum sample volume required

NOTE:
If a measurement is performed using sample below minimum volume, an error may occur or the measurement results may be inaccurate.

NOTE:
Be sure to use a SPOTCHEM D cuvette (for D-Concept only) for measurement.

REFERENCE:
The cuvette has two gauge lines as shown below.



Cuvette

■ Measurement of a Serum or Plasma Sample

❶ Place the sample into a cuvette with a gray cap.

❷ Place the cap on the cuvette to prevent contamination or evaporation if you are not measuring the sample right away.

■ Measurement of a Whole Blood Sample

❶ Place the sample into a cuvette with a green cap.

❷ Place the cap on the cuvette and gently invert it several times to mix.

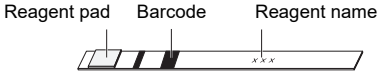
NOTE:
The sample may appear staying still even when the cuvette is inverted. In this condition, lithium heparin is mixed with the sample. So do not forcefully shake the cuvette, but gently invert it several times.

2-2-3 Preparing the Reagent

This instrument uses SPOTCHEM D single/multiple reagents and electrolyte plates sold separately. This instrument uses three types of SPOTCHEM D reagents. Use the type of reagent that best matches your measurement needs.

■ Single Reagent

You can measure one item per reagent.



■ Multiple Reagent

You can measure several items per reagent according to your measurement needs.

■ Electrolyte Plate

You can measure three items per electrolyte plate.

2-3 Measurement

You can measure a maximum of 15 items at a time for each sample using a SPOTCHEM D single/ multiple reagent or electrolyte plate.

- **Wear protective gloves to prevent exposure to pathogenic microbes.**
- **For disinfection of the device, lightly wipe the disinfecting area with a cotton swab or gauze moistened with a disinfectant, then wipe the disinfectant with a cotton swab or gauze moistened with water, and then wipe it dry. Use 70% isopropanol as the disinfectant. If the sample is not removed from the instrument, the user or other individuals may become infected by pathogenic microbes.**
- **Discard used samples, tips, reagents, cuvettes and parts in accordance with local regulations for biohazardous waste.**

Carefully remove the cap from the cuvette to prevent the sample from spilling.

70% isopropyl alcohol is readily combustible, therefore handle it carefully and keep away from flames, electrical sparks and sources of heat. Also, ventilate the room sufficiently during use.

1 Check the status of the instrument

Check that the instrument is in standby.

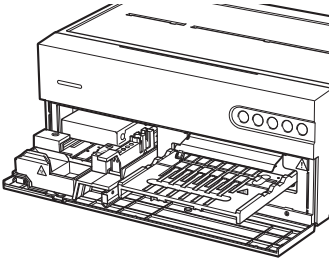
2 Enter the measurement information.

Enter the following measurement information as necessary, referring to the Application Manual.

- Measurement number
- Sample ID
- Sample type
- Patient type

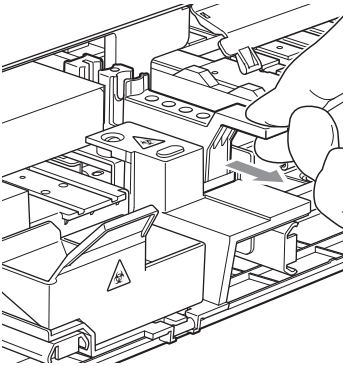
3 Place the tips in the instrument

❶ Press the ⏻ button. The front cover opens and the reagent table and plate table extend toward you.

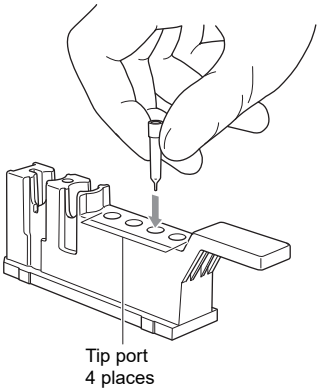


❷ Remove the tip case.

REFERENCE:
When measuring for the first time after installing the instrument, set the tip case and disposal case in the accessory case in the instrument before measurement.



❸ Place the tips in the tip port.

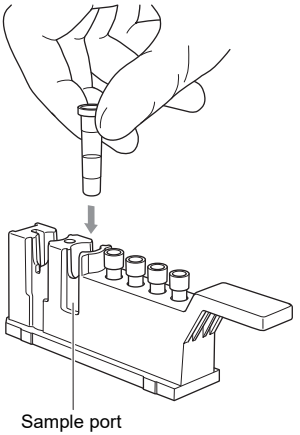


NOTE:
Do not touch the end of the tips with unprotected hands. Contamination on the tip end may lead to inaccurate results.

NOTE:
The number of tips required for measurement varies depending on the combination of reagents being measured at the same time.
Single reagent: 1 tip
Multiple reagent: 1 tip
Electrolyte plate: 2 tips
Single reagent + multiple reagent: 2 tips
Single reagent + electrolyte plate: 3 tips
Multiple reagent + electrolyte plate: 3 tips
Single reagent + multiple reagent + electrolyte plate: 4 tips

4 Set the sample

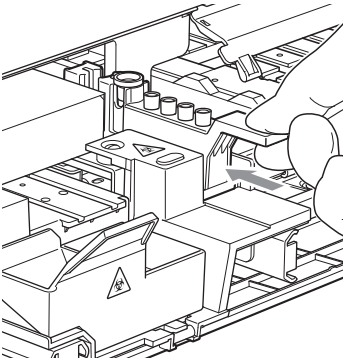
❶ Remove the cap from the cuvette with the sample and place the cuvette in the sample port on the tip case.



IMPORTANT:
Remove any bubbles or film from the liquid surface of the sample. Otherwise, inaccurate results may be obtained.

NOTE:
Placing the centrifuge cup in the centrifuge without first removing the cap will cause the nozzle to break. Be sure to remove the cap before placing the centrifuge cup in the centrifuge.

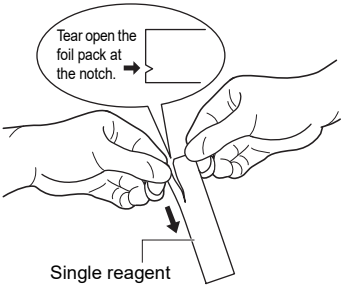
❷ Return the tip case to its original position.

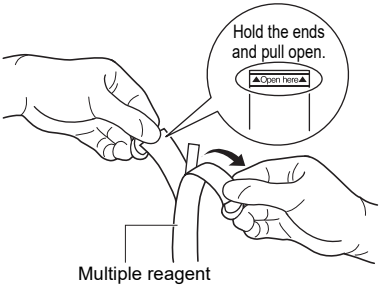


NOTE:
Insert the tip case fully to the back of the instrument.

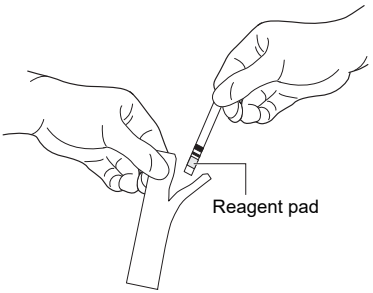
5 Place the single/multiple reagent in the instrument

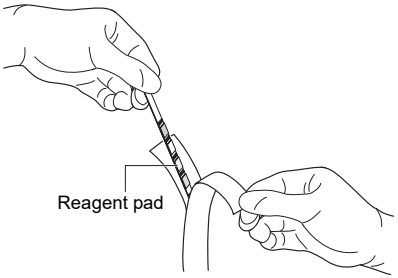
❶ Open the foil pack of the single/multiple reagent as shown below.





❷ Remove the single/multiple reagent without touching the reagent pad.



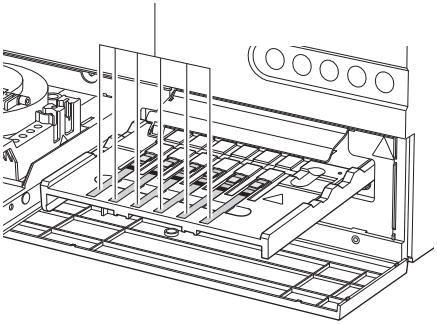


IMPORTANT:
Be careful not to fold or bend the single/multiple reagent when taking it out from the foil pack. Test by using a folded or bent single/multiple reagent may lead to inaccurate results.

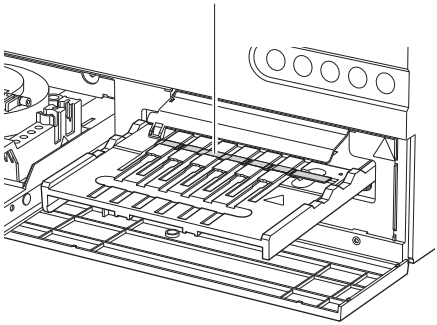
❸ Place the single/multiple reagent on the reagent table as shown below.

IMPORTANT:
Insert the end of a single/multiple reagent strip into the opening at the end of the groove on the reagent table and then fit the entire strip in the groove. If the single/multiple reagent strip is warped and/or not fitting on the groove, it may become jammed inside the instrument or lead to inaccurate results.

Single reagent (6 places)



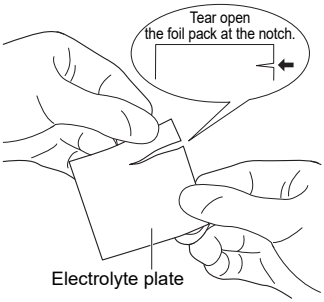
Multiple reagent (1 place)



6 Place the electrolyte plate and reference solution in the instrument

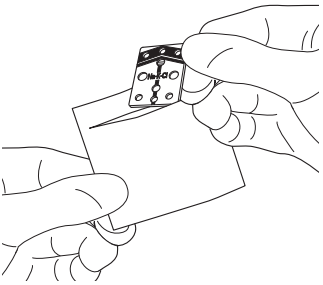
❶ Open the foil pack of the electrolyte plate.

NOTE:
Be careful not to put excessive pressure on the electrolyte plate.



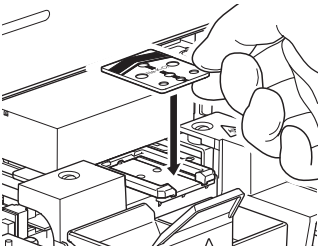
❷ Take out the electrolyte plate.

NOTE:
Be careful not to touch the holes on the electrolyte plate when removing it from the foil pack.



❸ Place the electrolyte plate on the plate table.

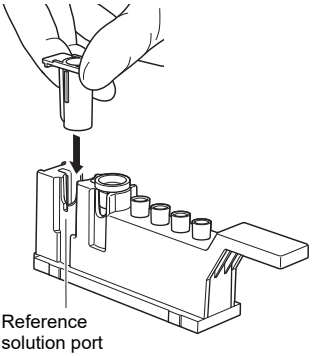
NOTE:
Be sure to correctly position the electrolyte plate on the plate table. If the electrolyte plate is not correctly positioned on the plate table, the instrument may become damaged.



❹ Remove the tip case.

❺ Remove the foil seal from the reference solution and place the reference solution into the reference solution port.

NOTE:
Measuring without removing the foil seal from the reference solution will cause the nozzle to break. Be sure to remove the foil seal from the reference solution before placing it in the reference solution port.



❻ Return the tip case to its original position.

NOTE:
Insert the tip case fully to the back of the instrument.

7 Start measurement

For more details, see the Application Manual.
When using the optional printer, the measurement result is printed. For more details about the measurement result, see “2-4-1 Measurement Results” (page 2-14).

NOTE:
Do not open the maintenance cover or front cover during measurement. If the front cover is opened during measurement, an E-104 error occurs.

REFERENCE:
To cancel measurement, press the ▽ button.

8 Dispose of the used tips, samples and reagents

NOTE:
Each time after using 10 tips, a message is displayed after measurement is completed. You can change the number of tips for displaying the message. For more details, see the Application Manual.

❶ Remove the disposal case and dispose of all used tips and electrolyte plates.

❷ Remove the tip case and dispose of all used cuvettes and reference solution.

❸ Dispose of the used single/multiple reagents on the reagent table.

❹ Return the disposal case and tip case to their original positions.

❺ If you do not continue operations, press the ▽ button. The reagent table and plate table retract and then the front cover closes.

9 Inspect the reagent table

Read the chapter “Daily Cleaning” (page 3-3) and inspect the reagent table for any areas that require cleaning. Clean the reagent table as necessary.

NOTE:
When measurement for the day is completed, be sure to dispose of all used tips in the disposal case.

2-4 Viewing the Measurement Result

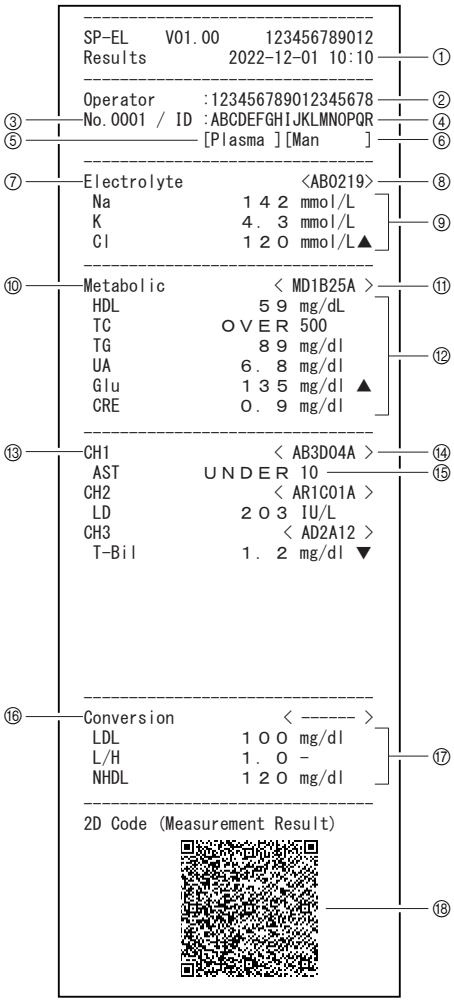
When using the optional printer, the measurement result is printed.

*To check the measurement results on the operation application, see the Application Manual.

2-4-1 Measurement Results

This section explains how to read the printed measurement result.

[Print example]



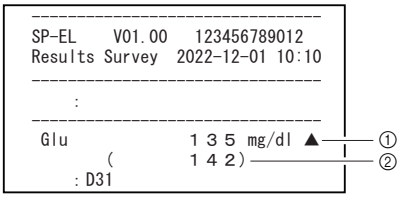
No.	Item	Description
①	Measurement date	Indicates the measurement date and time. If the measurement is performed in simple mode, “#Results#” is printed instead of “Results”.
②	Operator ID	Indicates the ID of the person who performed the measurement, entered in the measurement conditions. You can set On/Off for printing this item.
③	Measurement number	The numbers are based on the number of measurements.
④	Sample ID	Indicates the sample ID entered in the measurement conditions. If no data has been registered, “-” is printed.
⑤	Sample type	Indicates the sample type entered in the measurement conditions.
⑥	Patient information	Indicates the patient information entered in the measurement conditions.
⑦	Electrolyte plate measurement	Printed only when this channel is used.
⑧	Electrolyte plate lot information	Printed only when this channel is used.
⑨	Electrolyte plate measurement result	Printed only when this channel is used. The following abnormal value marks are printed depending on the measurement value. ▲: The value is higher than the normal range ▼: The value is lower than the normal range OVER: The value is higher than the measurable range UNDER: The value is lower than the measurable range The upper or lower limit of the measurement range is printed after “OVER” or “UNDER”. ------: Measurement is impossible ??????: Stability error ******: Liquid junction error
⑩	Multiple reagent name	Printed only when this reagent is used.
⑪	Multiple reagent lot information	Printed only when this channel is used.
⑫	Multiple reagent item name and measurement result	Printed only when this channel is used. Indicates the measurement result of each item. The following abnormal value marks are printed depending on the measurement value. ▲: The value is higher than the normal range ▼: The value is lower than the normal range OVER: The value is higher than the measurable range UNDER: The value is lower than the measurable range The upper or lower limit of the measurement range is printed after “OVER” or “UNDER”. ?????? : Abnormal application
⑬	Single reagent name	Printed only when this reagent is used.
⑭	Single reagent lot information	Printed only when this channel is used.

No.	Item	Description
⑮	Single reagent item name and measurement result	Printed only when this channel is used. Indicates the measurement result of each item. The following abnormal value marks are printed depending on the measurement value. ▲: The value is higher than the normal range ▼: The value is lower than the normal range OVER: The value is higher than the measurable range UNDER: The value is lower than the measurable range The upper or lower limit of the measurement range is printed after “OVER” or “UNDER”. ?????? : Abnormal application
⑯	Conversion result of converted item	Only converted items are printed.
⑰	Converted item name and measurement result	Only converted items are printed. Indicates the conversion result of each item. The following abnormal value marks are printed depending on the measurement value. ▲: The value is higher than the normal range ▼: The value is lower than the normal range OVER: The value is higher than the measurable range UNDER: The value is lower than the measurable range The upper or lower limit of the measurement range is printed after “OVER” or “UNDER”.
⑱	2D code	The system information and measurement information are embedded in the 2D code. Printing this item can be disabled by settings.

2-4-2 Survey Mode Measurement Result

This section explains how to read the printed survey mode measurement result.

[Print example]



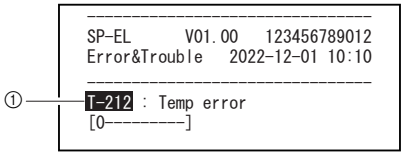
No.	Item	Description
①	Measurement result 1	Prints the item name, measurement results for which correlation correction is performed, unit, and abnormal value mark.
②	Measurement result 2	Prints the measurement results for which correlation correction is not performed, as well as the unit.

According to the setting, both measurement result 1 and 2, or only one of them, can be printed.

2-4-3 Printing Troubles

This section explains how to read the printed error and trouble information.

[Print example]



No.	Item	Description
①	Information about the error/ trouble that has occurred	1st line: Prints the error/trouble number and error name. 2nd line: Prints the additional information (only when there is additional information). 3rd line onwards: Up to two lines of supplementary information (text) for errors may be printed.

Chapter 3 Management Operation

This chapter describes the settings available on the menu screen, maintenance, quality control, and reagent information setting.

3-1 Settings Available on Operation Application

The following operations are available on the operation application. For more details, see the Application Manual.

- **Checking the instrument status (wireless connection status/standby/measuring status)**
- **Viewing/reprinting measurement results**
- **Security control for operator IDs, etc.**
- **Maintenance (“3-2 Maintenance” (page 3-2))**
- **Quality control (“3-3 Quality Control (QC)” (page 3-12))**
- **Reagent information setting (“3-4 Reagent information setting” (page 3-14))**
- **Parameter settings (“3-5 Parameter Settings” (page 3-19))**

3-2 Maintenance

This section explains the maintenance items.

Wear protective gloves to prevent exposure to pathogenic microbes.

70% isopropyl alcohol is sometimes used to clean the instrument. 70% isopropyl alcohol is readily combustible, therefore handle it carefully and keep away from flames, electrical sparks and sources of heat. Also, ventilate the room sufficiently during use.

■ Description of Maintenance

The table below shows the type of maintenance required for this instrument and the maintenance schedule. To ensure accurate measurement results, it is recommended that you perform regular maintenance.

Item	Description	Maintenance timing
Daily cleaning	Performing measurements over time may cause samples and soil to adhere to the rubber plate, reagent table, white plate/black plate and disposal case. Be sure to clean these parts when measurement for the day is completed.	Daily
Automatic cleaning of optical window	Performing measurements over time may cause the optical window to become dirty. Because the optical window is inside of the unit and difficult to reach, use “Automatic cleaning of optical window”.	After every approx. 300 measurements
Cleaning of optical window	If the optical window becomes very dirty, you may not be able to fully clean it using “Automatic cleaning of optical window”. In this case, manually clean the optical window.	When automatic cleaning of the optical window is not sufficient
Cleaning of nozzle Nozzle tube replacing	Samples and reagents adhering to the nozzle tip may cause clogging of the nozzle and nozzle tube. Clean the nozzle when a warning, error or malfunction is displayed, or after the set number of measurements is performed. Replace the nozzle tube when it becomes clogged.	After every approx. 1000 measurements or when a related warning, error or malfunction occurs
Replacement of nozzle	The O-ring attached to the nozzle deteriorates over time. With deteriorated O-ring, suction and discharge of the sample and reagent become less accurate. Replace the nozzle when a warning, error or malfunction is displayed, or after the set number of measurements is performed.	After every approx. 3000 measurements or when a related warning, error or malfunction occurs

Select a necessary item from the maintenance menu of the operation application to perform maintenance. For more details, see the Application Manual.

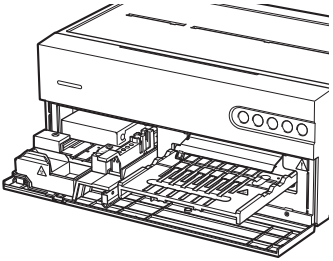
■ Daily Cleaning

Prepare: Cotton swab, distilled water, soft cloth, blower brush, 70% isopropyl alcohol and protective gloves

1 Prepare for daily cleaning

❶ Select “Daily cleaning” from the maintenance menu of the operation application and start the process.

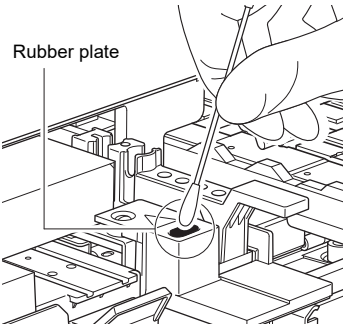
❷ The front cover opens and the reagent table and plate table extend.



2 Clean the rubber plate

❶ Use a cotton swab moistened with distilled water to remove any stains on the rubber plate.

❷ Use a dry cotton swab to remove any moisture remaining on the rubber plate.

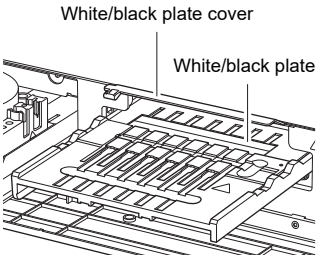


3 Clean the white/black plate

❶ Lift the white/black plate cover.

❷ Use a soft cloth moistened with distilled water to remove any stains on the white/black plate.

❸ Dry the white/black plate with a soft and dry cloth.



IMPORTANT:
Be careful not to touch the white/black plate with unprotected hands (which may leave sebum on the surface), apply pressure, or scratch the surface. Otherwise, inaccurate results may be obtained.

4 Clean the reagent table and plate table

❶ Use the supplied blower brush to blow away any debris.

❷ Use a soft cloth to remove any stains.

5 Clean the disposal case

If the disposal case is very dirty, wash the disposal case.

❶ Remove the disposal case.

❷ Disinfect the disposal case with 70% isopropyl alcohol and then rinse the case to remove any stains.

❸ Use a cloth to dry the disposal case.

❹ Attach the disposal case.

✣ ## ■ Automatic Cleaning of Optical Window

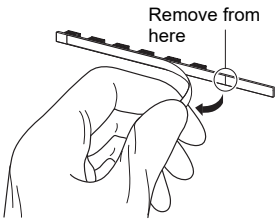
Prepare: Cleaning paper, container (for D-Concept only), distilled water, tips and protective gloves

1 Place the container and cleaning paper in the instrument

✣ ❶ Select “Automatic cleaning of optical window” from the maintenance menu of the operation application and start the process.

❷ Remove the double-sided tape from the back of the cleaning paper.

❸ Place the cleaning paper on the multiple reagent set position of the reagent table.



NOTE:
Be sure to securely place the cleaning paper on the reagent table without any warping or lifting of the cleaning paper.

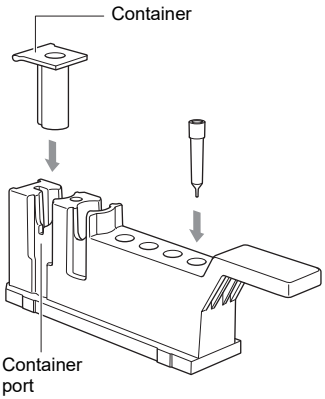
❹ Add approximately 200 µL (about halfway) of distilled water to the container.

❺ Remove the tip case.

❻ Place a tip and the container with distilled water into the tip port and the cleaning solution port respectively.

❼ Return the tip case to its original position.

NOTE:
Insert the tip case fully to the back of the instrument.



2 Begin automatic cleaning

✣ ❶ Operate the operation application to start the process.
If the optical window is not sufficiently cleaned even after the automatic cleaning is completed, an E-151 error occurs. In this case, follow the instructions for "Cleaning of Optical Window" (page 3-6).

REFERENCE:
"Automatic cleaning of the optical window" may take approximately from 6 to 13 minutes depending on the amount of dirt on the optical window.

3 Remove the container and cleaning paper

❶ When the optical window is completely cleaned, the front cover opens and a message is displayed on the screen.

❷ Remove the cleaning paper and the container with distilled water.

■ Cleaning of Optical Window

Prepare: Cotton swab, distilled water and protective gloves

1 Select a maintenance item

❶ Select “Cleaning of optical window” from the maintenance menu of the operation application and start the process.

❷ The front cover opens and the instrument power turns off.

❸ Remove the tip case and disposal case.

2 Disconnect the power cord, cables, etc., and clean the optical window

❶ Disconnect the power cord, cables, etc., at the rear side of the instrument.

❷ Move the instrument to a location where you can perform cleaning.

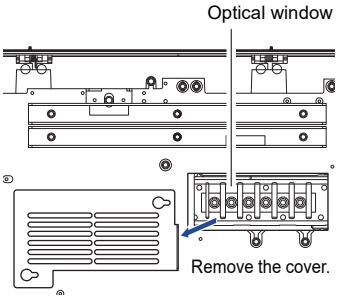
❸ Lift the front of the instrument and carefully stand it with the front side up.

NOTE:
Remove the tip case and disposal case before moving the instrument.

❹ Remove the thumb screws to remove the optical section cover on the bottom of the instrument.

❺ Use a cotton swab moistened with distilled water to remove any stains on the optical window.

❻ Dry the optical window with a dry cotton swab.



3 Return the instrument to its original position

❶ Attach the optical section cover to the bottom of the instrument.

❷ Attach the fixing bracket.

❸ Place the instrument in its original position and reconnect the power cord, cables, etc., to the rear side of the instrument.

■ Cleaning of Nozzle

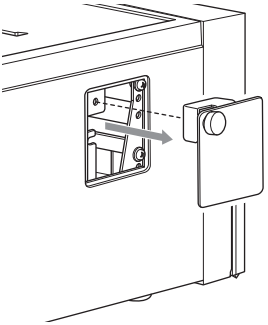
Prepare: Cleaning wire, nozzle tube, protective gloves, and tweezers

1 Move the nozzle to the maintenance position.

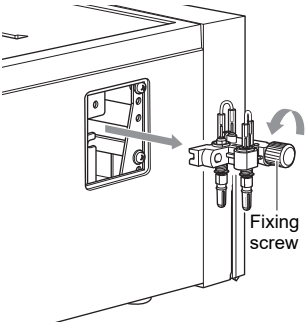
❶ Select “Cleaning of nozzle” from the maintenance menu of the operation application and start the process.

❷ Remove the maintenance cover in accordance with the messages on the operation application.

❸ Starting the cleaning on the operation application moves the nozzle to the maintenance position.



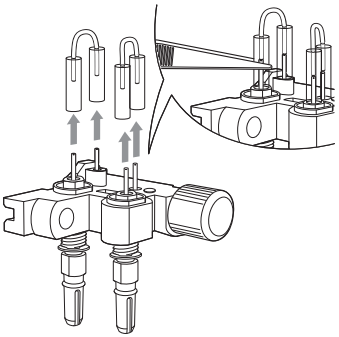
❹ Manually rotate the fixing screw of the nozzle maintenance holder and remove it, as shown in the diagram.



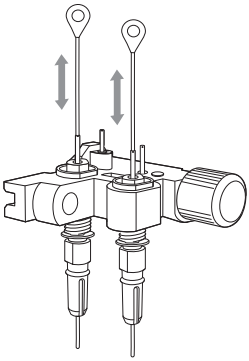
Do not touch the instrument while the nozzle is moving. Touching the internal parts during nozzle movement may damage the unit and result in personal injury.

2 Clean the nozzle

❶ Remove the nozzle tube using the tweezers.



❷ Insert the cleaning wire into the nozzle and move it up and down two or three times to clean the inside of the nozzle.

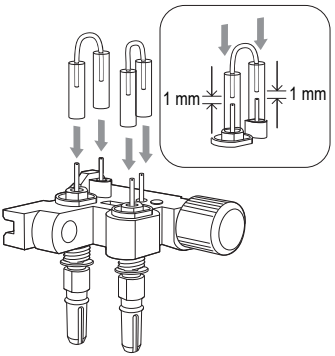


❸ Use a piece of tissue paper to remove any debris from the tip of the nozzle.

3 Attach the nozzle tube

❶ If the nozzle tube is clogged or stained, replace it with a new nozzle tube.
If the nozzle tube is not clogged or stained, attach the removed nozzle tube.

NOTE:
When attaching the nozzle tube, be careful not to insert it too far over the nozzle.



4 Attach the nozzle maintenance holder to the instrument

❶ Attach the nozzle maintenance holder.

NOTE:
Securely attach the nozzle maintenance holder.

❷ Attach the maintenance cover and fix it with the screws.

■ Replacement of Nozzle

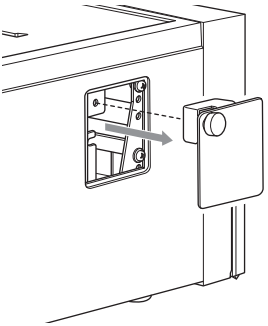
Prepare: Nozzle, wrench set for replacing nozzle and protective gloves

1 Move the nozzle to the maintenance position.

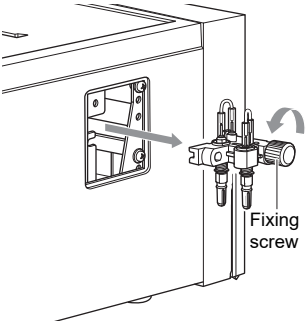
❶ Remove the maintenance cover.

❷ Select “Replacement of nozzle” from the maintenance menu of the operation application.

❸ Starting “Replacement of nozzle” moves the nozzle to the maintenance position.



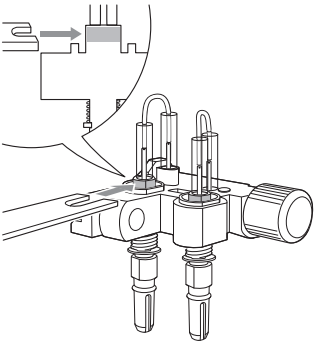
❹ Manually rotate the fixing screw of the nozzle maintenance holder and remove it, as shown in the diagram.



Do not touch the instrument while the nozzle is moving. Touching the internal parts during nozzle movement may damage the unit and result in personal injury.

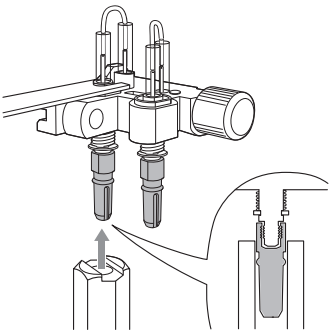
2 Replace the nozzle

❶ Fix the top part of the nozzle using the smaller end of the wrench.

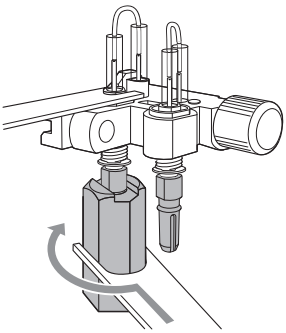


NOTE:
Be sure to fix the top part of the nozzle with the wrench before removing or attaching the nozzle. Otherwise, the nozzle may be damaged.

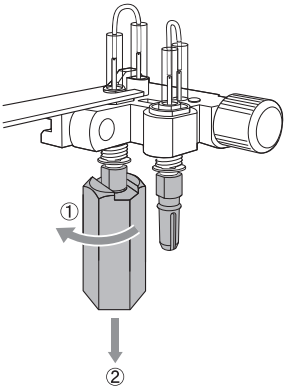
❷ Attach the adapter to the bottom of the nozzle.



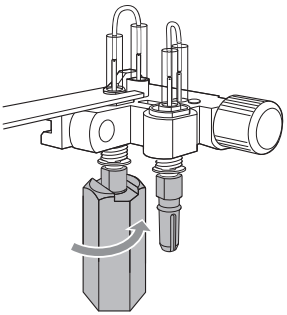
❸ Use the larger end of the wrench to rotate the adapter and loosen the nozzle attachment.



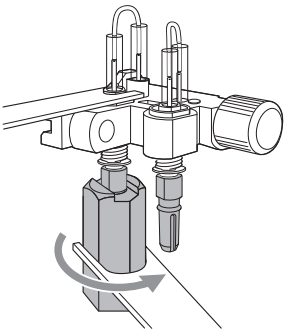
❹ Manually rotate the adapter in the direction of the arrow and remove the nozzle.



❺ Place the new nozzle on the adapter. Attach the adapter to the nozzle maintenance holder and gently tighten by hand.



❻ Use the smaller end of the wrench to fix the top part of the nozzle and use the larger end of the wrench to rotate and further tighten the adapter (at least 90°).



3 Attach the nozzle maintenance holder to the instrument

❶ Attach the nozzle maintenance holder.

NOTE:
Securely attach the nozzle maintenance holder.

❷ Attach the maintenance cover and fix it with the screws.

3-3 Quality Control (QC)

3-3-1 QC Tests

QC tests are required for quality control. To obtain accurate results in sample measurement, it is necessary to perform QC tests periodically to ensure that the results are within acceptable ranges.

3-3-2 Precautions for Handling Controls

For information on how to use controls, please read the package insert supplied with each control.

3-3-3 Lockout Function

The QC lockout function can be used to prohibit the measurement of samples that have not “passed” the QC test within a certain period of time or a certain number of sample measurements in the recent past. Sample measurement is also prohibited in case of a “failure” in the QC test. In these cases, sample measurement can be conducted again if a new QC test is “passed”. When the QC lockout function is not used, there will be no restrictions on sample measurements.

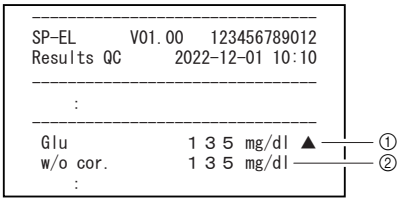
REFERENCE:
For details on executing QC tests, checking the measurement results, and setting the QC lockout function, see the Application Manual.

3-3-4 Measurement Results (Control Measurement)

When using the optional printer, the measurement result is printed.

To check the measurement results on the Application Manual, see the Application Manual.

[Print example]



No.	Item	Description
①	Measurement result	Item name and measurement value for which unit conversion and correlation correction are performed
②	QC test result	Measurement value for which correlation correction is not performed

3-4 Reagent information setting

The available setting parameters are shown in the following table.

Item	Description	See page
Single reagent information	• Sets the correlation correction factor of the parameters for each instrument. • Sets the normal range for items and patient type. • Prints item information.	page 3-14
Multiple reagent information	Prints item information.	page 3-16
Electrolyte item information	• Sets the correlation correction factor of the parameters for each instrument. • Sets the normal range for items and patient type. • Prints item information.	page 3-16
Electrolyte plate information	Prints item information.	page 3-18
Lot information	Selects the calibration method.	page 3-18

3-4-1 Single Reagent Information (Single info)

You can set the correlation correction factor and normal range for single reagent information. You can print out and check these settings. The available settings are shown in the following table.

Item	Description	Setting range	Default setting
Correlation correction factor	Enables setting of coefficients (A to D) to calibrate the output result for each patient type. $Y=AX^3+BX^2+CX+D$	-99.999 to 99.999	A,B,D: 0.000 C: 1.000
Normal range setting	Enables setting of the lower (L) and upper (H) limits of the normal range for each patient type.	0.00 to 9999.99	L: Lower limit of measurement range H: Upper limit of measurement range

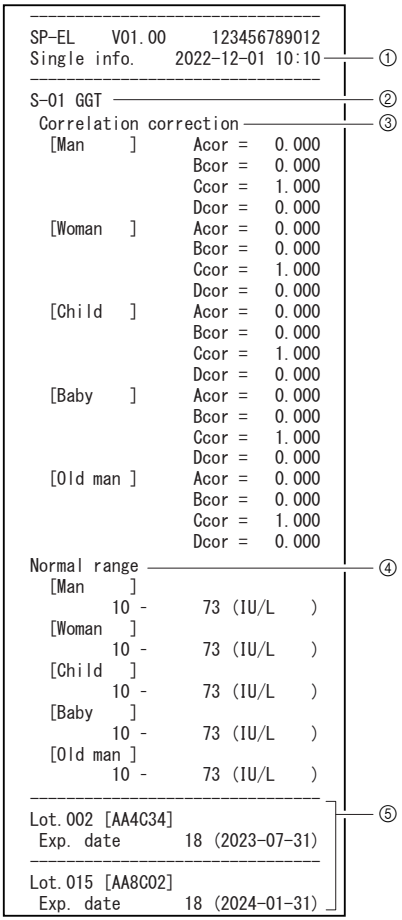
■ Setting the Single Reagent Information

For details on setting the single reagent information, see the Application Manual.

■ Printing Result of the Single Reagent Information

This section explains how to read the printed result.

[Print example]



No.	Item	Description
①	Measurement date and time	
②	Single reagent name	The reagent number and single reagent name are printed.
③	Correlation correction factor	The correlation correction factors are printed.
④	Normal range	The upper and lower limits of normal range are printed. When the patient types are registered, this information is printed for each patient type.
⑤	Calibration information	The calibration information is printed.

3-4-2 Multiple Reagent Information

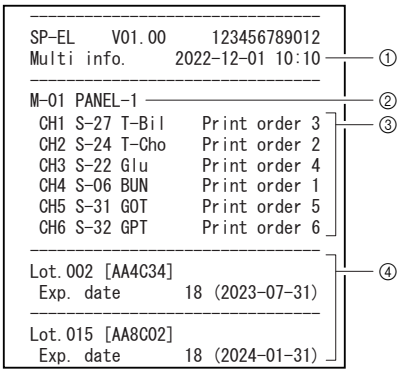
■ Printing the Multiple Reagent Information

For details on printing the multiple reagent information, see the Application Manual.

■ Printing Result of the Multiple Reagent Information

This section explains how to read the printed result.

[Print example]



No.	Item	Description
①	Measurement date and time	
②	Multiple reagent name	The reagent number and multiple reagent name are printed.
③	Item information	The channel number, item number and item name are printed.
④	Calibration information	The calibration information is printed.

3-4-3 Electrolyte item information

You can set the correlation correction factor and normal range for single reagent information. You can print out and check these settings. The available settings are shown in the following table.

Item	Description	Setting range	Default setting
Correlation correction factor	Enables setting of coefficients (A to D) to calibrate the output result for each patient type. $Y=AX^3+BX^2+CX+D$	-99.999 to 99.999	A,B,D: 0.000 C: 1.000
Normal range setting	Enables setting of the lower (L) and upper (H) limits of the normal range for each patient type.	0.00 to 9999.99	L: Lower limit of measurement range H: Upper limit of measurement range

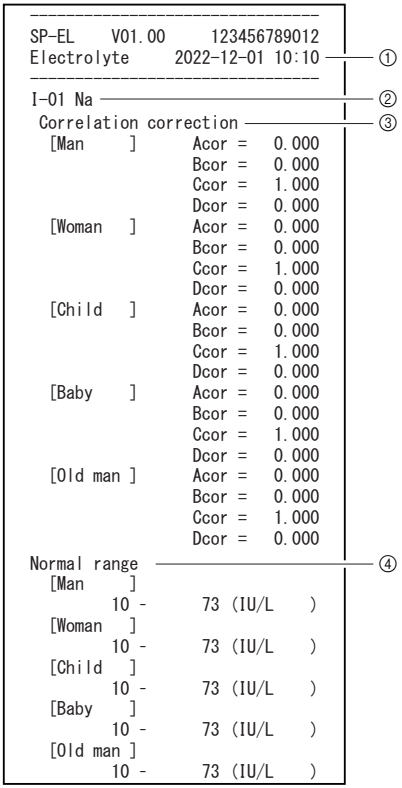
■ Setting the electrolyte item information

For details on setting the electrolyte item information, see the Application Manual.

■ Printing results of the electrolyte item information

This section explains how to read the printed result.

[Print example]



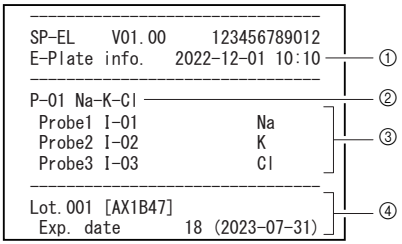
No.	Item	Description
①	Printed date and time	
②	Basic electrolyte item information	The reagent number and electrolyte item name are printed.
③	Correlation correction factor	The correlation correction factors are printed.
④	Normal range	The upper and lower limits of normal range are printed. When the patient types are registered, this information is printed for each patient type.

3-4-4 Electrolyte plate information

■ Printing the electrolyte plate information

For details on printing the electrolyte plate information, see the Application Manual.

[Print example]



No.	Item	Description
①	Printed date and time	
②	Basic electrolyte plate information	The reagent number and electrolyte plate reagent name are printed.
③	Item information	The probe number, item number and item name are printed.
④	Calibration information	The calibration information is printed.

3-4-5 Lot Information

■ Setting the Lot Information

For details on setting the lot information, see the Application Manual.

3-5 Parameter Settings

3-5-1 Unit Information Setting (Unit info setting)

The following settings are available on the menu screen of the operation application. For more details, see the Application Manual.

- **Unit name**
- **Status indication LED color**
- **Speaker volume**
- **Warning sound pattern**

3-5-2 Mode Setting

Select the measurement result printing mode and measurement mode. The available settings are shown in the following table. For more details, see the Application Manual.

Printing mode

Item	Description
Normal	Prints the normal measurement values.
QC measurement	Adds and prints the QC measurement values for which correlation correction is not performed.
Survey	Adds and prints the survey measurement values for which correlation correction is not performed.

REFERENCE:
For more details about the printed measurement result, see “2-4 Viewing the Measurement Result” (page 2-14).

Chapter 4 Troubleshooting

If a warning, error or malfunction occurs during measurement operation or processing with this instrument, a message may be displayed on the screen. This chapter describes the content of these messages and troubleshooting techniques.

4-1 Message Types

A trouble message appears on the display when the instrument has a problem. There are three levels of such messages based on the severity of the problem.

Message type	Description
Warning	Displayed as “W-0XX”. Follow the displayed message to solve the problem. If the message is repeatedly displayed, turn off the instrument and contact your distributor.
Error	Displayed as “E-1XX”. See “4-3 Error Messages” (page 4-4) to solve the problem. If the message is repeatedly displayed, turn off the instrument and contact your distributor.
Trouble	Displayed as “T-XXX”. A major error has occurred in the instrument. See the message for details. Turn off the instrument and contact your distributor.

NOTE:
Please inform your local distributor of the correct type and number of the message.

4-2 Warning Messages

W-001	Printer error
Possible solution	①Set the printing paper correctly. ②Set the printing paper and close the printer cover. ③Turn the printer off and on again.

W-002	Disposal case not set.
Possible solution	①Place the disposal case.

W-011	Tip case is not set.
Possible solution	①Place the tip case.

W-012	The tip case is not set correctly.
Possible solution	①Check if the tip case is set correctly. ②Check that the tip case is clean, and if not, clean it.

W-013	There are not enough tips in the set.
Possible solution	①Place more tips than the number of tips required for the measurement.

W-021	Specimen is not set.
Possible solution	①Place the cuvette.

W-022	Sample volume is outside the default range.
Possible solution	①The required sample volume varies depending on the measurement item. Use a cuvette with an appropriate sample volume. ②Correctly place the sample cuvette in the instrument. ③Clean the nozzle. (See “Cleaning of Nozzle” (page 3-7).) ④Replace the nozzle. (See “Replacement of Nozzle” (page 3-9).)

W-031	Reagent is not set.
Possible solution	①Place reagent strips in the instrument.

W-032	We started the measurement with the used reagent.
Possible solution	①Place a new reagent strip in the instrument. ②Clean the white/black plates. (See “Daily Cleaning” (page 3-3).) ③Clean the optical window. (See “Automatic Cleaning of Optical Window” (page 3-4) or “Cleaning of Optical Window” (page 3-6).)

W-033	I’m detecting reagent residue.
Possible solution	①Remove the electrolyte plate. ②Clean the plate table. (See “Daily Cleaning” (page 3-3).)

W-041	Insufficient reagent information for measurement items
Possible solution	①Enter the Reagent Info. of the reagent lot used for measurement.

W-042	The barcode could not be read properly.
Possible solution	①Check that the read 2D code contains the reagent lot information (Reagent Info.). ②Check if the 2D code is damaged or dirty.

W-043	Read expired reagent information code.
Possible solution	①Enter the Reagent Info. of a reagent lot that is not expired.

W-044	Expired reagents were measured.
Possible solution	①Use a reagent strip that is not expired. ②Check if the barcode printed on the reagent strip is dirty.

W-051	Measurement cannot be performed due to QC lockout
Possible solution	①Perform a QC test.

W-052	The maintenance cover is not open.
Possible solution	①Open the maintenance cover.

W-092	Reference fluid is not set.
Possible solution	①Set the reference solution correctly.

W-093	The EL-Plate is not set.
Possible solution	①Set the electrolyte plate correctly. ②Dispose of the container of the used reference solution.

4-3 Error Messages

E-101	The program version of the device has changed.
Possible solution	①Cancel the error in accordance with the instructions on the operation application.

E-102	Date and time anomalies
Possible solution	①Set the correct date/time. (See the Application Manual.)

E-103	Cannot enter the measurement standby state because the state is not ready for measurement
Possible solution	①Turn the instrument off and on again.

E-104	The cover was opened during the measurement operation or startup process.
Possible solution	①Check that the front cover and maintenance cover are closed, and remove any foreign bodies if present.

E-105	The power was turned off during measurement operation.
Possible solution	①Cancel the error in accordance with the instructions on the operation application.

E-111	Can't install the tip.
Possible solution	①If the O-ring on the nozzle has deteriorated, replace the nozzle. (See "Replacement of Nozzle" (page 3-9).)

E-112	Can't remove the tip.
Possible solution	①If the disposal case is full of tips, remove the tips from the disposal case.

E-113	Abnormal piping pressure, leakage
Possible solution	①Clean the rubber plate for pressure testing. (See "Daily Cleaning" (page 3-3).) ②Clean the nozzle. (See "Cleaning of Nozzle" (page 3-7).) ③Check the piping system and connect it if disconnected. (See "Nozzle tube replacing" (page 3-2).)

E-121	Suction abnormality was detected during measurement.
Possible solution	①Remove the bubbles or foreign bodies. ②Clean the nozzle. (See "Cleaning of Nozzle" (page 3-7).) ③Replace the nozzle. (See "Replacement of Nozzle" (page 3-9).)

E-131	The reagent barcode could not be read.
Possible solution	①Check that the reagent strip is not warped, and place it on the reagent table without floating. ②Place a new reagent strip in the instrument.

E-141	Data abnormality in reagent information (specification number)
Possible solution	①Check that the read 2D code contains the reagent lot information (Reagent Info.). ②Check if the 2D code is damaged or dirty.

E-151	White board, black board, and photometric window are dirty.
Possible solution	①Clean the white/black plates. (See “Daily Cleaning” (page 3-3).)

E-161	Communication error with host
Possible solution	①Check that the devices connected to the instrument are functioning properly. ②Check if the cables are connected correctly.

4-4 Trouble Messages

T-201	Communication with the Sub-MCU is abnormal.
Possible solution	①Turn the instrument off and on again.

T-202	Timer IC abnormal
Possible solution	①Set the correct date/time. (See the Application Manual.)

T-203	Memory abnormality
Possible solution	①Turn the instrument off and on again.

T-211	Temperature and humidity sensor abnormal
Possible solution	①Turn the instrument off and on again.

T-212	Temperature adjustment of each part is not completed after a certain period of time.
Possible solution	①Check the installation/operating environment and use the instrument in an appropriate location.

T-213	Temperature control abnormality detected.
Possible solution	①Check the installation/operating environment and use the instrument in an appropriate location.

T-214	Abnormality of the tip attachment detection sensor
Possible solution	①Turn the instrument off and on again.

T-221	Abnormality in nozzle vertical drive
Possible solution	①Turn the instrument off and on again.

T-222	Abnormality in left/right nozzle drive
Possible solution	①Turn the instrument off and on again.

T-223	Sampling pump drive error
Possible solution	①Turn the instrument off and on again.

T-224	Abnormal reagent table drive
Possible solution	①Turn the instrument off and on again.

T-231	Light intensity of light source LED is unstable
Possible solution	①Turn the instrument off and on again.

T-232	Optical gain cannot be set.
Possible solution	①Clean the white/black plates. (See “Daily Cleaning” (page 3-3).)

T-261	Radio module malfunction
Possible solution	①Turn off the instrument and unplug the power cord plug from the power outlet. Then, connect the power plug to the outlet again and turn on the instrument.

T-262	Ether microcomputer connection error
Possible solution	①Turn the instrument off and on again.

T-292	EL base front/rear drive abnormal
Possible solution	①Turn the instrument off and on again.

T-293	Plate guide driving abnormality
Possible solution	①If an electrolyte plate is jammed in the plate delivering section, remove it.

T-294	EL block vertical drive abnormal
Possible solution	①If an electrolyte plate is jammed in the plate delivering section, remove it.

T-295	ELectrolyte A/D communication error
Possible solution	①Turn the instrument off and on again.

T-999	Software error
Possible solution	①Turn the instrument off and on again.

Chapter 5 Appendix

5-1 Patient Type

Notation in the Manual

■ Notation Related to Operation

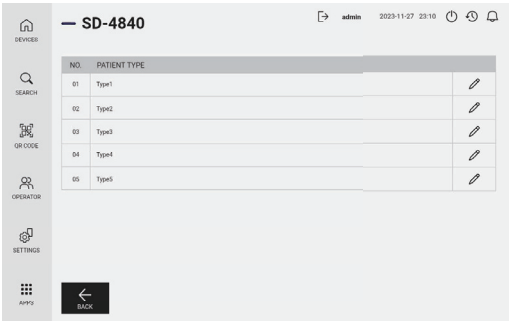
Indicates “tapping” an icon or button.

Indicates “selecting” an item.

Indicates tapping the input field and “entering” numbers or letters.

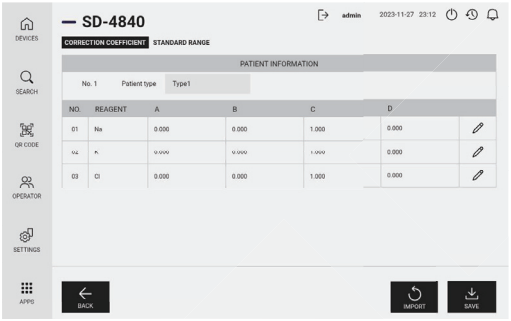
1 Setting mark of the instrument to be operated » Patient type settings

2 For the patient type you want to edit,



■ When changing the patient type name

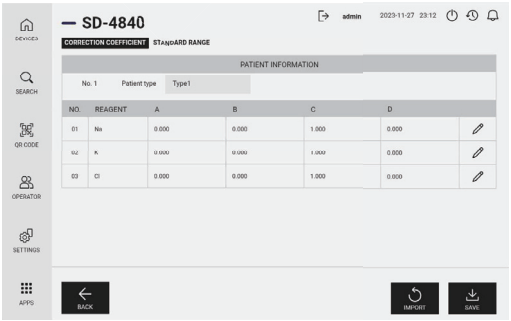
3 **Paitent type name**



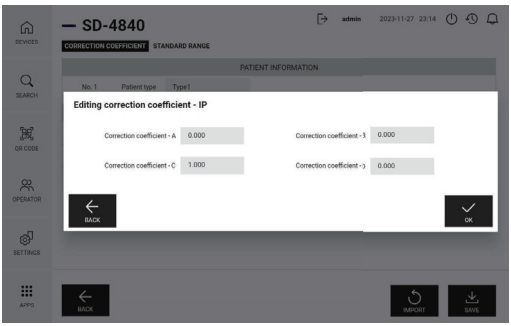
4 **SAVE** SAVE

■ When changing the correction coefficient

3 **For the reagent you want to change,**



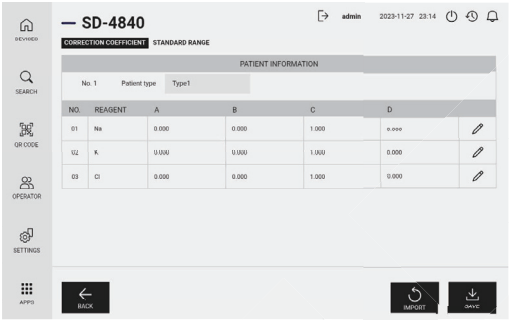
4 **Correciton coefficient A/B/C/D**



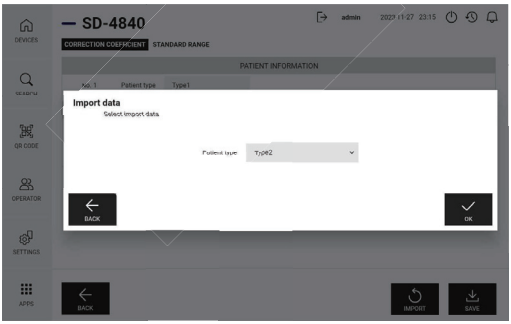
5 **OK** OK **» SAVE** SAVE

■ When importing the correction coefficient

3 IMPORT 



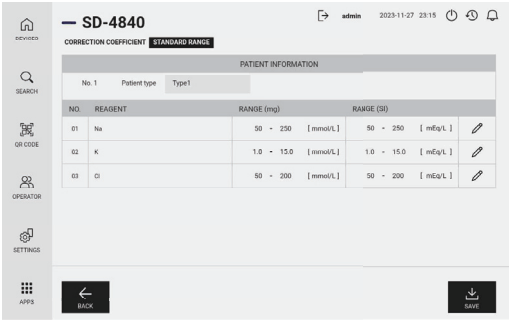
4 Patient type



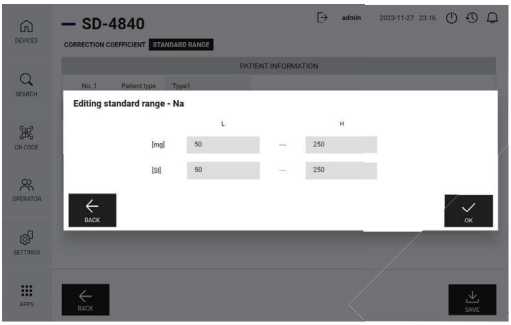
5 OK  » SAVE 

■ When changing the standard range

3 **For the reagent you want to change,**



4 **Standard range**



5 **OK** **» SAVE**

5-2 Computation Items

This system supports the following computation items.
The computation items are added to measurement results only when the relevant 2D code is read to set ON, with all values necessary for calculation properly measured. Note that all items are set to OFF by default.

NOTE:
Please read the 2D code of computation items using the handheld barcode reader.

Item name	Indication	Formula	Lower limit	Upper limit	Unit	Result digits	Remarks
LDL-Cholesterol	LDL	TC value - HDL value - (TG value/5)	35	385	mg/dL	Integers	Refer to this item only when TG is less than 400 mg/dL.
non-HDL-Cholesterol	non-HDL	TC value - HDL value	40	390	mg/dL	Integers	
Urea nitrogen/ Creatinine ratio	UN/CRE	UN value/CRE2 value	1	400	mg/mg	Integers	
AST/ALT ratio	AST/ALT	AST value/ALT value	0.1	100.0	-	First decimal place	
γ-globulin	GLOB	TP value - ALB2 value	1.0	5.0	g/dL	First decimal place	Computation is possible only for ALB2 (modified BCP assay) measurement.
Albumin/ γ-globulin ratio	A/G	ALB2 value/(TP value - ALB2 value)	0.2	6.0	-	First decimal place	Computation is possible only for ALB2 (modified BCP assay) measurement.
Sodium/ Potassium ratio	Na/K	Na value/K value	3	250	-	Integers	

Item name	ON	OFF
LDL-Cholesterol		
non-HDL-Cholesterol		
Urea nitrogen/ Creatinine ratio		
AST/ALT ratio		

Item name	ON	OFF
γ-globulin		
Albumin/ γ-globulin ratio		
Sodium/ Potassium ratio		

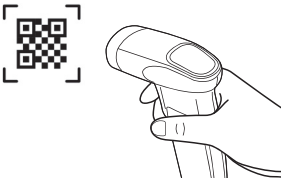
Note) Computation items may involve large errors as they are calculated from respective measured values.

Note) Up to five computation items can be registered. To add a new item when five items are already ON, first set one of the registered items to OFF, and add the new item.

5-3 Simple Mode Measurement Settings

When not using the operation application (simple mode measurement)

You can set measurement conditions by reading the 2D code before starting measurement.
To read the 2D code, use the supplied handheld barcode reader.



Operator ID/Sample ID

First read the following 2D codes and then read the ID barcode.

Operator ID

Sample ID

Sample type

You can overwrite the setting by rereading the desired 2D code.

Plasma

Serum

Whole blood

Others

Patient type

You can overwrite the setting by rereading the desired 2D code.

Type1

Type2

Type3

Type4

Type5

Measurement result output

Output1

Outputs the most recent measurement result.

Output2

Outputs all measurement results from the final measurement date.

Output3

Outputs all measurement results.

Clear

Clears the set measurement conditions.

Chapter 6 Index

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