Semi-automatic Urine Analyzer

AutionIDaten

AE-4070 | Operating Manual

arkray,inc.

1 Premise

Thank you for purchasing our semi-automatic urine analyzer, the AutionIDaten AE-4070.

This manual contains important information on the functions of the AutionIDaten AE-4070.
This manual is issued by ARKRAY, Inc.
Read carefully prior to starting up the unit.
It is recommended to retain this manual for future use.

The AutionIDaten AE-4070 is intended for the qualitative and/or semi-quantitative measurement of several physiological markers in urine: Glucose, Protein, Bilirubin, pH, Blood, Urobilinogen, Ketones, Nitrite, Leukocytes, Creatinine, Albumin, Specific Gravity, P/C (Ratio of Protein to Creatinine) and A/C (Ratio of Albumin to Creatinine).
These measurements are used for screening of kidney disease, liver disease, diabetes mellitus and urinary tract infection in general screening populations. This instrument is automated. For in vitro diagnostic use and professional use only.

This product conforms to the EMC Standard IEC61326-2-6:2012(EN61326-2-6:2013).
Class of emission: CISPR 11 Class A
This instrument is an IVD medical instrument.

CE

This product conforms to European 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.

2 Introduction

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

- BE CAREFUL WHEN HANDLING URINE. This system uses urine as sample and as an ingredient of Control. Urine may be contaminated by pathogenic microorganisms that can cause infectious diseases.
  Improper handling of urine 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 operating manual before use.
- Never touch the test strip tray, carrying arm, or other parts where sample may adhere with unprotected hands. During cleaning or maintenance of these parts, wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples, test strips, spare parts and instrument in accordance with local regulations for biohazardous waste.

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

3 Symbols

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

■ Personal Injury

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

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

■Damage to the Product or Its Performance

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

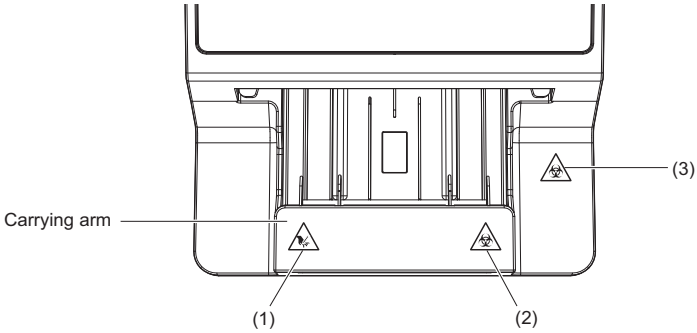
NOTE:
Information useful for preventing damage to the instrument or parts, and other important information you should keep in mind.

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

4 Caution Labels

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

■ Front



(1) Carrying arm

The carrying arm moves during measurement. While the carrying arm is moving, keep your hands away from the arm so as to avoid being caught or pinched.

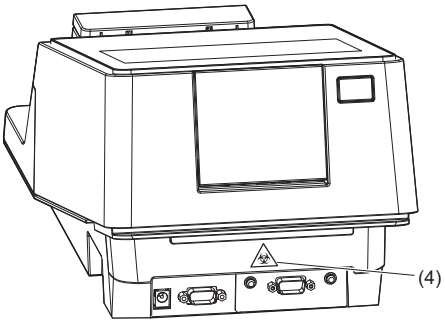
(2) Carrying arm

Never touch the carrying arm with unprotected hands. During cleaning or maintenance of the carrying arm, wear protective gloves to prevent exposure to pathogenic microorganisms.

(3) Maintenance cover and inside the instrument

Never touch the maintenance cover or inside the instrument with unprotected hands. During cleaning or maintenance of these parts, wear protective gloves to prevent exposure to pathogenic microorganisms.

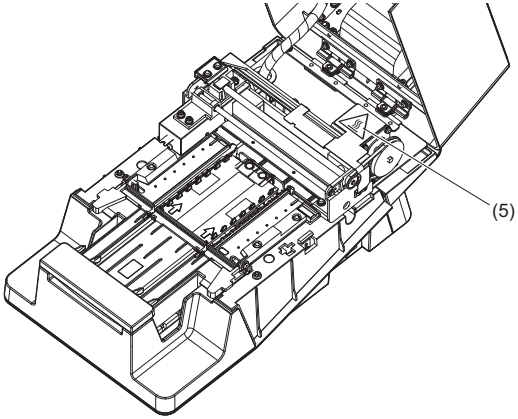
■ **Rear**



(4) Waste box

Never touch the waste box with unprotected hands. During cleaning or maintenance of the waste box, wear protective gloves to prevent exposure to pathogenic microorganisms.

■ **Inside**



(5) Motor

Do not touch the motor or its surrounding areas especially during operation and just after the instrument is turned off. It may burn hands.

5 Table of Contents

Chapter 1 Before Use

This chapter describes information you should know before using the instrument.

1.1 Outline of AE-4070

1.1.1 Measurement Types

■ Measurement of the Sample

● Normal measurement

In Normal measurement mode, multiple samples are measured consecutively.

If the test strip is dipped in the sample and placed on the test strip tray, it is automatically transported to the optical unit*, and measurement starts.
When the measurement is complete, the measurement result is printed from the printer.
* This operation is performed in the initial setting “Auto Start Mode”. → See “3.2.4. Setting the Measurement Operation” on page 3-6.

The test strip is transported in 7 seconds. By repeating the procedures of “Dipping the test strip” and “Setting the test strip”, a large number of samples can be efficiently and smoothly measured.

A measurement number indicating the sequence of measurement is assigned to each of the measurement results.
It is also possible to set a patient ID for the sample. The measurement number and patient ID are printed on the measurement result.

Meas. No.: MEAS. 0000 to 9999
Patient ID: An alphanumeric number of up to 18 digits

● STAT measurement

The STAT measurement mode is used in the following cases:
- When an urgent sample needs to be measured while normal measurement is being performed.
- When measurement is to be performed with a test strip different from the one used for normal measurement.
- When a measurement result is required in an output format (concentration value/reflectance) different from that of normal measurement

A measurement number different from that is for normal measurement is assigned to the measurement result of STAT measurement.
It is also possible to set a patient ID for the sample.

Meas. No.: STAT 0000 to 9999
Patient ID: An alphanumeric number of up to 18 digits

■ Control Measurement

In Control measurement mode, accuracy control of the instrument can be performed by periodically measuring the Controls.

If control measurement is not performed by the set deadline, a QC Lock-Out occurs and the measurement of the sample will be prohibited. If control measurement is performed, the sample can be measured again. As a result, accurate measurement results can be obtained at all times.

Meas. No.: CONTROL 0000 to 9999

■ Check Measurement

This mode is used to verify that the instrument is working normally. Perform check measurement using the special check strips supplied with the instrument, if you feel that actual sample measurement results are odd or questionable.

1.1.2 Features

AutionIDaten AE-4070 is a semi-automatic urine analyzer that uses test strip method. This compact instrument is capable of performing a variety of functions.

● Compact and lightweight, with simple structure

This instrument can be installed in various locations and can be carried easily, thanks to its lightweight construction of 5.0 kg. Despite its compactness, the instrument has sophisticated functions such as a display, built-in printer, section that removes surplus urine, test strip feed mechanism, mechanism for automatically discarding used test strips, and a back-up memory that can store the results of up to 520 samples.

● Semi-automatic operation

The user dips test strips into samples and then places them on the test strip tray. The user does not need to pour samples from collection cups into sample containers, which enables efficient measurement.

● Dipping timing signal

The duration of dipping the test strips in the sample, and the timing of placing them on the test strip tray can be known by a buzzer. By performing the operation according to the buzzer, the test strip reaction time can be kept constant and stable measurement result can be obtained.

● Measurement of one sample every seven seconds

The instrument measures one sample every seven seconds at its maximum speed. This enables a maximum system output of 514 samples per hour.

● Auto start, and non-directional test strip placement

When a test strip is placed on the test strip tray, the carrying arm automatically transports it and the measurement starts. It is not necessary to perform operations such as pressing the Start button. Measurement can be performed regardless of the orientation of the part from where the test strip is held (pointing right or left).

● Measurement auto-stop function

Measurement stops automatically if a test strip is not set for a certain period of time. It is not necessary to perform operations such as pressing the Stop button.

● Test strip type auto-detection

The instrument automatically identifies the type of test strips (assuming they have auto-classification marks). There is no need to set the type of the test strip before measurement.
* However, this function is not supported if Uriflet S is selected.

● Temperature correction function

The optimum ambient temperature range for test strips used with this instrument is from 20 to 25°C. The environment outside this range may cause inaccurate measurement results. The temperature correction function of the instrument compensates for any deviation caused by ambient temperature. Therefore, correct measurement results can be obtained in a range of 10 to 30°C where the room temperature can be easily adjusted.

● Color tone determination

The instrument measures the color tone of samples. By measuring the light and shade and hue of samples, the instrument obtains the urine color tone data corresponding to 23 categories.
→ See "■ Color Tone Correction" on page 1-6.

● Abnormal color detection

The instrument automatically detects urine containing medicine, and prints an abnormal mark "!" with the measurement result.
* Only applicable to the following measurement items: KET, BIL, and URO.

● Turbidity input function

The urine turbidity based on visual inspection can be selected from "-", "1+", and "2+", and can be printed with the measurement result.
* The instrument does not have a function for automatically determining the turbidity of the urine.

● Prints measurement results in bold

The instrument prints measured values by using bold-type and larger characters for easy and fast reading.
→ See "2.11. How to Read Measurement Results" on page 2-28.

● Easy to maintain

Components that require daily maintenance, such as the carrying arm, test strip tray, and waste box, have simple structures that can easily be detached and reattached.

● Stores measurement results up to 520 samples

The measurement result can be searched for by measurement mode*, and if necessary, it can be reprinted and re-transmitted. Only measurement results containing abnormal values can also be searched for.
* Normal measurement, STAT measurement, control measurement

● ID can be input using a barcode

The patient ID and operator ID can be easily input by reading the barcode. This eliminates the need of a tap operation, and enables quick and accurate input of important information.
* An optional hand-held barcode reader is required.

● A wide variety of communication functions

An RS-232C terminal is provided as a standard equipment that enables a direct connection with a terminal such as a PC, and transmission of the measurement result. By replacing the terminal with an optional product, it is possible to connect the instrument to a wired LAN.

1.1.3 Specifications

Product	AutionIDaten AE-4070
Configuration	Analyzer and accessories
Measurement objects	Urine
Test strips	AUTION Sticks, Uriflet S, AUTION SCREEN
Measurement items	GLU, PRO, BIL, URO, KET, pH, NIT, BLD, LEU, specific gravity, color tone, ALB, CRE, A/C, P/C
Measurement ranges	Test strip: Rank table (See “1.1.5. Rank Tables” on page 1-6.) Color tone: Color tone classification chart (See “■ Color Tone Correction” on page 1-6.)
Measurement principle	Test strip method Dual-wavelength reflection photometric method (single wavelength for BLD)
Measurement wavelength	4-wavelength LED (430, 565, 635, and 760 nm)
Processing speed	514 samples per hour (maximum processing mode: 7-second interval)
Display	7-inch color LC display with touch panel
Printer	For use with 58-mm width thermal printer paper
Memory capacity	520 samples
External output	Conforms to RS-232C standard (serial) Options: Ethernet board
Communication system	One-way communication system (RS-232C) Two-way communication system (RS-232C, Ethernet)
Communication speed	RS-232C: Select from 300, 600, 1200, 2400, 4800, 9600, 19200 bps Ethernet: 10BASE-T, 100BASE-TX
Measurement environment (Temperature correction)	Temperature: 10 to 30°C, Humidity: 30 to 60% R.H. (non-condensing)
Storage environment	1 to 30°C, Humidity: 20 to 80% R.H. (non-condensing)
Environment during transport	Temperature: -10 to 60°C, Humidity: 20 to 80% R.H. (non-condensing)
Dimensions	206 (width) × 365 (depth) × 180 (height) mm
Weight	Approx. 5.0 kg
Power requirements	AC adapter:100 to 240 V AC ± 10%, 50/60 Hz Instrument main unit:12 V DC
Power input	AC adapter:60 VA Instrument main unit:12 V DC/4.2 A
Sound pressure level	Less than 80 dB
Location of use	For indoor use only
Altitude	2000 m
Pollution degree	2
Over voltage category	II
Expected life	5 years (According to company data)

1.1.4 Measurement Principle

This instrument measures designated test strips using dual- or single wavelength reflection.

■ Measuring Test Strips

Dip a test strip in the sample for 2 seconds and place it on the test strip tray. The carrying arm then transports the test strip from the test strip feed mechanism to the photometric section. The reflectance is measured in the photometric section 60 seconds after dipping (duration for which the test strip reacts and changes color). When measurement is complete, the test strip is discarded in the waste box.

In the photometric section, LEDs shine dual-wavelength light upon the test strip pad area, and reflections are received at the detector. Different combinations of light are applied for each measurement item. Furthermore, photometric measurements carried out in the color tone correction section correct variability in the amount of reflected light and sample coloring.

The reflectance is obtained using the following equation:

$$R = Tm \cdot Cs / Ts \cdot Cm$$

R: Reflectance
Tm: Amount of reflected light at the measurement wavelength of the test section (Pad area)
Ts: Amount of reflected light at the reference wavelength of the test section (Pad area)
Cm: Amount of reflected light at the measurement wavelength of the color tone correction section
Cs: Amount of reflected light at the reference wavelength of the color tone correction section

The measurement item BLD item alone is calculated using the following equation and single wavelength measurement.

$$R = Tm / Cm$$

The reflectance R is compared with the calibration curve for the instrument, and is output as the measurement result.

Additionally, in order to eliminate the influence of ambient temperature fluctuation upon measurements, temperature corrections are applied as follows.

$$Rt = R + A \cdot (T-27) \cdot R^2 \cdot (1-R)^2$$

Rt: Reflectance after temperature correction
A: Correction coefficient of the measurement items
T: Internal ambient temperature of the instrument during measurement

● Measurement wavelength of each measurement item

Measurement items	Measurement wavelength (nm)	Reference wavelength (nm)
GLU	635	760
PRO	635	760
BIL	565	760
URO	565	760
PH	635	760
S.G.	635	760
BLD	635	– – –
KET	565	760
NIT	565	760
LEU	565	760
ALB	565	760
CRE	635	760

■ Color Tone Correction

R (635 nm), G (565 nm), B (430 nm), and IR (760 nm) wavelengths are applied to the color tone correction section of a test strip. By measuring the various reflections, the sample's hue, light and shade values can be determined. The results will correspond to one of the 23 categories of color tone listed in the table on the right.

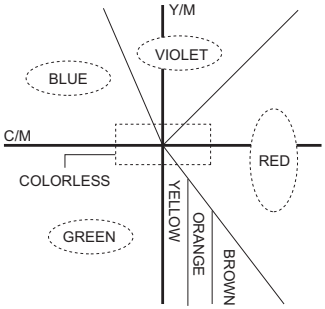
● Light and shade, and hue (23 color tones)

COLORLESS		
LIGHT (NORMAL) DARK	X	YELLOW
		ORANGE
		BROWN
		RED
		VIOLET
		BLUE
		GREEN
OTHER		

The hue is obtained from the location in the coordinate system illustrated at the right.

Y: Reflectance of 430 nm beam
M: Reflectance of 565 nm beam
C: Reflectance of 635 nm beam
r: Reflectance of 760 nm beam

● Color tone classification chart



The light and shade of the hue (except for YELLOW, ORANGE, and BROWN) are obtained using the following equation. The results are classified into 3 color tones (light, normal, dark) for evaluation.

$$\sqrt{\left(1+a-\frac{Y}{r}\right)^2+\left(1+a-\frac{M}{r}\right)^2+\left(1+a-\frac{C}{r}\right)^2}$$

a: Correction constant

1.1.5 Rank Tables

IMPORTANT:
- As for the ranks indicated by , the abnormal mark (*, !) is printed in the measurement result.
- The abnormal mark is not added to PH, S.G., ALB, CRE and TURB.

● GLU (Glucose)

Rank No.	1	2	3	4	5	6	7	8	9	10	11
Qualitative value	-	±		1+		2+		3+		4+	
Semiquantitative value (mg/dL)		30	50	70	100	150	200	300	500	1000	OVER
Semi-quantitative (mmol/L)		1.7	2.8	3.9	5.6	8.3	11	17	28	56	OVER

● PRO (Protein)

Rank No.	1	2	3	4	5	6	7	8	9	10	11
Qualitative value	-	±		1+			2+		3+		4+
Semiquantitative value (mg/dL)		10	20	30	50	70	100	200	300	600	OVER
Semi-quantitative (g/L)		0.1	0.2	0.3	0.5	0.7	1	2	3	6	OVER

● BIL (Bilirubin)

Rank No.	1	2	3	4	5	6	7	8	9	10
Qualitative value	-	1+		2+			3+			4+
Semiquantitative value (mg/dL)		0.5	1	2	3	4	6	8	10	OVER
Semi-quantitative (umol/L)		8.5	17	34	50	70	100	140	170	OVER

● URO (Urobilinogen)

Rank No.	1	2	3	4	5	6	7	8
Qualitative value	NORMAL	1+		2+		3+		4+
Semiquantitative value (mg/dL)		2	3	4	6	8	12	OVER
Semi-quantitative (umol/L)		34	50	70	100	140	200	OVER

● PH (pH)

Rank No.	1	2	3	4	5	6	7	8	9
Measured value	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0

● S.G. (Specific gravity)

Rank No.	1	2	3	4	5	6
Measured value	< 1.005	1.010	1.015	1.020	1.025	> 1.030

● BLD (Blood)

Rank No.	1	2	3	4	5	6	7	8
Qualitative value	-	±	1+		2+		3+	
Semiquantitative value (mg/dL)		0.03	0.06	0.1	0.2	0.5	1.0	OVER
Semi-quantitative (mg/L)		0.3	0.6	1.0	2.0	5.0	10.0	OVER

● KET (Ketones)

Rank No.	1	2	3	4	5	6	7	8	9	10
Qualitative value	-	±	1+		2+		3+		4+	
Semiquantitative value (mg/dL)			10	20	40	60	80	100	150	OVER
Semi-quantitative (mmol/L)			1	2	4	6	8	10	15	OVER

● NIT (Nitrite)

Rank No.	1	2	3
Qualitative value	-	1+	2+

● LEU (Leukocytes)

Rank No.	1	2	3	4	5
Qualitative value	-				
Semiquantitative value (Leu/uL)		25	75	250	500

● ALB (Albumin)

Rank No.	1	2	3	4	5
Semiquantitative value (mg/L)	10	30	80	150	OVER

● CRE (Creatinine)

Rank No.	1	2	3	4	5	6
Semiquantitative value (mg/dL)	10	50	100	200	300	OVER
Semiquantitative value(g/L)	0.1	0.5	1.0	2.0	3.0	OVER

● A/C (Ratio between Albumin/Creatinine)

Rank No.	1	2	3	4	5
Qualitative value	NORMAL	1+		2+	
Semiquantitative value (mg/gCr)	< 30	100	200	> 300	OVER

● P/C (Ratio between Protein/Creatinine)

Rank No.	1	2	3	4	5	6
Qualitative value	DILUTE	NORMAL	1+		2+	
Semiquantitative value (mg/gCr)		< 150*	200	400	> 500	OVER

* This value can be changed to "< 80". To change the setting, contact your distributor.

● TURB (Turbidity)

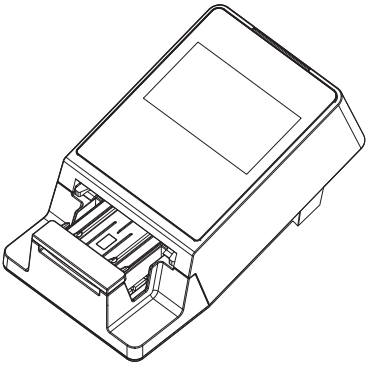
Input No.	0	1	2
Turbidity	-	1+	2+

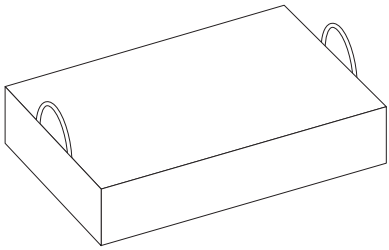
1.2 Unpacking

Make sure you have all items listed in this section. If anything is missing or damaged, contact your distributor.

NOTE:
Test strips and controls are not included with the instrument.

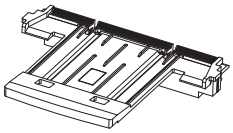
1.2.1 Items in the Instrument Package





Item No.	Packaged products	Description	Quantity
(1)	Instrument main unit	AutionIDaten AE-4070	1
(2)	Accessory kit box	→ See “1.2.2. Accessory Kit Box” on page 1-11.	1

1.2.2 Accessory Kit Box



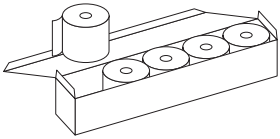
(1) Test strip tray

(2) Check strip set

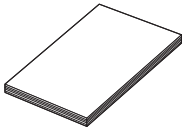
(3) Stylus pen

(4) AC adapter

(5) Power cord



(6) Thermal recording paper

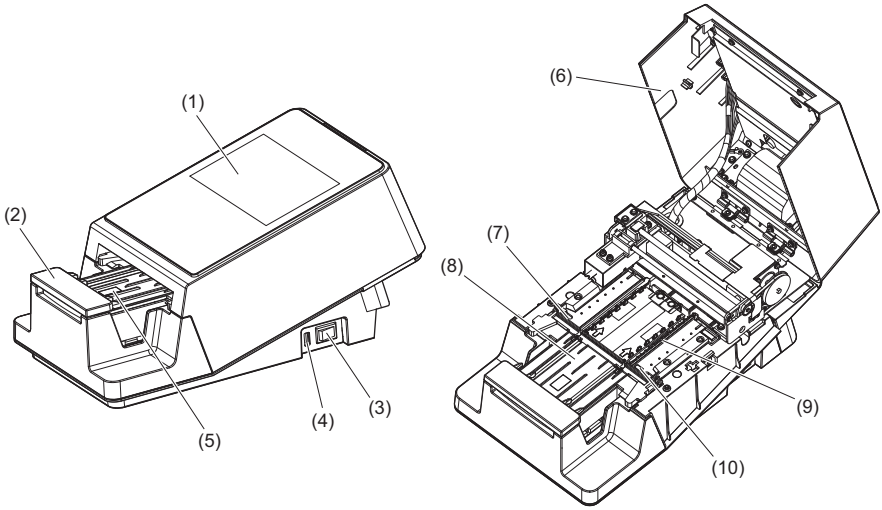


(7) Operating manual

Item No.	Product	Description	Quantity
(1)	Test strip tray	Spare	1
(2)	Check strip set	2 check strips (white) 2 check strips (gray)	1
(3)	Stylus pen	-	1
(4)	AC adapter	-	1
(5)	Power cord	Rating: 125V 7A (A type plug) and 250V 2.5A (C type plug) Please use the appropriate power cord for your region's power voltage.	1
(6)	Thermal recording paper	58 mm width, 5 rolls	1
(7)	Operating manual	-	1

1.3 Part Names and Functions

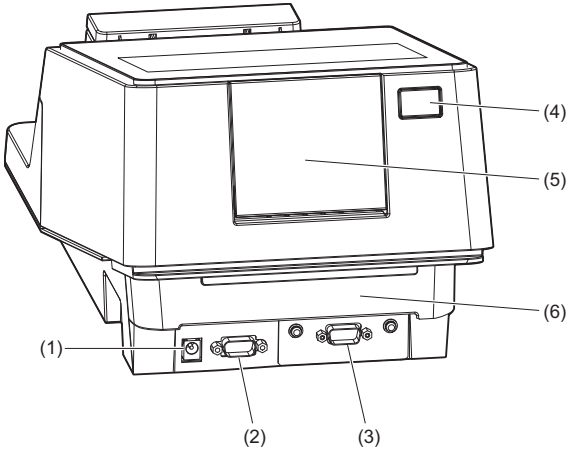
■ **Front**



* Maintenance cover opened

Item No.	Product	Function
(1)	Touch panel	See “1.5. Basic Operations” on page 1-22.
(2)	Carrying arm	Carries the test strip placed on the test strip tray to the suction ports while the tray rails adjust the position.
(3)	Power switch	Turns the power ON/OFF.
(4)	USB terminal	Used by an Arkray service person.
(5)	Test strip detection window (Auto start sensor)	Detects when a test strip is placed on the test strip tray.
(6)	Maintenance cover	Prevents any light from entering the instrument. The instrument turns OFF when this cover is opened. Do not open this cover unless instructed, such as during installation or maintenance.
(7)	Suction ports	Absorbs surplus sample adhering to the test strip.
(8)	Test strip tray	Used to place the test strip dipped in the sample.
(9)	Test strip feed mechanism	Transfers the test strips to the photometric section. When measurement is complete, this mechanism will discard the test strip into the waste box.
(10)	Incoming strip sensor windows	The incoming test strip is detected here, and is allocated a measurement number and a patient ID.

■ Rear



Item No.	Product	Function
(1)	Power input terminal	Terminal for connecting the supplied AC adapter.
(2)	B.C.R. terminal	Terminal for connecting the optional hand-held barcode reader.
(3)	RS-232C terminal	Terminal for connecting the cable of an external device.
(4)	Printer button	Press this button to open the printer cover.
(5)	Printer cover	Open this cover to replace the thermal recording paper.
(6)	Waste box	Used test strips are discarded in this box.

REFERENCE:

The RS-232C terminal can be replaced by an Ethernet port (Option: Ethernet board). For more information, contact your distributor.

1.4 Installing the Instrument

1.4.1 Precautions for Instrument Installation

Before installation of the instrument, read the following notes and always take proper safety precautions.

- Ensure at least 20 cm of clearance between the wall and the rear panel. Inadequate clearance between the instrument and walls may cause an undesirable load on cable connections, thus resulting in fire.
- Use the instrument at the correct supply voltage. The wrong supply voltage may cause fire or damage to the instrument and consequently lead to personal injury.
- Install the instrument on a level, vibration-free sturdy platform. Operation of the instrument in an unstable place may cause trouble with or malfunction of the instrument, resulting in personal injury.
- Do not install the instrument near places that store chemicals or near equipment that generates corrosive gas or electrical noise. Chemicals, corrosive gases and electrical noise may cause damage to or malfunction of the instrument and consequently lead to personal injury.
- Install the instrument in a place where condensation, direct sunlight or wind can be avoided. These factors may cause inaccurate measurement results, as well as deformation of or damage to the instrument.
- Use the specified RS-232C-compliant cross cable to connect an external device to the instrument. Connection using other than an RS-232C cable may cause electric shock or fire.
- Do not disassemble the instrument. Do not modify the instrument without reason. Doing so may cause fire or damage to the instrument and consequently lead to personal injury.

IMPORTANT:

Install the instrument where temperature and humidity can be maintained in the following ranges:
Temperature: 10 to 30°C
Humidity: 30 to 60%
Installation in the environment outside these ranges may cause inaccurate measurement results.

NOTE:

Use an external communication cable shorter than 30 m. External communication cables are for indoor use only.

1.4.2 Installing the Instrument

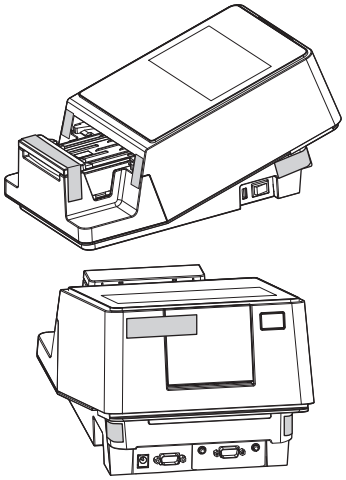
Each component is held securely using fixing tape to protect the instrument from damage during transportation. Remove the fixing tape from the instrument before using it.

- Before starting the installation work, be sure to read "1.4.1. Precautions for Instrument Installation" on page 1-14.
- Use an RS-232C-compliant cable to connect an external device to the instrument. Connection using other than an RS-232C cable can cause electric shock and fire. For more information, contact your distributor.

Items required: AC adapter (supplied), power cord (supplied),
RS-232C-compliant cross cable (double-shielded) (sold separately: when connecting an external device)

1 Release the outer fixing tape.

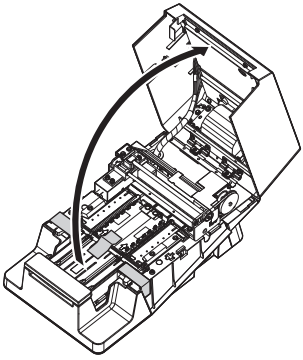
❶ Peel off the fixing tape (6 locations).



2 Open the maintenance cover.

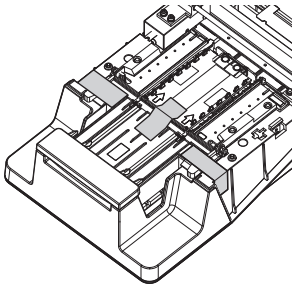
❶ With your hands on the sides of the maintenance cover, pull up the front of the maintenance cover.
• The lock will be released when a click sound is heard.

❷ Slowly open the maintenance cover until it becomes almost vertical.

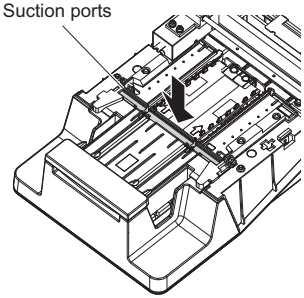


3 Release the inner fixing tape.

❶ Peel off the fixing tape (3 locations).

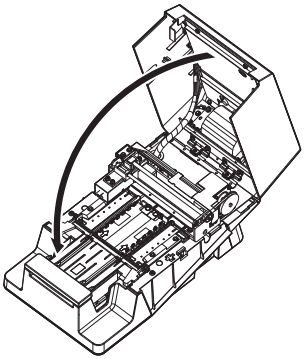


❷ Press the suction ports with your finger and ensure that the part is securely fixed in its proper position.



4 Close the maintenance cover.

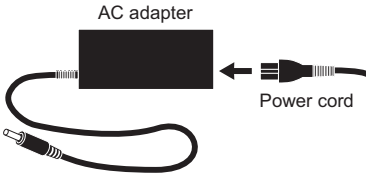
❶ Slowly close the maintenance cover.
- Finally, press and lock the maintenance cover until it clicks closed.



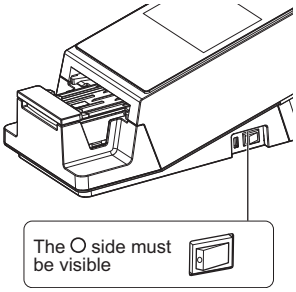
5 Connect the power cord.

> Be sure to use the AC adapter and power cord supplied with the instrument. Using an AC adapter and power cord other than that supplied with the instrument may cause electric shock and fire.

❶ Connect the power cord to the AC adapter.



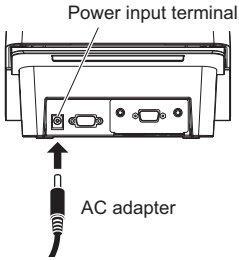
❷ Make sure the power is OFF.



- The "○" side of the power switch should be visible.

❸ Connect the AC adapter to the power input terminal.

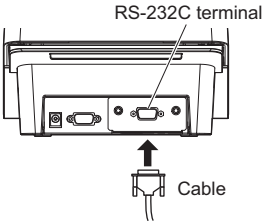
❹ Connect the plug of the power cord to a wall outlet.



6 Connect an external device (if necessary).

❶ Connect the cable from the external device to the RS-232C terminal.

❷ Tighten the stopper screws (2 locations) in the connector part of the cable.



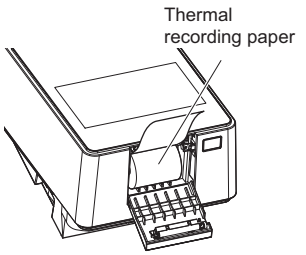
This completes the installation of the instrument.

1.4.3 Turning ON the Power/Preparing the Instrument

Once installation is complete, load the thermal recording paper and set the date and time.

1 Load the thermal recording paper.

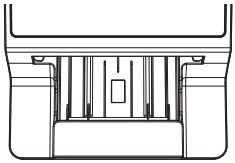
❶ Load the thermal recording paper in the built-in printer.
- See step 1-❷ to step 3-❶ in "4.3. Replacing the Thermal Recording Paper" on page 4-12.



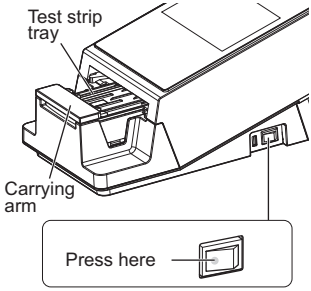
2 Turn ON the instrument.

❶ Make sure nothing is loaded on the test strip tray.

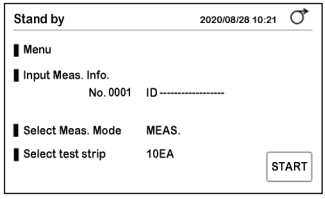
NOTE:
When you turn ON the power, the carrying arm moves to and fro on the test strip tray. Be careful not to pinch your fingers.



❷ Press the Power switch.
- The instrument will start and the carrying arm will move forwards and backwards.

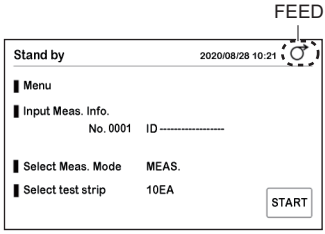


- The [Stand by] screen will appear.



3 Feed the thermal recording paper.

❶ Tap [FEED].
- The thermal recording paper will be fed.



NOTE:
If the thermal recording paper is not fed, the measurement result will not be printed.

4 Set the date and time.

❶ Set the current date and time.
- See “3.2.1. Setting the Date and Time” on page 3-3.

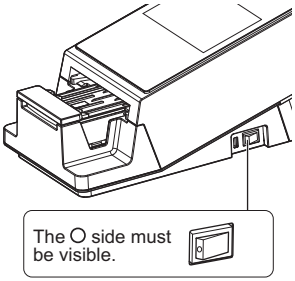
You can now perform measurement.

1.4.4 Turning OFF the Power

❶ Make sure the [Stand by] screen is displayed.

REFERENCE:
- When another screen is displayed
  Tap [BACK] to return to the [Stand by] screen.

❷ Press the Power switch.
- The power will turn OFF.



1.4.5 Moving the Instrument

❶ Turn OFF the Power switch.
- See “1.4.4. Turning OFF the Power” on page 1-19.

❷ Pull out the power cord from the outlet.

❸ Pull out the AC adapter from the instrument.

❹ Remove all items connected to the instrument.
- RS-232C-compliant cross cable
- LAN cable
- Hand-held barcode reader (option)

❺ Close the printer cover.

❻ Close the waste box.

Moving the instrument with the waste box open may result in exposure to pathogenic microorganisms.

❼ Move the instrument.

- Place both hands under the instrument to lift it up.
- Do not subject the instrument to strong impact or vibration. Rough handling may damage the instrument.

■ Shipping the Instrument to Other Locations

NOTE:
The instrument must be fixed and packaged. For more information, contact your distributor.

IMPORTANT:
Make sure that the following environment can be maintained during shipping of the instrument. Failure to do so may cause inaccurate measurement results.
Temperature: -10°C to 60°C, Humidity: 20 to 80% R.H. (non-condensing)

1.4.6 Disposing of the Instrument

■ Before Disposing of the Instrument

NOTE:
This instrument stores data containing personal information such as measurement results and the operator ID. Before disposing of the instrument, contact your distributor.

■ When Disposing of the Instrument

- Discard the instrument parts and the instrument in accordance with local regulations for biohazardous waste.
- If you need to disassemble the instrument, wear protective gloves to prevent exposure to pathogenic microorganisms.

1.5 Basic Operations

This section describes the basic operation method of the touch panel.

1.5.1 Using the Touch Panel

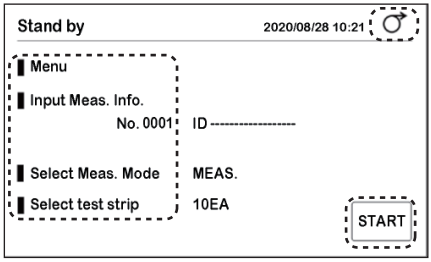
NOTE:
Do not apply a strong impact to the touch panel or press it with a sharp object. Doing so may damage the instrument or lead to personal injury.

■ Tapping the Instrument Panel

The locations on the touch panel that can be tapped are indicated with a light blue color (area marked by the dotted line in the figure below).

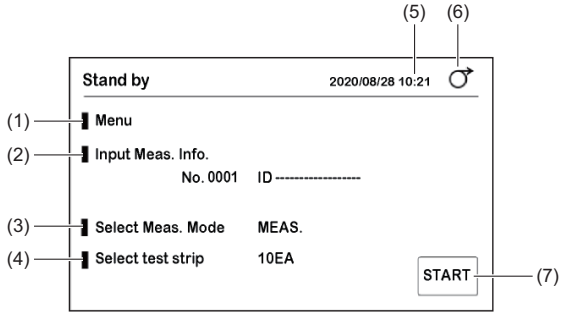
On the [Stand by] screen

Example)
Tap [Menu] to view the [Menu] screen.



1.5.2 Stand by Screen

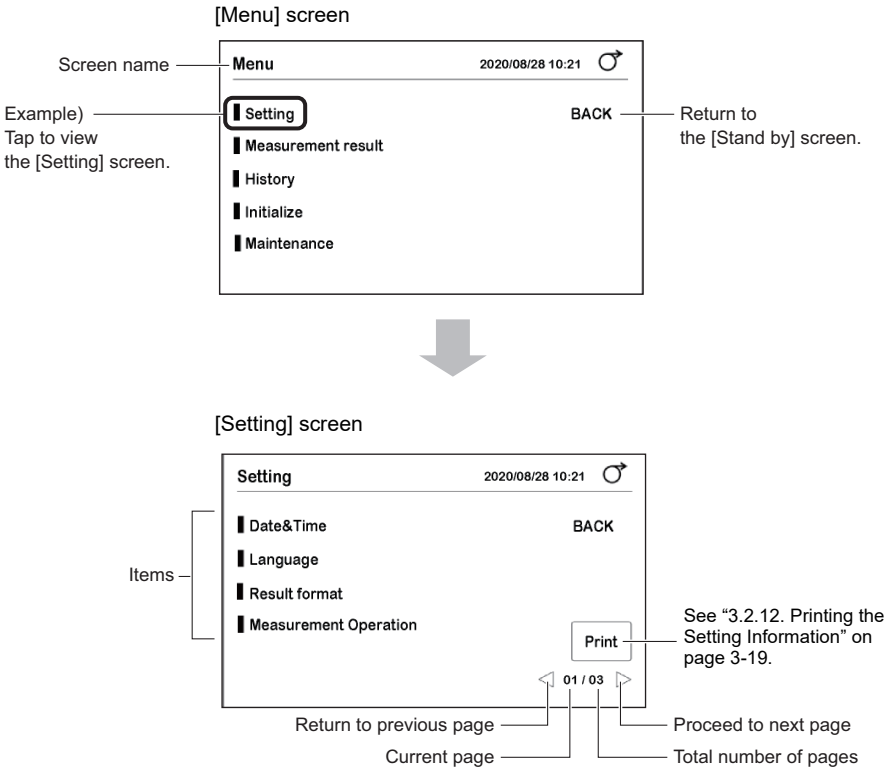
When the power is turned ON and the instrument is started, the [Stand by] screen appears.



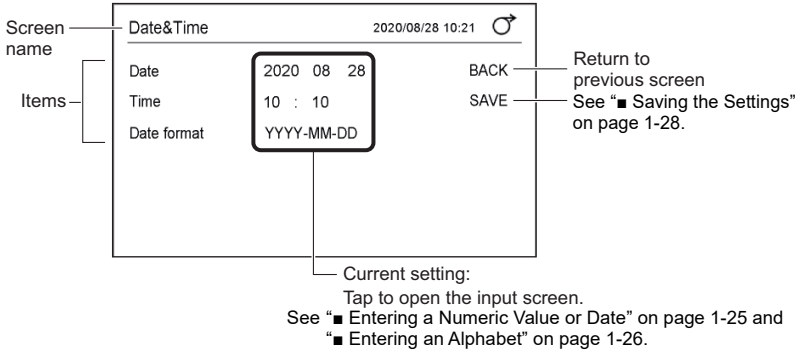
Item No.	Name	Function
(1)	Menu	→ See “3.1. Menu Screen” on page 3-1.
(2)	Input Meas. Info.	→ See “2.6. Setting the Measurement Information” on page 2-9. The measurement number and patient ID of the next sample to be measured are displayed at the bottom right.
(3)	Select Meas. Mode	Used to select the measurement mode. The current measurement mode is displayed on the right side. MEAS.: Normal measurement STAT: STAT measurement CONT.: Control measurement CHECK: Check measurement
(4)	Select test strip	→ See “2.4. Selecting the Test Strips” on page 2-7. The test strip selected in the current measurement mode is displayed on the right side. For devices with 10V specifications, the default display is “10V”.
(5)	2020/08/28 10:21	Indicates the current date and time.
(6)	[FEED]	Used to feed paper to the printer.
(7)	[START] button	Used to start measurement. This button is used in Cycle start mode.

1.5.3 Menu Screen

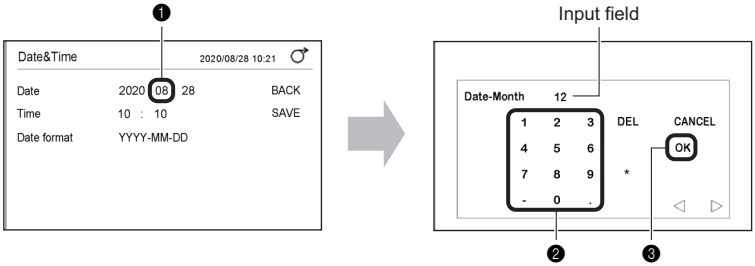
Tap [Menu] on the [Stand by] screen to view the [Menu] screen.



1.5.4 Setup Screen



■ Entering a Numeric Value or Date



❶ Tap the numeric value to change.

❷ Use the number buttons to enter a new numeric value.
- The numeric value will be displayed in the input field.

❸ Tap [OK].
- The new numeric value will be set in the previous screen.

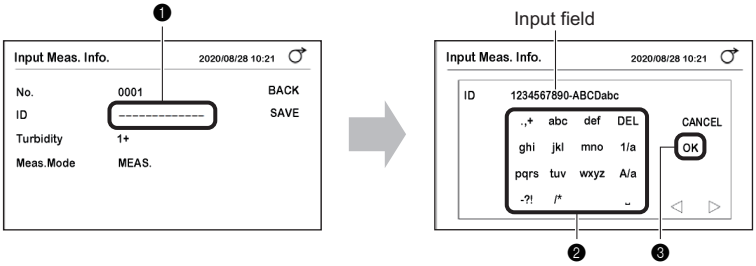
Name	Function
◁ ▷	Used to move the cursor.
[CANCEL] button	Used to cancel the numeric value and close the screen.
[OK] button	Used to confirm the numeric value.
Number/symbol buttons	Used to enter a number or symbol. The type of the symbol changes according to the item.
[DEL] button	Used to delete one digit.

REFERENCE:

- When the numeric value is not saved even after tapping [OK]
  A numeric value outside the range may have been entered. Check the correct range and enter the numeric value again.

■ Entering an Alphabet

You can use alphabets for the patient ID and operator ID.



❶ Tap "----------" or the current ID.

❷ Use the alphabet buttons to enter characters.

- The characters will be displayed in the input field.

❸ Tap [OK].

- The ID will be set in the previous screen.

Name	Function
◁ ▷	Used to move the cursor. Use ▷ to also consecutively input characters corresponding to the same button.
[CANCEL] button	Used to cancel the ID and close the screen.
[OK] button	Used to confirm the ID.
Alphabet/symbol buttons	Used to enter an alphabet or symbol.
[DEL] button	Used to delete one character.
[1/a] button	Used to switch between number/alphabet buttons.
[A/a] button	Used to switch between upper-case/lowercase characters.
␣	Used to enter a space.

Button	1 time	2 times	3 times	4 times	5 times
.,+	.	,	+	Return to “.”	
abc	a	b	c	Return to “a”	
def	d	e	f	Return to “d”	
ghi	g	h	i	Return to “g”	
jkl	j	k	l	Return to “j”	
mno	m	n	o	Return to “m”	
pqrs	p	q	r	s	Return to “p”
tuv	t	u	v	Return to “t”	
wxyz	w	x	y	z	Return to “w”
-?!	-	?	!	Return to “-”	
/*	/	*	Return to “/”		

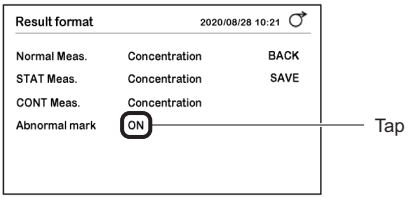
Example 1) To input “c”
Tap the [abc] button 3 times.

Example 2) To input “abc”
Tap in the following order.

[abc] ▷ [abc] [abc] ▷ [abc] [abc] [abc]
a b c

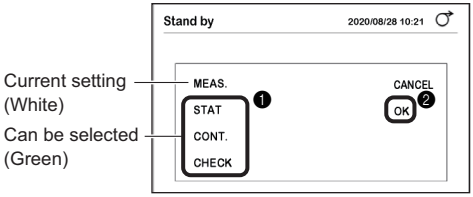
■ Toggling

The setting is switched each time [ON] or [OFF] is tapped.



REFERENCE:
If [ON] or [OFF] is tapped consecutively, there may not be any switching between ON and OFF. Tap slowly.

■ Changing the Settings



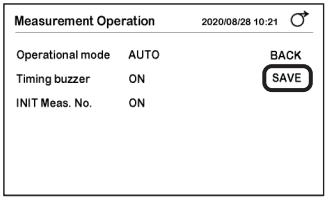
❶ Tap the item to select it.

❷ Tap [OK].
- The setting will be saved and the screen will close.

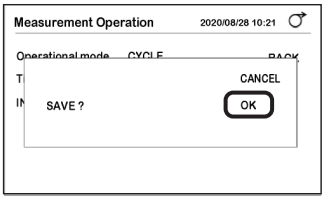
■ Saving the Settings

Save the setting after changing it.

❶ Tap [SAVE].



❷ Tap [OK].



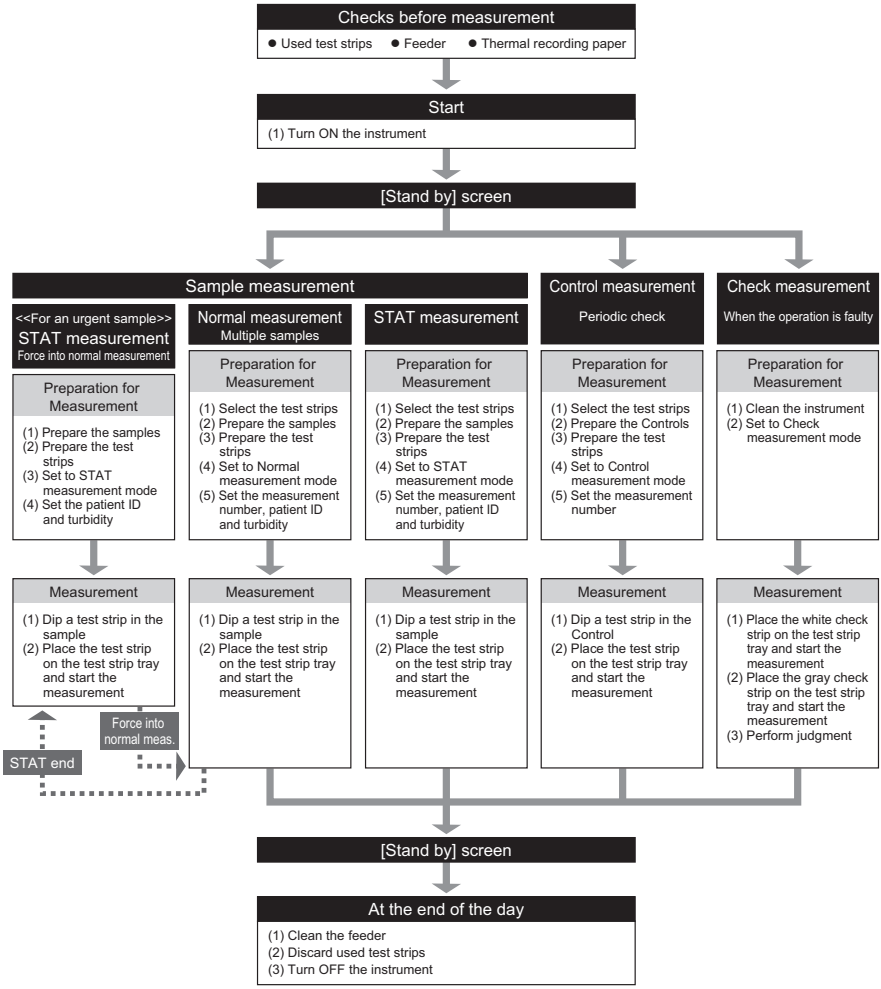
REFERENCE:
- To cancel the setting
  Tap the [CANCEL] button.

Chapter 2 Measurement

This chapter describes about normal measurement, STAT measurement, control measurement, and check measurement. A print example of the measurement results is also provided at the end of the chapter.

2.1 Before Measurement

2.1.1 Measurement Procedure



2.2 Measurement Precautions

2.2.1 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 operating manual before use.
- Never touch the test strip tray, carrying arm, or other parts where sample may adhere with unprotected hands. During cleaning or maintenance of these parts, wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples, parts and liquid waste in accordance with local regulations for biohazardous waste.

- Always use the instrument in the proper environment. Before turning ON the instrument, check that the "1.4.1. Precautions for Instrument Installation" on page 1-14 have been followed.
- Ensure proper indoor environment.
  Measurement environment:
  Temperature 10 to 30°C, Humidity 30 to 60%
  * Accurate measurement results are obtained with the temperature correction function.
  Optimum measurement conditions:
  Temperature 20 to 25°C, Humidity 30 to 60%
  * More accurate measurement results are obtained.
- Do not place containers or bottles that contain liquid such as sample on the instrument. Sample or other liquid that gets inside the instrument may cause trouble.
- If you feel that the instrument is operating abnormally, or detect abnormal odors or smoke, immediately turn OFF the power and unplug the power cord. Continuing operation in such conditions may cause fire or damage to the instrument and consequently lead to personal injury.
- In case of instrument trouble, contact your distributor for repairs. Unauthorized servicing or modification may damage the instrument and consequently lead to injury.

IMPORTANT:

- Do not move the instrument or subject it to vibration during measurement. Doing so may cause a malfunction and inaccurate measurement results. Doing so may also cause test strips to get jammed inside the instrument.
- Dip test strips in samples for exactly 2 seconds according to the timing buzzer. Insufficient dipping of test strips may cause insufficient color change, while dipping too long may cause the reagent to drain out of the test strip, both of which will prevent accurate measurement results from being obtained.
- When dipping a test strip into a sample, dip the whole the test strip pad area at once. However, do not dip the black mark area of the test strip. If the black mark area is wet, accurate measurement results may not be obtained.

2.2.2 Handling Samples

This instrument uses urine as a sample and as an ingredient of control solutions. Urine may be contaminated by pathogenic microorganisms that can cause infectious diseases. TAKE THE UTMOST CARE WHEN HANDLING URINE. Improper handling of urine may cause infection to the user or other individuals from pathogenic microorganisms.

IMPORTANT:

- Use fresh urine, within 1 hour after collection, when measuring samples. If measurement cannot be done immediately after collection, seal the sample in a vessel and store it in the refrigerator. When using samples that have been stored in the refrigerator, allow them to return to room temperature before performing measurements.
- Stir samples well before measurement. However, avoid subjecting them to centrifugation. Centrifugal force may cause undesirable sedimentation of blood cells and/or other sample contents and prevent obtaining accurate measurement results.
- Prepare a sufficient volume of samples so that the entire test strip pad area can be dipped in a single dipping motion.
- Measure collected samples directly from collection. Do not add any antiseptic, antimicrobial agent, or detergent.
- Do not expose samples to direct sunlight. Exposure to direct sunlight may change their properties and prevent obtaining accurate measurement results.
- Sample containing ascorbic acid may cause the measurement values for GLU and BLD to be lower than they actually are.
- Do not measure bloody urine, which may cause inaccurate measurement results.

2.2.3 Handling Test Strips

IMPORTANT:

- Use only the test strips dedicated to the AutionIDaten. Thoroughly read the test strip package insert and use the test strips by the expiry date.
- Do not use any test strips whose expiry date has passed. Do not use any test strips whose pad area shows signs of discoloration, even if the expiry date has not yet passed. Doing so may cause inaccurate measurement results.
- Take out only the number of test strips required for measurement from the bottle. Unused test strips exposed to the air will absorb moisture or be contaminated with dust or dirt, which will cause inaccurate measurement results. After taking out the test strips, immediately close the bottle cap securely.
- Touching the test strip pad area with bare hands may cause sebum to adhere, which will cause inaccurate measurement results.
- Before measurement, select the type of test strip to use. Using test strips of a different type from that which the instrument is set to use will cause inaccurate measurement results.
- Do not discard the desiccant in the bottle before using all the test strips inside. Without the desiccant, the remaining test strips will absorb moisture in the air, which would change their properties and cause inaccurate measurement results.

2.3 Preparation for Measurement

To use the instrument correctly, prepare for measurement according to the procedure below.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Discard used samples, test strips, and protective gloves in accordance with local regulations for biohazardous waste.

REFERENCE:
The special test strips for the AutionIDaten do not come with the instrument. Please purchase a sufficient supply before starting measurement.

2.3.1 Checking for Waste and Consumables [Before Turning ON the Instrument]

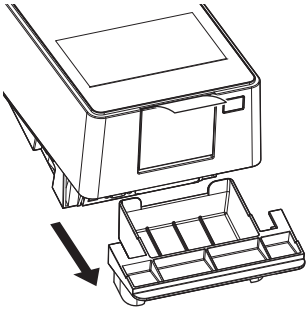
Items required: Cloth

1 Check for used test strips.

❶ Pull out and remove the waste box.

❷ Make sure there are no used test strips in the waste box.
- If test strips are present, discard them.

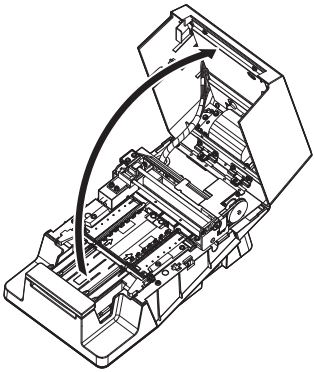
❸ Install the waste box back into the instrument.



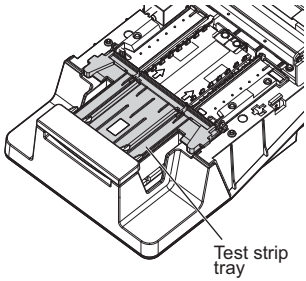
2 Check the feeder.

❶ With your hands on the sides of the maintenance cover, pull up the front of the maintenance cover.
- The lock will be released when a click sound is heard.

❷ Slowly open the maintenance cover until it becomes almost vertical.



❸ Wipe off the crystallized surplus urine adhering to the test strip tray.
- Wipe with a dry cloth.



NOTE:
- Do not use alcohol. The incoming strip sensor windows of the test strip tray may become cloudy, and the test strips may not be correctly detected.
- Make sure not to scratch the test strip tray. If the test strip tray is scratched, the test strips may not be fed smoothly.

❹ Close the maintenance cover.
- Finally, press and lock the maintenance cover until it clicks closed.

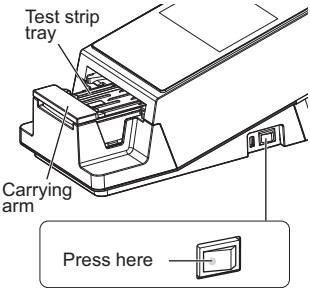
3 Check the thermal recording paper.

❶ If a red line appears on both sides of the thermal recording paper, install a new roll of thermal recording paper.
- See “4.3. Replacing the Thermal Recording Paper” on page 4-12.

REFERENCE:
If the instrument is turned ON without the thermal recording paper, an error will occur and measurement cannot be performed.

2.3.2 Starting the Instrument

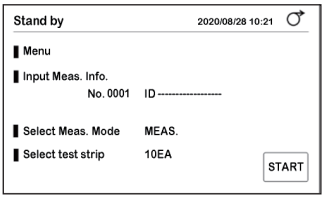
❶ Make sure nothing is loaded onto the test strip tray.



NOTE:
When you turn ON the power, the carrying arm moves to and fro on the test strip tray. Be careful not to pinch your fingers.

❷ Press the Power switch.

- The instrument will start and the carrying arm will move forwards and backwards.
- The [Stand by] screen will appear.



Measurement can now be started.

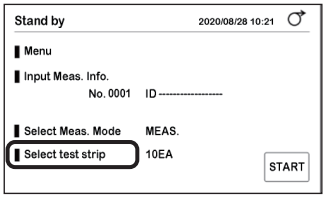
2.4 Selecting the Test Strips

Select the test strips to be used for normal measurement, STAT measurement, and control measurement.

REFERENCE:

- When using test strips with auto-classification marks
  The type of test strips is automatically determined. Therefore, the settings given below are not required.

❶ On the [Stand by] screen, tap [Select test strip].

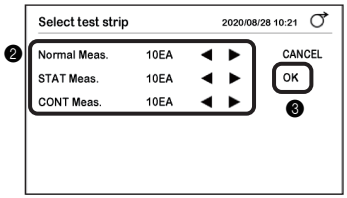


❷ Select the test strips to be used in each measurement mode.

- Tap ◀ ▶ to switch the test strips.

❸ Tap [OK].

- The display will return to the [Stand by] screen.

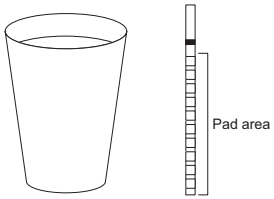


2.5 Sample Preparation

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Discard used samples, collection cups, and protective gloves in accordance with local regulations for biohazardous waste.
- For details on handling samples, see “2.2.2. Handling Samples” on page 2-3.

❶ Prepare samples in collection cups.

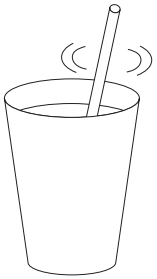
IMPORTANT:
Prepare a sufficient sample amount so that the entire test strip pad area can be dipped in a single movement.



Prepare sufficient volume for the entire test strip pad area to be dipped in a single movement

❷ Stir the samples well.

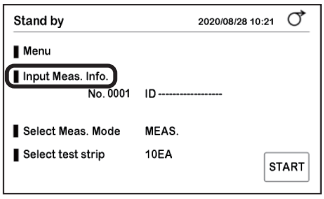
IMPORTANT:
Do not subject the samples to centrifugation. Centrifugal force may cause undesirable sedimentation of blood cells and/or other sample contents and prevent obtaining accurate measurement results.



2.6 Setting the Measurement Information

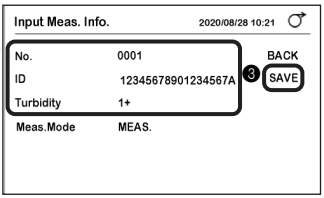
Set the measurement number, the patient ID, and turbidity of the sample to be measured.

❶ On the [Stand by] screen, tap [Input Meas. Info.].



❷ Set the measurement information.
- See the table below.

❸ Tap [SAVE].
- The settings will be saved and the display will return to the [Stand by] screen.



Item	Description
No.	Set the measurement number. This number is used to identify the measurement result and is printed in the first row of the measurement result. Measurement mode / Print / Range / Default setting Normal measurement / MEAS / No. 0000 to 9999 / 0001 STAT measurement / STAT / No. 0000 to 9999 / 0001 Control measurement / CONTROL / No. 0000 to 9999 / 0001 • A number incremented by 1 is automatically assigned to the following measurement result. • Each time the instrument is turned ON, the measurement number returns to “0001”. * A measurement number cannot be set during check measurement.
ID	Set a patient ID for the sample. The patient ID can be set during normal measurement and STAT measurement. • Maximum number of digits: 18 • Enabled characters: a to z, A to Z, 0 to 9, symbols (. , + - ? ! / *) • The patient ID can be read from the barcode with an optional hand-held barcode reader.
Turbidity	Enter the turbidity of the sample. * This item is displayed when [Turbidity input] is set to [ON]. → See “3.2.8. Configuring the Turbidity Input Setting” on page 3-10. ❶ Visually check the sample. ❷ Select the turbidity from [-] [1+] and [2+]. ❸ Tap [OK].

2.7 Consecutive Measurement of Samples [Normal Measurement]

In the Normal measurement mode, multiple samples are measured consecutively.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Discard used samples, collection cups, test strips, and protective gloves in accordance with local regulations for biohazardous waste.

REFERENCE:
- The special test strips for the AutionIDaten do not come with the instrument. Please purchase a sufficient supply before starting measurement.
- Switching between Auto start mode and Cycle start mode
  → See “3.2.4. Setting the Measurement Operation” on page 3-6.

2.7.1 Measuring in Auto Start Mode [Initial Setting]

Measurement starts automatically, simply by placing the test strips on the test strip tray.

First sample: The timing buzzer does not sound.
Time the dipping period (2 seconds) of test strips yourself and perform measurement.

Second and subsequent samples: The timing buzzer sounds.
Measurement can be performed while timing the dipping period of test strips with the buzzer sound.

REFERENCE:
- Setting the timing buzzer
  Initial setting: ON
  → See “3.2.4. Setting the Measurement Operation” on page 3-6.

1 Select the test strips.

See “2.4. Selecting the Test Strips” on page 2-7.

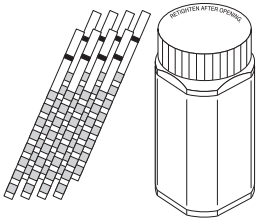
2 Prepare the sample.

See “2.5. Sample Preparation” on page 2-8.

3 Prepare the test strips.

❶ Take out the required number of test strips from the bottle.

❷ Close the test strip bottle cap immediately.

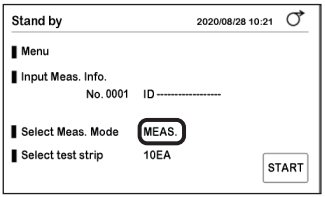


NOTE:
Failure to immediately close the cap may cause the test strips in the bottle to absorb moisture in the air and/or the dust to adhere to the test strips, which may then cause the reagents to deteriorate and make the test strips useless.

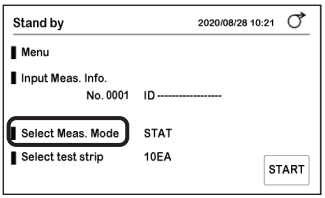
4 Set to Normal measurement mode.

❶ Make sure [Select Meas. Mode] is set to [MEAS.] on the [Stand by] screen.

- If set to [MEAS.]: Proceed to step 5.
- If set to a mode other than [MEAS.]: Proceed to step 4-❷.



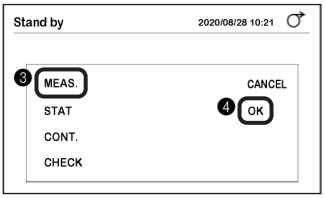
❷ Tap [Select Meas. Mode].



❸ Tap [MEAS.].

❹ Tap [OK].

- Measurement mode will change to Normal measurement mode.

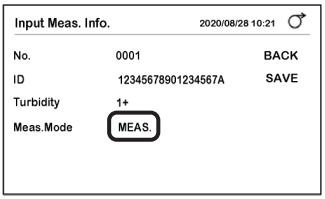


5 Set the measurement information.

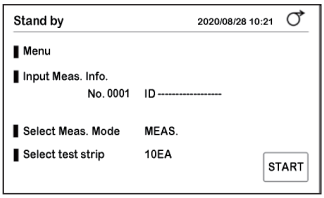
❶ Set the measurement number, patient ID, and turbidity.

- See “2.6. Setting the Measurement Information” on page 2-9.

REFERENCE:
Make sure [MEAS.] is displayed in [Meas. Mode].



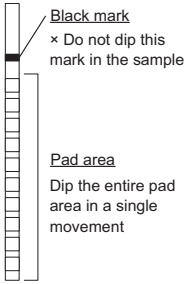
❷ Make sure the [Stand by] screen is displayed.



6 Dip a test strip in the first sample [without the timing buzzer].

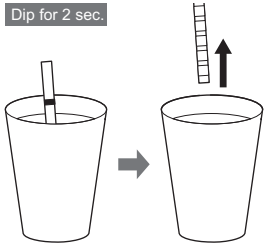
❶ Check the portion of the test strip that is to be dipped in the sample (see the figure on the right).

IMPORTANT:
Do not dip the black mark area into the sample. Doing so may cause inaccurate measurement results.



❷ Dip the test strip in the sample for 2 seconds, and then withdraw it.

IMPORTANT:
- Always dip the test strip for 2 seconds.
- Insufficient dipping of test strips may cause insufficient color change, while dipping too long may cause the reagent to drain out of the test strip, either of which will prevent accurate measurement result.



❸ Remove excess urine using the edge of the collection cup.

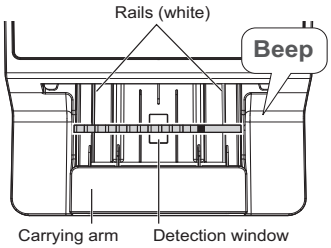
7 Set the test strip and start measurement.

NOTE:
If the test strip is set on the test strip tray, the carrying arm immediately moves forwards and backwards. Be careful not to pinch your fingers.

❶ Hold the test strip with the pad area facing upward.

❷ Place the test strip on the detection window (see the figure on the right), and immediately move away your hands.

- Upon detecting the test strip, the instrument will make a beep sound and the test strip will be transported.



IMPORTANT:
If the test strip is not set correctly, it cannot be transported and may get jammed inside the instrument, which may cause inaccurate measurement results.

REFERENCE:

- If the test strip is not detected
  Take note of the following points and set the test strip again:
  - Place the test strip at the center of the detection window
  - Make sure that the test strip is placed on top of the two white rails
- If the test strip is held by the left hand
  Measurement can be performed even if the test strip is placed with its holding part facing the left side.

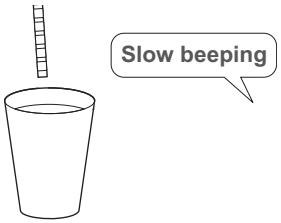
8 Measure the next sample [when measurement is performed according to the timing buzzer].

The timing buzzer will start to sound when the measurement starts.

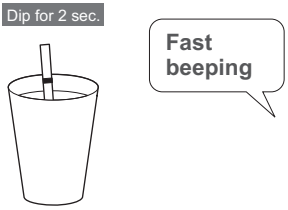
REFERENCE:

- When the timing buzzer is OFF
  Dip the test strip in the sample for exactly 2 seconds and perform measurement (see step 6).

❶ Slow beeping
Prepare the test strip.



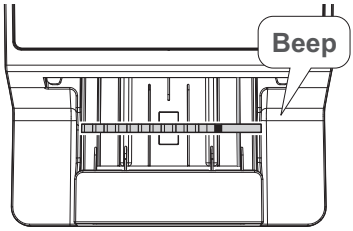
❷ Fast beeping
Dip the test strip in the sample (2 seconds).



❸ Withdraw the test strip when the buzzer sound stops.

❹ Remove excess urine using the edge of the collection cup.

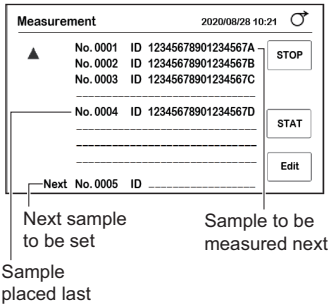
❺ Place the test strip on the test strip tray.
- Upon detection, the test strip will be immediately transported.



❻ Measure the next sample.
- Return to the procedure in step 8-❶.

9 While measurement is in progress.

- The measurement number and patient ID of the next sample to be set are displayed at the bottom of the screen.
- The measurement number and patient ID are displayed in the order of placement of test strips.
- Measurement will start when the measurement number and patient ID are displayed at the top.
- ▲ flashes during measurement.



REFERENCE:
- To stop measurement
  Tap [STOP]. If a test strip is being transported, measurement will stop after the completion of measurement of the test strip.
- To edit the measurement number, patient ID, and turbidity
  Tap [Edit].
  You can edit the information of the next sample.
  → See “2.6. Setting the Measurement Information” on page 2-9.

NOTE:
- When “Waste box is full” and “Measurement” are displayed alternately
  → See ”E005 Waste box is full” on page 5-4.
- When “Surplus urine is full” and “Measurement” are displayed alternately
  → See "E006 Surplus urine is full" on page 5-4.

10 When measurement is complete.

- The measurement result will be printed.
  → See "2.11. How to Read Measurement Results" on page 2-28.

GLU	NORMAL	mg/dL
PRO	+−	20 mg/dL
BIL	−	mg/dL
URO	NORMAL	mg/dL
PH		7.0

REFERENCE:
- When an external device is connected
  See "3.2.6. Configuring the Communication Setting" on page 3-8.

❶ If necessary, cut the print-out of the measurement result with scissors.
- When measurement of the test strip placed in the end is complete, the display will return to the [Stand by] screen.

NOTE:
- Before the waste box becomes full
  Discard the used test strips. The waste box becomes full after around 100 measurements. Overflowing test strips may cause troubles.

2.7.2 Measuring in Cycle Start Mode

Place the test strip on the test strip tray and tap the [START] button to start measurement.

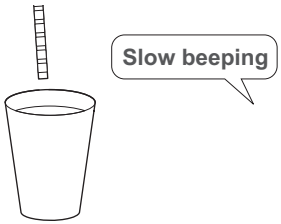
1 Prepare a test strip and a sample, and set the measurement information.

See step 1 to step 5 in "2.7.1. Measuring in Auto Start Mode [Initial Setting]" on page 2-10.

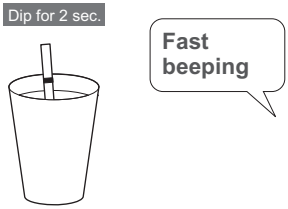
2 Measure the sample.

❶ On the [Stand by] screen, tap [START].
- The timing buzzer will start to sound.

❷ Slow beeping
Prepare the test strip.



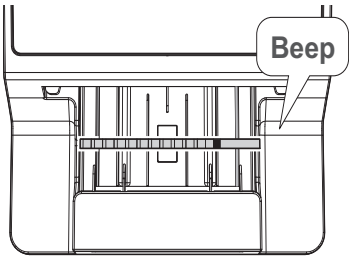
❸ Fast beeping
Dip the test strip in the sample (2 seconds).



❹ Withdraw the test strip when the buzzer sound stops.

❺ Remove excess urine using the edge of the collection cup.

❻ Place the test strip on the test strip tray.
- Upon detection, the test strip will be immediately transported.



❼ Measure the next sample.
- Return to the procedure in step 2-❷.

● Subsequent operations
See step 9 to step 10 in “2.7.1. Measuring in Auto Start Mode [Initial Setting]” on page 2-14.

2.8 STAT Measurement

The STAT measurement mode is used in the following cases:

- When an urgent sample is to be needs to be measured while normal measurement is being performed.
- When measurement is to be performed with a test strip different from the one used for normal measurement.
- When a measurement result is required in an output format (concentration value/reflectance) different from that of normal measurement.

→ See "3.2.3. Setting the Data Format for the Measurement Result" on page 3-5.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used samples, collection cups, test strips, and protective gloves from general waste and discard them in accordance with local regulations for biohazardous waste.

REFERENCE:

- To perform STAT measurement from the standby state
  Select [STAT] in [Select Meas. Mode] on the [Stand by] screen. The other operations are the same as the ones for normal measurement.
  → See "2.7. Consecutive Measurement of Samples [Normal Measurement]" on page 2-10.

■ Measuring an Urgent Sample While Normal Measurement is Being Performed

IMPORTANT:
Use the test strip set beforehand for STAT measurement.
See "2.4. Selecting the Test Strips" on page 2-7.

1 Prepare an urgent sample.

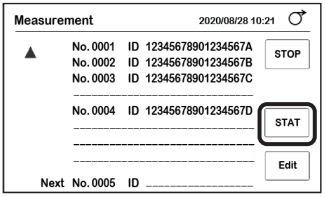
REFERENCE:
See "2.5. Sample Preparation" on page 2-8.

2 Prepare the test strips.

REFERENCE:
See step 3 in "2.7.1. Measuring in Auto Start Mode [Initial Setting]" on page 2-11.

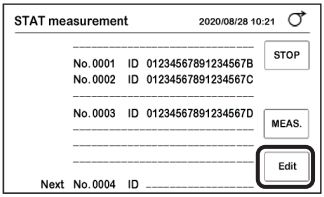
3 Switch to STAT measurement mode.

❶ Tap the [STAT] button during normal measurement.



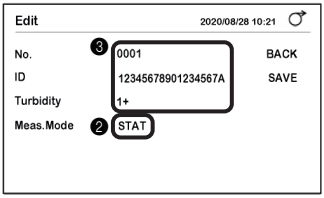
4 Set the measurement information of the urgent sample.

❶ Tap [Edit] on the [STAT measurement] screen.
- The timing buzzer will stop.



❷ Make sure [STAT] is displayed in the [Meas.Mode] section.

❸ Enter the measurement number, patient ID, and turbidity.
- See “2.6. Setting the Measurement Information” on page 2-9.

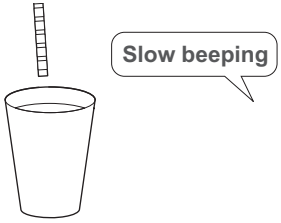


❹ Tap [SAVE].
- The timing buzzer will sound again.

5 Measure the urgent sample.

REFERENCE:
See step 8 in “2.7.1. Measuring in Auto Start Mode [Initial Setting]” on page 2-13.

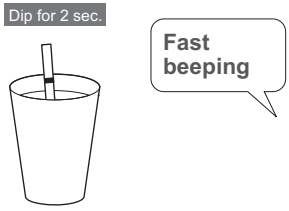
❶ Slow beeping
Prepare the test strip.



❷ Fast beeping
Dip the test strip in the sample (2 seconds).

❸ Withdraw the test strip when the buzzer sound stops.

❹ Remove excess urine using the edge of the collection cup.



❺ Place the test strip on the test strip tray.

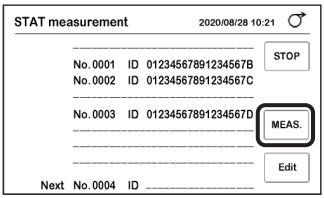
- The measurement will start.

REFERENCE:

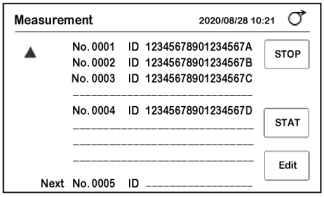
- To measure the next urgent sample
  Return to the procedure in step 4.

6 When the measurement of the urgent sample is complete.

❶ Tap [MEAS.].



- The display will return to Normal measurement mode.



2.9 Control Measurement

In Control measurement mode, the measurement accuracy of the instrument is controlled by periodically measuring the control solution.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used control solution, collection cups, test strips, and protective gloves from general waste and discard them in accordance with local regulations for biohazardous waste.

NOTE:
Before using control solution, read carefully its package insert.

Items required: control solution (commercial product or an Arkray-designated product), test strips, protective gloves

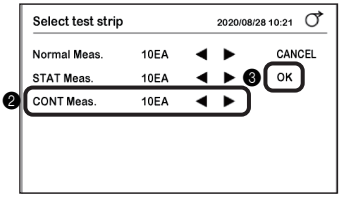
1 Select the test strips.

REFERENCE:
See “2.4. Selecting the Test Strips” on page 2-7.

❶ On the [Stand by] screen, tap [Select test strip].

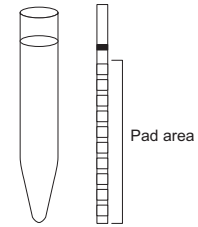
❷ Select the test strips to be used for control measurement.
- Tap ◀ ▶ to switch the test strips.

❸ Tap [OK].
- The display will return to the [Stand by] screen.



2 Prepare the control solution.

❶ Place the control solution in a container.
- Prepare a sufficient volume of the control solution so that the entire test strip pad area can be dipped.

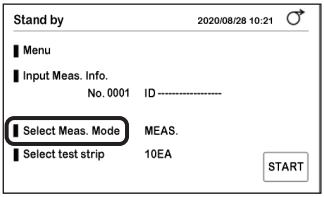


3 Prepare the test strips.

REFERENCE:
See step 3 in “2.7.1. Measuring in Auto Start Mode [Initial Setting]” on page 2-11.

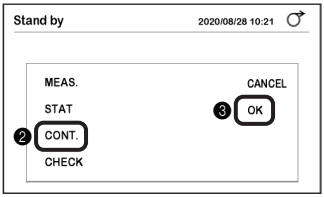
4 Switch to Control measurement mode.

❶ On the [Stand by] screen, tap [Select Meas. Mode].

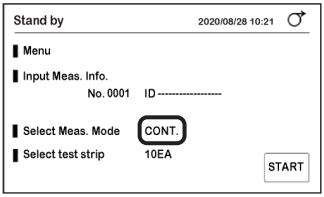


❷ Tap [CONT.].

❸ Tap [OK].



- The measurement mode will change to Control measurement mode.



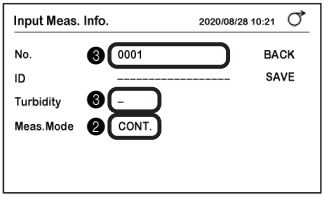
5 Set the measurement information.

❶ On the [Stand by] screen, tap [Input Meas. Info.].

❷ Make sure [CONT.] is displayed in the [Meas.Mode] section.

❸ Set the measurement information.

- See step ❷ to step ❸ in “2.6. Setting the Measurement Information” on page 2-9.

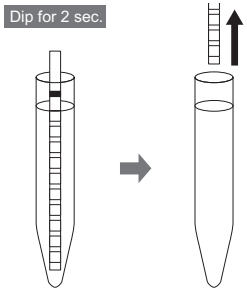


6 Dip a test strip in the control solution [without the timing buzzer].

REFERENCE:
See step 6 in “2.7.1. Measuring in Auto Start Mode [Initial Setting]” on page 2-12.

❶ Dip the test strip in the control solution for 2 seconds, and then withdraw it.

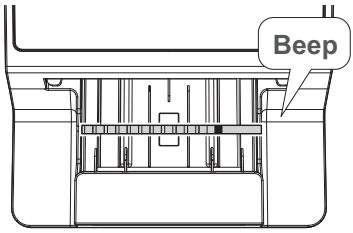
❷ Remove excess control solution from the test strip using the edge of the container.



7 Set the test strip and start Control measurement.

REFERENCE:
See step 7 in “2.7.1. Measuring in Auto Start Mode [Initial Setting]” on page 2-12.

❶ Place the test strip on the test strip tray.
- The measurement will start.



8 Measure the next control solution [when measurement is performed according to the timing buzzer].

REFERENCE:
See step 8 in “2.7.1. Measuring in Auto Start Mode [Initial Setting]” on page 2-13.

❶ Slow beeping
Prepare the test strip.

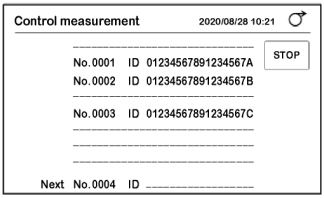
❷ Fast beeping
Dip the test strip in the control solution (2 seconds).

❸ Remove excess control solution from the test strip using the edge of the container.

❹ Place the test strip on the test strip tray.
- The measurement will start.

9 During the control measurement.

- “Control measurement” is displayed.



10 When control measurement is complete.

- The measurement result is printed.
- When measurement of the test strip that was placed last is complete, the display will return to the [Stand by] screen.

REFERENCE:
- If control measurement is performed after the occurrence of a QC Lock-Out
  When control measurement is complete, the QC Lock-Out will be canceled, and the sample can be measured again.

2.10 Check Measurement

If you feel that the sample measurement results are odd or questionable, you can verify the status of the instrument by performing check measurement.

Items required: Alcohol, cloth, check strips (one gray and one white), protective gloves

1 Clean the instrument.

NOTE:
If check measurement is performed without cleaning the instrument, the check strips may become soiled and ruined.

❶ Clean the feeder.
- See “4.2.1. Cleaning the Feeder” on page 4-2.

❷ Clean the waste box.
- See “4.2.2. Cleaning the Waste Box” on page 4-11.

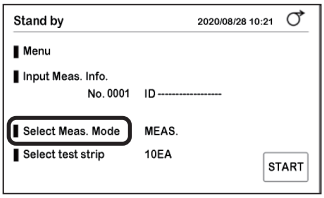
2 Turn ON the instrument.

❶ Turn ON the instrument.
- See “2.3.2. Starting the Instrument” on page 2-6.

❷ Make sure the [Stand by] screen is displayed.

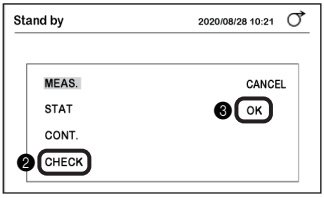
3 Switch to Check measurement mode.

❶ Tap [Select Meas. Mode].

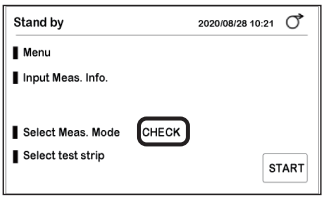


❷ Tap [CHECK].

❸ Tap [OK].



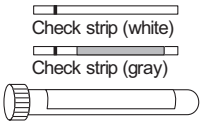
• The measurement mode will change to Check measurement mode.



4 Prepare the check strips.

IMPORTANT:
Do not touch the check strip surfaces. If sebum, etc. has adhered to the surface, it may result in inaccurate measurement results.

❶ Take out the check strips from the check strip bottle.
• White: 1, Gray: 1

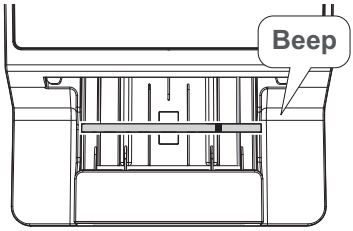


NOTE:
500 nm is not used as a measurement wavelength for the AutionIDaten AE-4070. Thus, check measurement results printout will not include a 500 nm result. The description of 500 nm in the reflectance label on the check strip bottle is for other types of devices.

5 Measure the white check strip.

REFERENCE:
See step 7 in “2.7.1. Measuring in Auto Start Mode [Initial Setting]” on page 2-12.

❶ Place the white check strip on the test strip tray.



NOTE:
Place the check strip on the test strip tray with the black mark facing up.

• The measurement will start.
• When the measurement is complete, the measurement result will be printed.

6 Measure the gray check strip.

❶ Place the gray check strip on the test strip tray.
• See step 5.

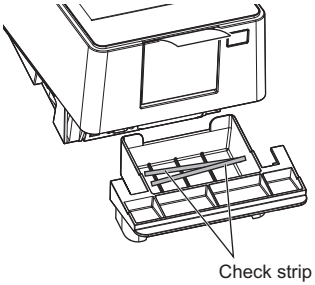
• When the measurement is complete, the measurement result will be printed.

7 Remove the check strips.

❶ Pull out the waste box to remove the check strips from the instrument.

❷ Place the check strips on a piece of tissue paper or something similar.

- Do not return the check strips to the check strip bottle.



8 Evaluate reflectance.

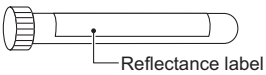
❶ Make sure the reflectance at each wavelength of the measurement result is within the range of the reference values.

NOTE:
500 nm is not used as a measurement wavelength for the AutionIDaten AE-4070. Thus, check measurement results printout will not include a 500 nm result. The description of 500 nm in the reflectance label on the check strip bottle is for other types of devices.

Measurement result

```
CHECK
Serial No.  12345678
            2020-08-07 13:24
********************************
430[nm]          47. 2%
565[nm]          77. 9%
635[nm]          82. 1%
760[nm]          94. 6%
```

REFERENCE:
●Range of reference values
Specified on the label of the check strip bottle.



● If the reflectance is within the range

- The instrument is functioning normally. This completes the check measurement.
- Place the check strips back in the check strip bottle and close the cap.

● If the reflectance is outside the range

- Either the check strip is defective or the instrument is not functioning properly.
- Repeat the check measurement using the other two check strips remaining in the check strip bottle.
- Return to the procedure in step 6.

IMPORTANT:

● "COM: W001"
Indicates that light entered the instrument and prevented proper measurement. After taking steps to remove the source of the intrusive light, repeat the check measurement using the same check strips.

● "COM: W003"
Indicates that the check strip was not placed in the correct position. Repeat the check measurement using the same check strips.

9 Perform re-evaluation.

❶ Check the reflectance of the second check measurement.

● If the reflectance is within the range

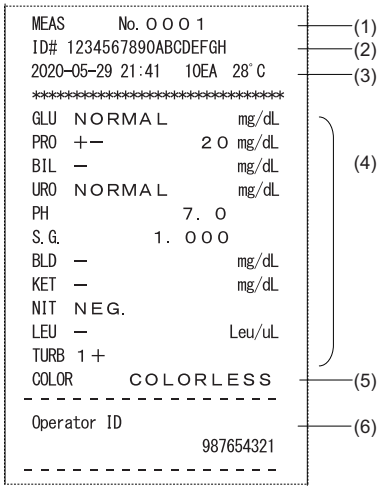
- The instrument is functioning normally.
- The check strips used for the first check measurement are faulty. Do not use these check strips again.

● If the reflectance is again outside the range

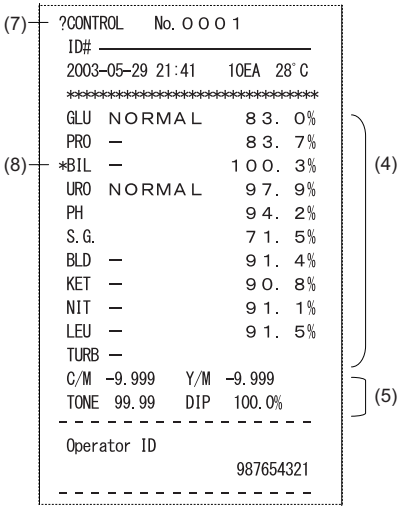
- The instrument is faulty.
- Perform optical adjustment.
  → See “3.6.1. Performing Optical Adjustment” on page 3-27.

2.11 How to Read Measurement Results

● Concentration value



● Reflectance



(1) Measurement mode/Measurement number

Normal measurement: MEAS No. 0000 to 9999
STAT measurement: STAT No. 0000 to 9999
Control measurement: CONTROL No. 0000 to 9999

(2) Patient ID

(3) Measurement date and time/Test strip/Internal ambient temperature of the instrument

Printed with the initial setting.

→ See “3.2.5. Configuring the Print Settings” on page 3-7.

(4) Measurement item name/Qualitative value/Semiquantitative value/Measurement unit

Indicates the measurement items and measured values of test strips.

→ See “1.1.5. Rank Tables” on page 1-6.
→ See “3.2.3. Setting the Data Format for the Measurement Result” on page 3-5.

(5) Result of color tone evaluation

→ See “■ Color Tone Correction” in “1.1.4. Measurement Principle” on page 1-6.

(6) Operator ID

Printed when the operator ID function is used.

→ See “3.2.9. Using the Operator ID Function” on page 3-11.

(7) Error mark

Printed on the left side of the measurement mode.

*	The measurement result is abnormal.
?	The instrument is faulty.

(8) Abnormal mark

Printed on the left side of the measured value.

*	Abnormal measured value
!	Abnormal color mark

REFERENCE:

- To print the error mark or abnormal mark in the measurement result
  → See “3.2.3. Setting the Data Format for the Measurement Result” on page 3-5.
- When a warning “W001 to W009” is printed
  → See “5.1. Measures If a Warning Occurs” on page 5-1.

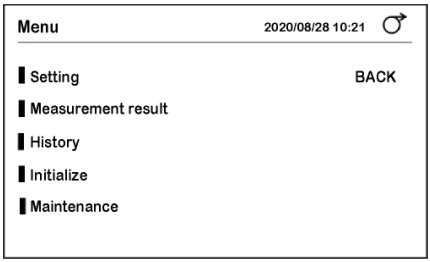
Chapter 3 Auxiliary Operations

This chapter describes auxiliary operations such as making the instrument settings, printing and sending the measurement result, and other operations.

3.1 Menu Screen

To view the [Menu] screen, tap [Menu] on the [Stand by] screen.

[Menu] screen



● Setting

Page	Item	Description	Page
01	Date&Time	Set the current date and time, and also the date format.	3-3
	Language	Set the language for display on the screen.	3-4
	Result format	Set the data format and abnormal mark for the measurement result.	3-5
	Measurement Operation	Set the measurement start method, timing buzzer, and measurement number initialization.	3-6
02	Print	Configure the settings related to the printer and printing.	3-7
	External output	Configure the settings related to communication with an external device.	3-8
	Barcode	Set the number of digits when reading the patient ID from the barcode.	3-9
	Turbidity input	Configure the settings related to turbidity input.	3-10
03	OperatorID	Configure the settings related to the operator ID.	3-11
	QC lock-out	Configure the settings related to the QC Lock-Out function.	3-16
	Backlight brightness	Set the backlight brightness.	3-18

● Measurement result

Search for the measurement result. If necessary, either reprint the measurement result, or send it to an external device.

● History

Item	Description	Page
History search	Search for the measurement result containing an abnormal value or the measurement result in which an abnormality has occurred.	3-23
Print trouble list	Print the number and the date and time of the troubles that have occurred until then.	3-24

● Initialize

Item	Description	Page
Parameter	Initialize the setting information of the instrument.	3-25

● Maintenance

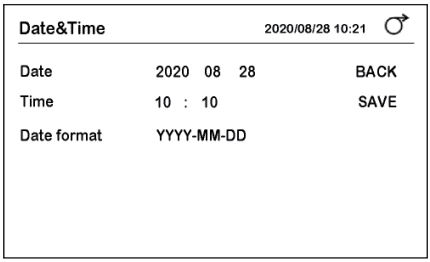
Item	Description	Page
Optical unit	Perform optical adjustment.	3-27
Color & W004	Readjust the color tone, and make adjustments if “W004” occurs frequently.	3-29

3.2 Various Settings

3.2.1 Setting the Date and Time

Set the current date and time, and also the date format.

TAP [Menu] → [Setting] → [Date&Time]



Item	Description (**Bold**: Initial setting)
Date	Set the current year, month, and day.
Time	Set the current hour and minutes.
Date format	Select the date format. **YYYY-MM-DD**: Year-Month-Day MM-DD-YYYY: Month-Day-Year DD-MM-YYYY: Day-Month-Year

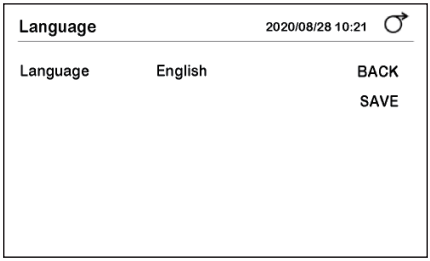
- If the settings are changed

  Tap in the order of [SAVE] → [OK] to save the settings.

3.2.2 Setting the Language

Set the language for display on the screen.

TAP [Menu] → [Setting] → [Language]



Item	Description (**Bold**: Initial setting)
Language	日本語, **English**, Deutsch, Italiano, Français, Español, Nederlands, Português, Ελληνικά

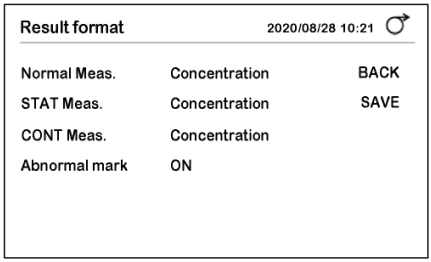
- If the setting is changed

  Tap in the order of [SAVE] → [OK] to save the setting.

3.2.3 Setting the Data Format for the Measurement Result

Select the data format of the measurement result from concentration and reflectance.
Also select whether to add an abnormal mark (*, ?) to an abnormal measured value.

TAP [Menu] → [Setting] → [Result format]



Item	Description (**Bold**: Initial setting)
Normal Meas. STAT Meas. CONT Meas.	Select whether to print/send the measurement result as concentration or reflectance. **Concentration**, Reflectance
Abnormal mark	Set whether to print an abnormal mark (*, ?) with the measurement result. **ON** : Printed. OFF: Not printed. → See “2.11. How to Read Measurement Results” on page 2-28.

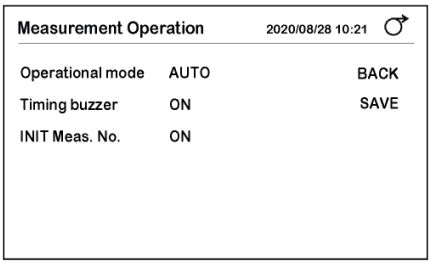
- If the settings are changed

  Tap in the order of [SAVE] → [OK] to save the settings.

3.2.4 Setting the Measurement Operation

Set the measurement start method, timing buzzer, and measurement number initialization.

TAP [Menu] → [Setting] → [Measurement Operation]



Item	Description (**Bold**: Initial setting)
Operational mode	**AUTO**: Sets it to Auto start mode. If a test strip is placed on a test strip tray, the measurement operation starts automatically. CYCLE: Sets it to Cycle start mode. If a test strip is placed on a test strip tray and the [START] button is tapped, the measurement operation starts.
Timing buzzer	If a timing buzzer is used, the duration of dipping the test strips in the sample (2 seconds) can be accurately measured. This makes it possible to obtain more accurate measurement results. **ON**: The timing buzzer sounds when the measurement operation starts. OFF: Does not sound. → See step 8 in "2.7.1. Measuring in Auto Start Mode [Initial Setting]" on page 2-13.
INIT Meas. No.	**ON**: Each time the instrument is turned ON, the measurement number returns to the initial setting "0001". OFF: Even if the instrument is turned ON again, the measurement number succeeding the previous one is assigned.

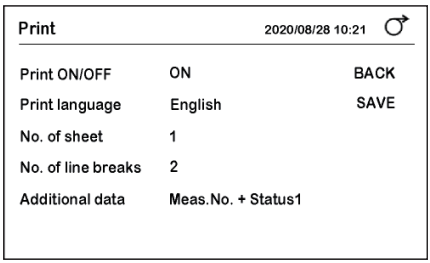
- If the settings are changed

  Tap in the order of [SAVE] → [OK] to save the settings.

3.2.5 Configuring the Print Settings

Configure the settings related to the printer and printing.

TAP [Menu] → [Setting] → ▷ → [Print]



Item	Description (**Bold**: Initial setting)
Print ON/OFF	Set whether to automatically print the measurement result immediately after measurement. **ON**: Printed immediately. OFF: Not printed. The saved measurement result can be printed. → See "3.3. Measurement Result" on page 3-20.
Print language	English, Deutsch, Italiano, Français, Español, Nederlands, Português, Ελληνικά
No. of sheet	Set the number of sheets of the measurement result to be printed after measurement. **1** to 3 sheets
No. of line breaks	Set the number of line breaks for automatic feeding of paper after the printing of the measurement result ends. The position of cutting the paper can be adjusted. 0 to 9 (Initial setting: **2**)
Additional data	Set the information to be printed at the beginning of the measurement result. Meas.No.: Measurement number only **Meas.No. + Status1**: Measurement number, measurement date and time, type of test strip, internal ambient temperature of the instrument Meas.No. + Status2: Measurement number, measurement date and time, type of test strip, internal ambient temperature of the instrument, patient ID

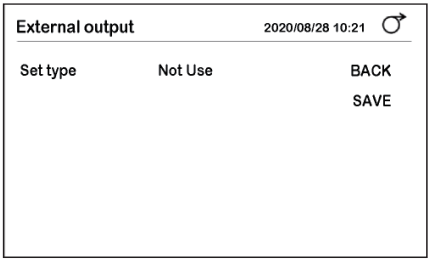
- If the settings are changed

  Tap in the order of [SAVE] → [OK] to save the settings.

3.2.6 Configuring the Communication Setting

Configure the settings related to communication with an external device.

TAP [Menu] → [Setting] → ▷ → [External output]



Item	Description (**Bold**: Initial setting)
Set type	Set the communication system for communicating with an external device. **Not Use**: A connection is not established to an external device. RS-232C: The external device is connected to an RS-232C terminal. ETHERNET: A connection is established to the LAN through an Ethernet cable.

- If the setting is changed

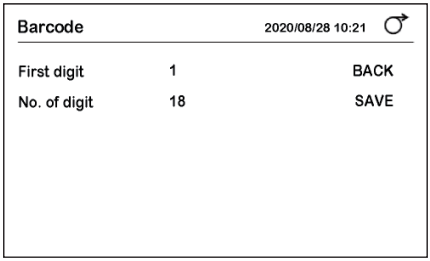
  Tap in the order of [SAVE] → [OK] to save the setting.

3.2.7 Configuring the Barcode Settings

Set the number of digits when reading the Patient ID from the barcode.

REFERENCE:
Configure the settings when the optional hand-held barcode reader is connected.

TAP [Menu] → [Setting] → ▷ → [Barcode]



Item	Description (**Bold**: Initial setting)
First digit	**1st** to 32nd digit
No. of digit	1 to **18** digits

REFERENCE:
- Setting example
  [First digit]: 3rd digit
  [No. of digit]: 15 digits
  In this case, several digits (3rd to 17th) will be read and displayed.

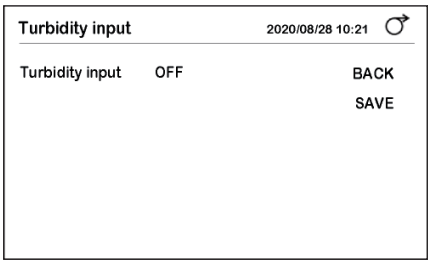
- If the settings are changed

  Tap in the order of [SAVE] → [OK] to save the settings.

3.2.8 Configuring the Turbidity Input Setting

Configure settings related to turbidity input.

TAP [Menu] → [Setting] → ▷ → [Turbidity input]



Item	Description (**Bold**: Initial setting)
Turbidity input	Set whether to input the turbidity of the sample before measurement. The turbidity is printed on the measurement result. ON: Turbidity is input. **OFF**: Turbidity is not input.

- If the setting is changed

  Tap in the order of [SAVE] → [OK] to save the setting.

3.2.9 Using the Operator ID Function

If the operator ID is registered, the ID of the user can be printed at the end of the measurement result. The functions to be used can be restricted for each user.

■ When the Operator ID Function is Used for the First Time

❶ First of all, register one or more operator IDs.
→ See "■ Registering the Operator ID" on page 3-13.

❷ Set the operator ID function to ON.
→ See "■ Setting the Operator ID Function" on page 3-15.

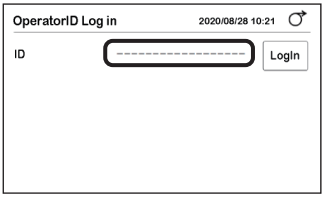
■ Logging In

If the operator ID function is set to ON, you must log in to the instrument when the instrument is started. You must log in again if a certain amount of time has passed since the last operation.
When you log in, you will be permitted to use the instrument.

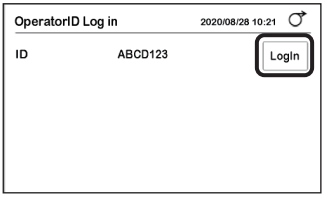
❶ Tap "----------".

❷ Enter the operator ID.
- See "■ Entering an Alphabet" on page 1-26.

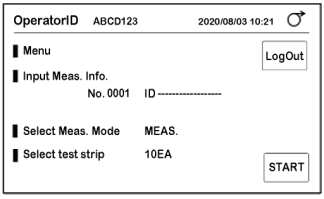
❸ Tap [OK].



❹ Tap [LogIn].



- The [Stand by] screen will appear.
- You are now permitted to use the instrument.

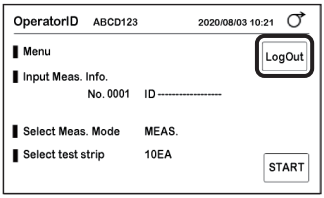


REFERENCE:
If you do not operate the instrument for a predetermined period of time, you will be automatically logged out. Log in again to continue the operation.

■ Logging Out

❶ Tap [LogOut].
- "Log out?" will appear.

❷ Tap [OK].
- The [OperatorID log in] screen will appear.



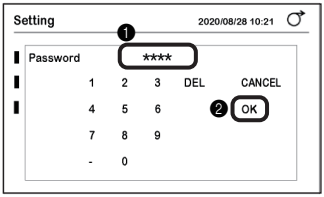
■ Entering the Password

To set the operator ID function, you must input the password.

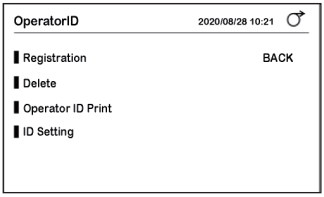
TAP [Menu] → [Setting] → ▷ → ▷ → [OperatorID]

❶ Enter the password.

❷ Tap [OK].



- The [OperatorID] screen will appear.



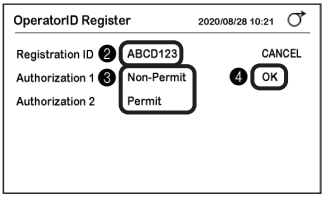
■ Registering the Operator ID

You can register up to 150 operator IDs.

TAP [Menu] → [Setting] → ▷ → ▷ → [OperatorID] → Password* → [Registration]
* See "■ Entering the Password" on page 3-12.

❶ Tap [----------].

❷ Enter the new operator ID.
- Up to 18 digits
- See "■ Entering an Alphabet" on page 1-26.



❸ Set the authorization.

Item	Description (**Bold**: Initial setting)
Authorization 1	**Permit**: The authorization to initialize the operator ID is set. Non-Permit: Not set.
Authorization 2	Permit: The authorization to enable measurement of the sample is set even if a QC Lock-Out occurs. **Non-Permit**: Not set.

❹ Tap [OK].
- "Register new ID?" will appear.

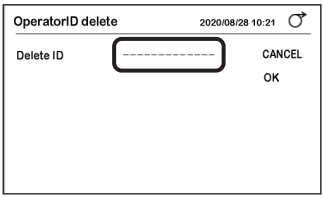
❺ Tap [OK].
- The operator ID will be registered.

■ Deleting the Operator ID

TAP [Menu] → [Setting] → ▷ → ▷ → [OperatorID] → Password* → [Delete]
* See "■ Entering the Password" on page 3-12.

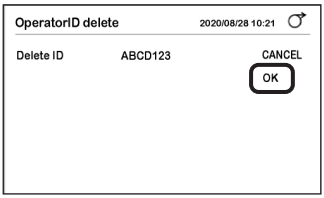
❶ Tap [----------].

❷ Enter the operator ID that is to be deleted.
- See "■ Entering an Alphabet" on page 1-26.



❸ Tap [OK].
- "Delete ID?" will appear.

❹ Tap [OK].
- The operator ID will be deleted.



■ Printing the List of Operator IDs

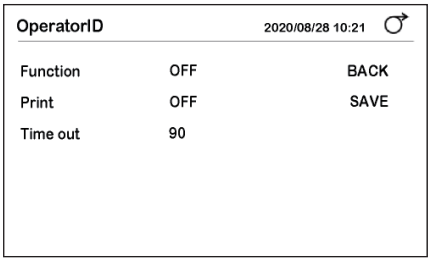
TAP [Menu] → [Setting] → ▷ → ▷ → [OperatorID] → Password* → [Operator ID Print]
* See "■ Entering the Password" on page 3-12.

- The list will be printed.

■ Setting the Operator ID Function

TAP [Menu] → [Setting] → ▷ → ▷ → [OperatorID]→ Password* → [ID Setting]

* See "■ Entering the Password" on page 3-12.



Item	Description (**Bold**: Initial setting)
Function	ON: The operator ID function is enabled. **OFF**: Disabled.
Print	ON: The operator ID is printed on the measurement result. **OFF**: Not printed.
Time out	Set the time from the last operation until logout is automatically performed. Range: 0 to **9999** seconds (Initial setting: **90**, No time out: 0)

- If the settings are changed

  Tap in the order of [SAVE] → [OK] to save the settings.

3.2.10 Setting the QC Lock-Out Function

■ When the QC Lock-Out Function is Used

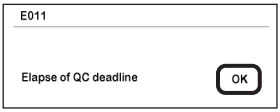
If control measurement is not performed until the set deadline, a QC Lock-Out occurs, and the measurement of the sample will be prohibited. If control measurement is performed, the measurement of the sample can again be performed. This makes it possible to obtain accurate measurement result at all times.

REFERENCE:
If the QC Lock-Out function is not used (initial setting), there are no restrictions for the measurement of the sample.

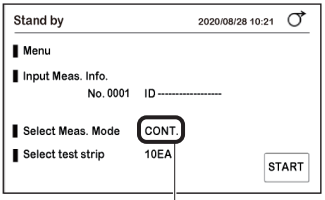
■ When a QC Lock-Out Occurs

"E011" will be displayed.

❶ Tap [OK].



- The instrument will switch to Control measurement mode, and the measurement of the sample can no longer be performed.



Control measurement mode

REFERENCE:
- Users having an operator ID with authorization 2
  Even if a QC Lock-Out occurs, the measurement of the sample can be performed. In such a case, "COM: W008" is printed on the measurement result.
  → See "3.2.9. Using the Operator ID Function" on page 3-11.

❷ Perform control measurement.
- See "2.9. Control Measurement" on page 2-20.
- The QC Lock-Out will be canceled, and the measurement of the sample can be performed.

■ When a QC Lock-Out Occurs during Measurement

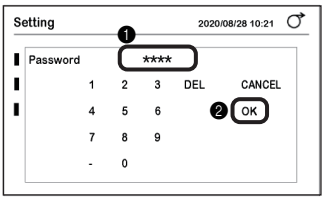
"COM: W008" will be printed on the measurement result.

■ Setting the QC Lock-Out function

TAP [Menu] → [Setting] → ▷ → ▷ → [QC lock-out]

❶ Enter the password.

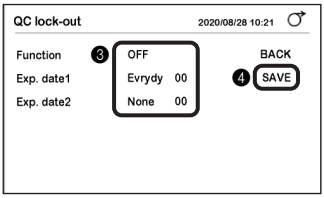
❷ Tap [OK].



❸ Set the items.
- See the table below.

❹ Tap [SAVE].

❺ Tap [OK].
- The setting will be saved.

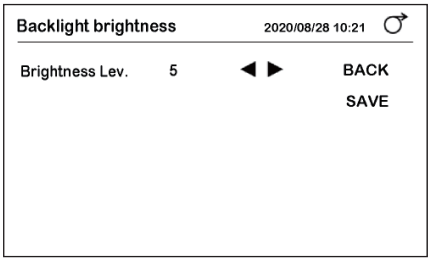


Item	Description (**Bold**: Initial setting)
Function	ON: The QC Lock-Out function is used. If control measurement is not performed within the specified period, the measurement of the sample is prohibited. PROMPT: The QC Lock-Out function is used. The instrument automatically switches to the control measurement mode after every fixed period, and notifies to perform control measurement. Even if control measurement is not performed, the measurement of the sample can again be performed by switching to the normal measurement mode. In such a case, “COM: W008” will be printed on the measurement result. **OFF**: Not used.
Exp. date1	Set the day and time on which a QC Lock-Out is to be performed. Day: **Evrydy**, Mon., Tue., Wed., Thu., Fri., Sat., Sun. Time: **00:00** to 23:00
Exp. date2	Set the day and time on which a QC Lock-Out is to be performed. If it is not necessary to set a QC Lock-Out, specify “None”. Day: **None**, Evrydy, Mon., Tue., Wed., Thu., Fri., Sat., Sun. Time: **00:00** to 23:00

3.2.11 Setting the Backlight Brightness

Set the backlight brightness.

TAP [Menu] → [Setting] → ▷ → ▷ → [Backlight brightness]



Item	Description (**Bold**: Initial setting)
Brightness Lev.	Set the backlight brightness. The actual backlight brightness varies depending on the setting. Range: 0 to 9 (**5**: Initial setting)

- If the setting is changed

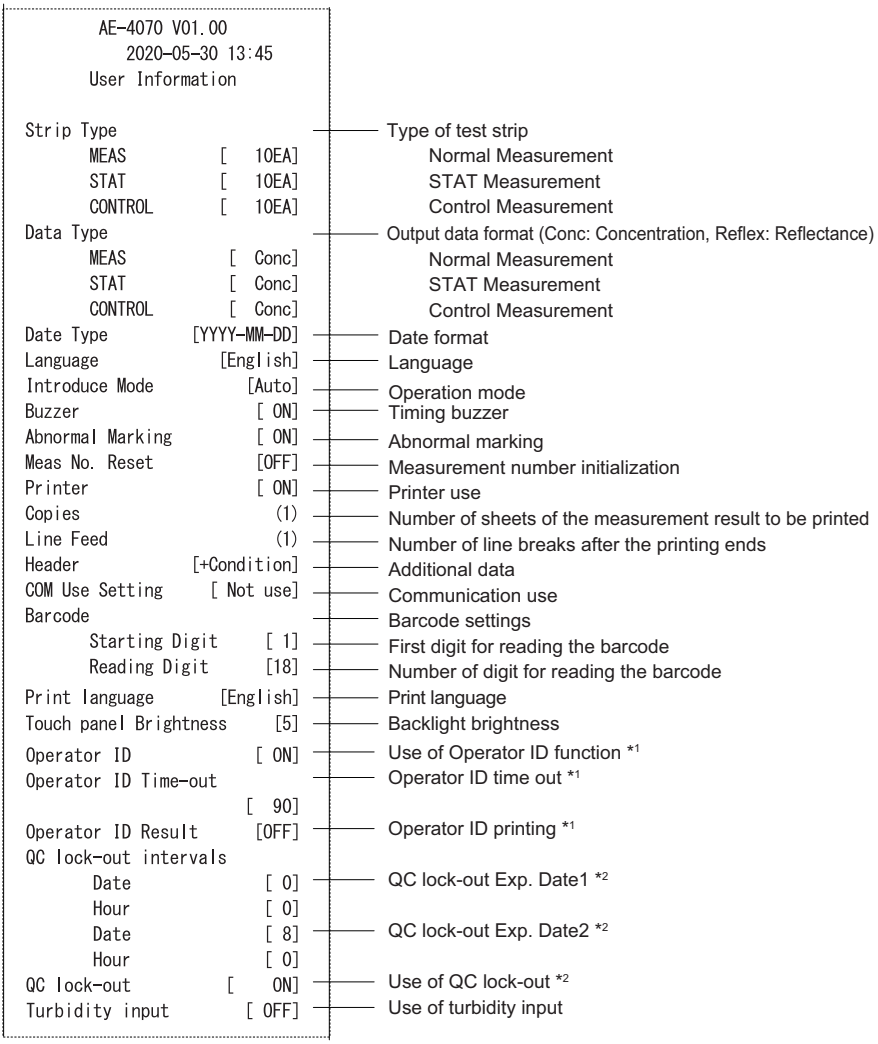
  Tap in the order of [SAVE] → [OK] to save the setting.

3.2.12 Printing the Setting Information

Print the current settings of the instrument.

TAP [Menu] → [Setting] → [Print]

● Sample print out



*1: Printed when the operator ID function is set to ON.
*2: Printed when the QC lock-out function is set to ON or PROMPT.

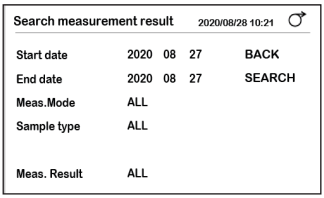
3.3 Measurement Result

Up to 520 measurement results can be saved (total of normal measurement, STAT measurement, control measurement, check measurement). A specific measurement result can be searched for and printed from the printer or sent to an external device.

REFERENCE:
If the memory becomes full, the oldest measurement result is deleted so as to save the new measurement result.

■ Searching for the Measurement Result

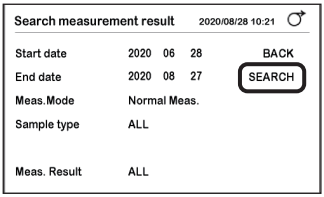
TAP [Menu] → [Measurement result]



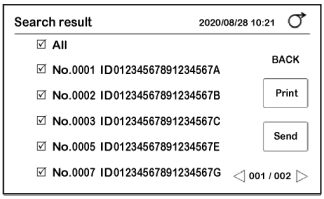
❶ Set the search conditions.
- See the table below.

Item	Description (**Bold**: Initial setting)
Start date End date	Set the scope of the measurement date. Set the [Start date] and [End date] as the same date, or set the [End date] as a later date. The initial setting is the current date.
Meas.Mode	Set the measurement mode. **ALL**: All measurements MEAS.: Normal measurement STAT: STAT measurement CONT.: Control measurement
Sample type	Set the search conditions. This item is enabled when [Meas.Mode] is set to [MEAS.] or [STAT]. **ALL**: All measurement results Meas.No.: Measurement result specified by measurement number If [Meas.No.] is selected, set the scope of the measurement number to [Start] and [End]. Sample type Meas.No. Start 0001 End 0001 Patient ID: Measurement result specified by the patient ID If [Patient ID] is selected, enter the patient ID. Patient ID can be entered by reading the barcode using the optional hand-held barcode reader. Sample type Patient ID ID 12345678901234567A
Meas. Result	**ALL**: All measurement results Normal: Normal measurement results Abnormal: Measurement results with the abnormal mark, or measurement results with an abnormal color mark

❷ Tap [SEARCH].



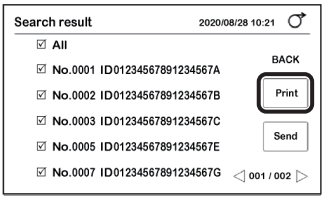
• The search result will be displayed.



REFERENCE:
- "E007 Data not found"
  There is no measurement result matching the conditions.
  Tap [OK].

■ Printing the Measurement Result

❶ Select the measurement result.
- Light blue: Selected White: Deselected
- At first, all measurement results are selected. Each time the measurement result is tapped, it switches between selected and deselected.
- Tap [All] to select all or cancel the selection of all.
  If [All] is selected: Selection of all is canceled
  If [All] is not selected: Selection of all

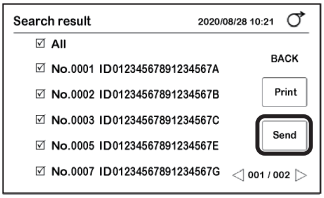


REFERENCE:
- [All] is not selected if there is at least one result that is not selected.

❷ Tap [Print].
- The measurement result will be printed.

■ Sending the Measurement Result to an External Device

❶ Select the measurement result.
- Light blue: Selected White: Deselected
- At first, all measurement results are selected. Each time the measurement result is tapped, it switches between selected and deselected.
- Tap [All] to select all or cancel the selection of all.
  If [All] is selected: Selection of all is canceled
  If [All] is not selected: Selection of all



REFERENCE:
- [All] is not selected if there is at least one result that is not selected.

❷ Tap [Send].
- The measurement result will be sent.

3.4 History

3.4.1 Searching the History

Search for a measurement result like the following that has occurred within a specific period of time.
- Measurement result containing an abnormal value (measured value with an "*")
- Measurement result obtained when an abnormality occurred during in the measurement (measurement result with a "?")

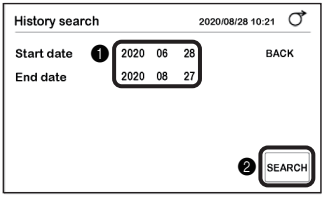
The searched measurement result can be printed.

■ Searching the History

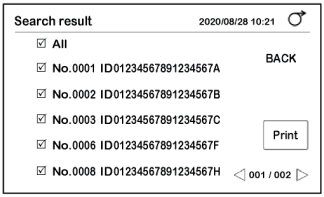
TAP [Menu] → [History] → [History search]

❶ Set the scope of the measurement date.
- Set the [Start date] and [End date] as the same date, or set the [End date] as a later date.

❷ Tap [SEARCH].



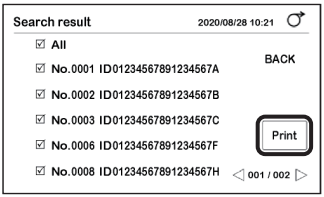
- The search result will be displayed.



REFERENCE:
- "E007 Data not found"
  There is no measurement result matching the conditions.
  Tap [OK].

■ Printing the History

❶ Select the measurement result.
- Light blue: Selected White: Deselected
- At first, all measurement results are selected. Each time the measurement result is tapped, it switches between selected and deselected.
- Tap [All] to select all or cancel the selection of all.
  If [All] is selected: Selection of all is canceled
  If [All] is not selected: Selection of all



REFERENCE:
- [All] is not selected if there is at least one result that is not selected.

❷ Tap [Print].
- Printing will start.

3.4.2 Printing the Trouble List

Print the number and the date and time of occurrence of the troubles that have occurred with the instrument.
Up to 20 troubles are printed.

TAP [Menu] → [History] → [Print trouble list]

- Printing will start.

● Sample print out

```
        2020-07-10 13:05

2020-06-29 10:45
T102
2020-06-29 10:45
T171
                .
                .
                .
2020-06-29 10:45
T123
```

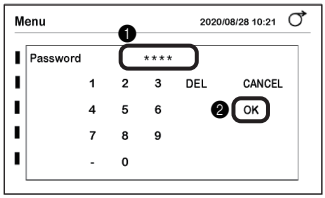
3.5 Initialization

Initialize the setting information of the instrument.

TAP [Menu] → [Initialize]

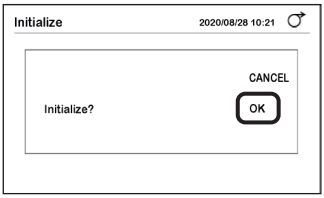
❶ Enter the password.

❷ Tap [OK].



❸ Tap [Parameter].
- "Initialize?" will appear.

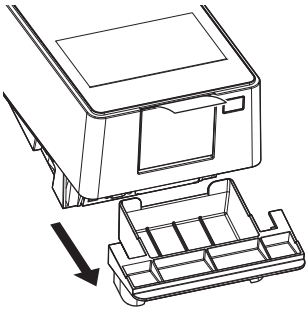
❹ Tap [OK].
- Initialization will start.



❺ Pull out and remove the waste box.

❻ Make sure there are no used test strips.
- If test strips are present, discard them.

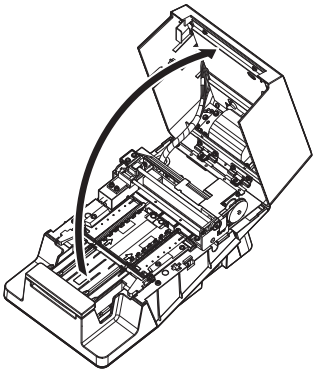
❼ Install the waste box back into the instrument.



1 Check the feeder.

❶ With your hands on the sides of the maintenance cover, pull up the front of the maintenance cover.

- The lock will be released when a click sound is heard.



3.6 Maintenance

If necessary, adjust the instrument.

Situation	Action
● If the check measurement results are as follows: the reflectance is found to be outside the range of reference values and an abnormality with the instrument is thought to have occurred	→ See “3.6.1. Performing Optical Adjustment” on page 3-27.
● If “W004” occurs frequently during measurement	→ See “3.6.2. Adjusting the Occurrence of Color & W004” on page 3-29.

REFERENCE:
- Periodic maintenance (cleaning of each part or replacement of thermal recording paper)
  → See “Chapter 4. Maintenance” on page 4-1.

3.6.1 Performing Optical Adjustment

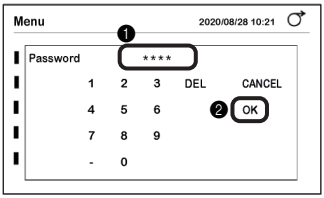
If the check measurement results are that the reflectance is found to be outside the range of reference values and an abnormality with the instrument is thought to have occurred, perform optical adjustment.

TAP [Menu] → [Maintenance]

1 Enter the password.

❶ Enter the password.

❷ Tap [OK].

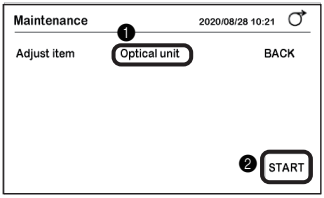


2 Perform optical adjustment.

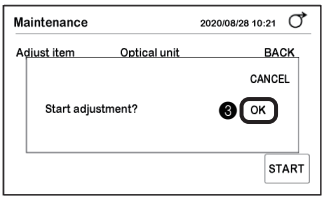
❶ Make sure that [Adjust item] is set to [Optical unit].

REFERENCE:
If [Color & W004] is displayed, tap it to switch to [Optical unit].

❷ Tap [START].



❸ Tap [OK].
- Optical adjustment will start and “Adjusting...” will be displayed.



● When adjustment is complete
- The adjusted value will be saved, and the display will return to the screen in step 2-❶.
- The adjustment record “Optical adjust OK” will be printed.

NOTE:
When “T180” is displayed
See "**T180**" in "Causes of and Solutions to Troubles" on page 5-10.

3 Check the operation of the instrument.

❶ Perform check measurement.
- See “2.10. Check Measurement” on page 2-24.

❷ Make sure the reflectance at each wavelength of the measurement result is within the range of the reference values.

● If the reflectance is within the range
- The instrument is functioning normally.

● If the reflectance is outside the range
- If the reflectance is outside the range in step 9 on page 2-27, there is an abnormality with the instrument. Contact your distributor.

3.6.2 Adjusting the Occurrence of Color & W004

If "W004" occurs frequently even if the test strips are properly dipped in the sample, measure purified water (or ion-exchanged water) five times continuously so that the instrument can be adjusted to prevent the occurrence of "W004".

IMPORTANT:

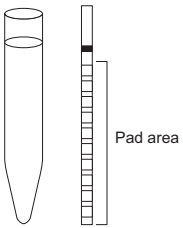
- Before starting the adjustment of the instrument
  If you make adjustments to prevent the occurrence of W004, the color tone is also adjusted simultaneously. Be sure to contact your distributor before performing the operation.
- Type of test strip
  Use the test strip specified in [Normal Meas.] on the [Select test strip] screen.
  → See "2.4. Selecting the Test Strips" on page 2-7.

Items required: Purified water (or ion-exchanged water), test strips (5, see [IMPORTANT] above), protective gloves

1 Prepare purified water (or ion-exchanged water).

❶ Place purified water (or ion-exchanged water) in a bottle.

- Prepare a sufficient volume so that the entire test strip pad area can be dipped.



2 Prepare the test strips.

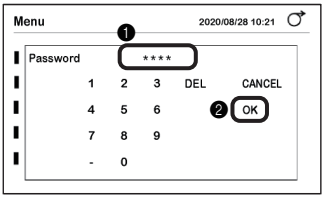
REFERENCE:
See step 3 in "2.7.1. Measuring in Auto Start Mode [Initial Setting]" on page 2-11.

3 Enter the password.

TAP [Menu] → [Maintenance]

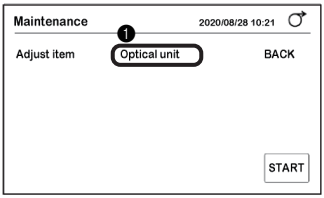
❶ Enter the password.

❷ Tap [OK].



4 Start adjustment.

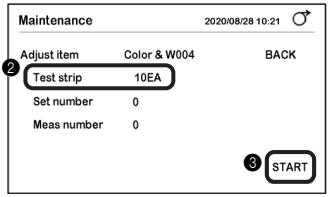
❶ Tap [Optical unit] for [Adjust item].
- [Color & W004] will be displayed.



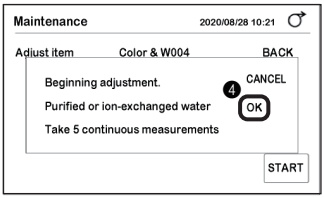
❷ Make sure the test strip displayed in [Test strip] is of the same type as the test strip at hand.

REFERENCE:
The test strip specified in [Normal Meas.] on the [Select test strip] screen is set as the [Test strip].

❸ Tap [START].



❹ Tap [OK].
- The timing buzzer will start to sound.

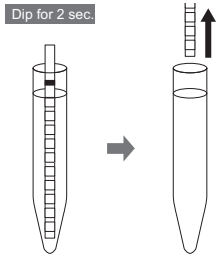


5 Dip the test strips in purified water (or ion-exchanged water).

REFERENCE:
See step 6 to step 8 “2.7.1. Measuring in Auto Start Mode [Initial Setting]” on page 2-12.

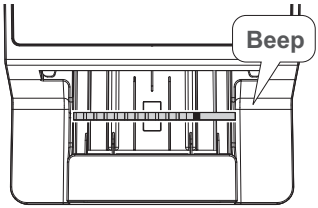
❶ Slow beeping
Prepare the test strip.

❷ Fast beeping
Dip the test strip in purified water (or ion-exchanged water) (2 seconds).



❸ Withdraw the test strip when the buzzer sound stops.

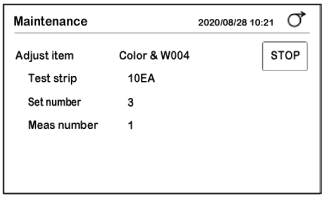
❹ Remove excess moisture from the test strip using the edge of the container.



❺ Place the test strip on the test strip tray.
- Upon detection, the test strip will be immediately fed.

❻ Measure the remaining four test strips by the same method.
- Return to the procedure in step 5-❶.

REFERENCE:
During adjustment, a screen such as that shown in the figure on the right appears.



Item	Description
Set number	The number of test strips that are placed is displayed.
Meas number	The completed number of measurements is displayed.
[STOP] button	Suspends adjustment.

6 Check the adjustment record.

Adjustment ends when the measurement of all test strips ends.

● When the adjustment record “Color & W004 OK” is printed

- The adjustment had ended normally. The adjusted value is saved, and the display returns to the screen in step 4-❷.

● When “Please readjust” is displayed

- Tap [OK] to return to the procedure in step 4-❸.
- If the same message appears again, contact your distributor.

REFERENCE:

● When “Different test strip is used” is displayed

The correct test strip is not used. Use the test strip specified in [Normal Meas.] on the [Select test strip] screen, and perform the operation again. Make sure the entire test strip pad area is dipped in the purified water (or ion-exchanged water).

Chapter 4 Maintenance

This chapter describes how to clean each part of the instrument and how to replace the thermal recording paper.

4.1 Frequency of Maintenance

The table below shows the positions that require maintenance and the timing of the maintenance. Use this table as a reference for periodic maintenance.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used test strips and cleaning equipment from general waste and discard them in accordance with local regulations for biohazardous waste.

Warning	Maintenance	Frequency	Reference page
	Cleaning the feeder	After measurement every day	4-2
	Cleaning the waste box	After approx. 100 measurements	4-11
	Replacing the thermal recording paper	After approx. 450 measurements	4-12

4.2 Daily Maintenance

4.2.1 Cleaning the Feeder

Clean the feeder after finishing measurements for the day.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used protective gloves from general waste and discard them in accordance with local regulations for biohazardous waste.

NOTE:
Do not clean the test strip tray with an organic solvent such as alcohol or thinners. Do not use ultrasonic cleaning. This could deform or discolor the test strip tray and make it unusable.

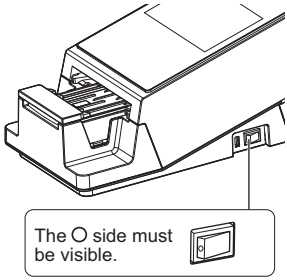
Items required: Alcohol (to sterilize the carrying arm), cloth, and protective gloves

■ Detaching the Feeder Parts

1 Turn OFF the power.

❶ Make sure the [Stand by] screen is displayed.

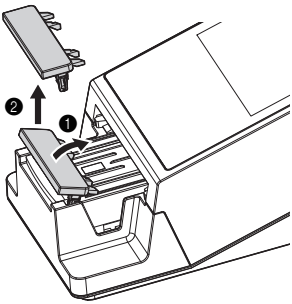
❷ Turn OFF the Power switch.



2 Detach the carrying arm.

❶ Hold the four corners of the carrying arm and tilt it slightly forward.

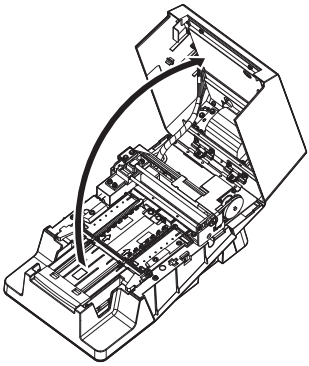
❷ Lift it up slowly.



3 Open the maintenance cover.

❶ With your hands on the sides of the maintenance cover, pull up the front of the maintenance cover.
- The lock will be released when a click sound is heard.

❷ Slowly open the maintenance cover until it becomes almost vertical.



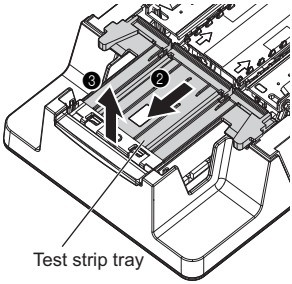
> ⚠ Do not touch the motor which may be hot.

4 Detach the test strip tray.

❶ Make sure there are no test strips left inside the test strip tray.

❷ Slide the test strip tray to the front.
- The lock will be released when a click sound is heard.

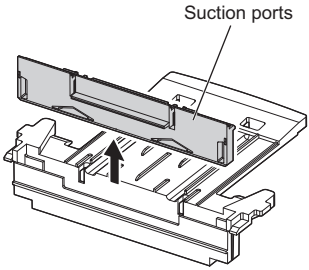
❸ Slowly lift up the test strip tray.



> **NOTE:**
> Be careful not to scatter surplus urine that collects on the test strip tray.

5 Detach the suction ports.

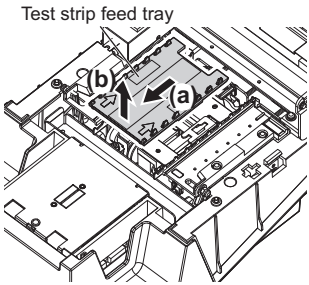
❶ Pull the suction ports straight up from the test strip tray to detach it.



> **NOTE:**
> Be careful not to scatter surplus urine that collects in the suction ports.

6 Detach the test strip feed tray.

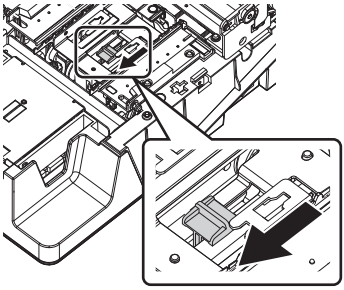
❶ Slide the test strip feed tray slightly to the front (a) and lift it upward (b).



7 Detach the feed lever.

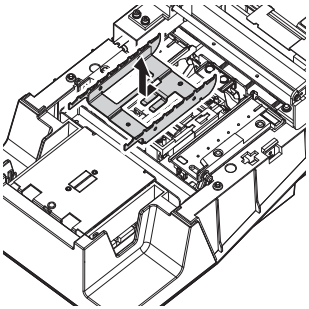
❶ Slide the lock switch to the front.

NOTE:
Do not push in the lock switch or apply excessive force to it. This could cause deformation and prevent smooth feeding of the test strips.



❷ Slightly lift the front of the feed lever and pull it out (forward) while avoiding the surrounding parts.

NOTE:
Remove the feed lever carefully as it is easily distorted.



■ Cleaning the Parts and Table

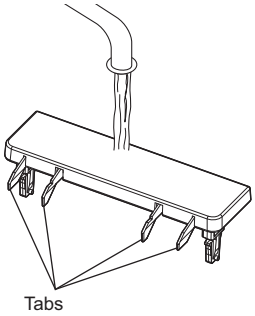
1 Sterilize and clean the carrying arm.

❶ Sterilize the carrying arm with alcohol.

❷ Rinse it with water.

NOTE:
Carefully wipe any contamination off the tabs. Any residual contamination could prevent smooth feeding of the test strips.

❸ Wipe away any moisture with a cloth and let it dry.

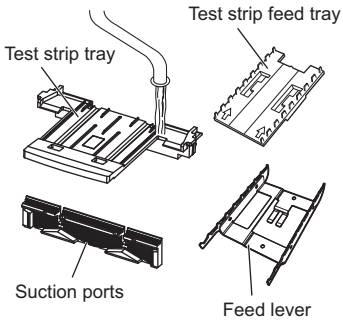


2 Rinse the remaining parts with water.

NOTE:
- Do not use alcohol. The incoming test strip sensor window of the test strip tray may become cloudy, and the test strips may not be correctly detected.
- Do not scratch the parts. If the parts are scratched, the test strips may not be fed smoothly.

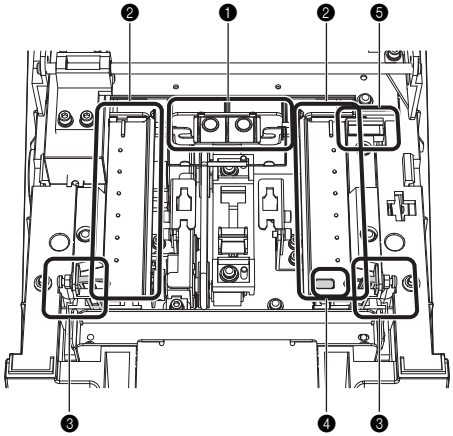
❶ Rinse the test strip tray, suction ports, test strip feed tray, and feed lever with water.

❷ Wipe away any moisture with a cloth and let it dry.

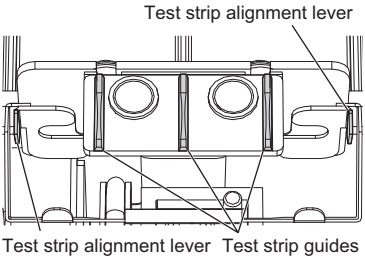


3 Clean the table.

Wipe any dirt from each part of the table with a clean cloth.

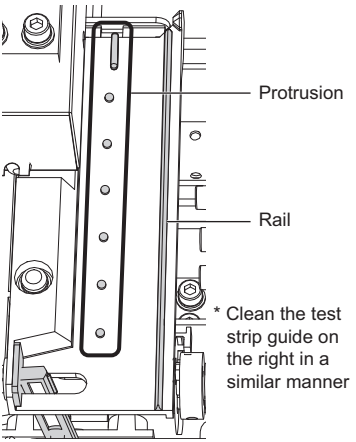


❶ Clean the test strip alignment levers and the test strip guides on the photometric table.



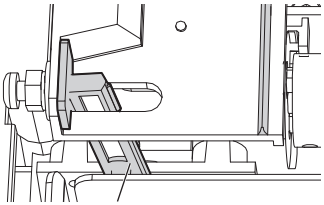
❷ Clean the rail and the protrusions on the right and left test strip guides.

● Test strip guide (left)



❸ Clean the alignment arms.

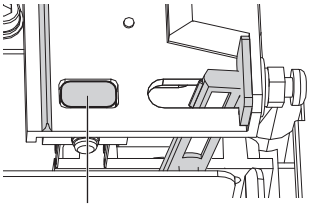
● Alignment arm (left)



Alignment arm

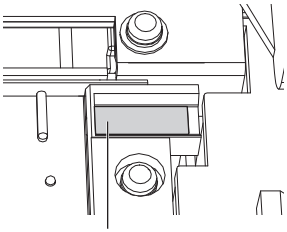
* Clean the alignment arm on the right in a similar manner

❹ Clean the incoming strip sensor window.



Incoming strip sensor window

❺ Clean the white plate.



White plate

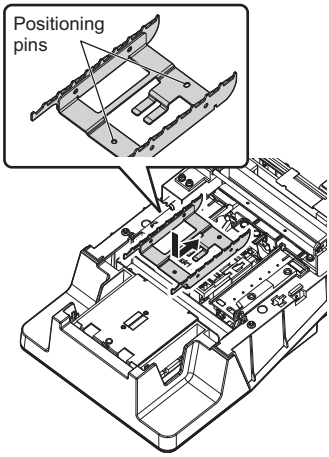
■ Attaching the Feeder Parts

1 Attach the feed lever.

❶ Check the orientation of the feed lever (see figure on the right).

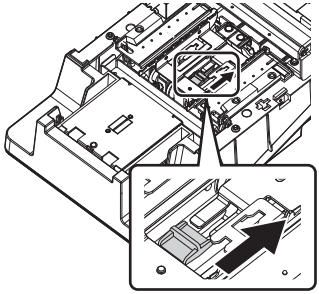
❷ Align the 2 holes in the feed lever with the positioning pins in the instrument and engage them.

❸ Make sure the feed lever is set horizontally.



❹ Slide the lock switch to the back until it clicks.

NOTE:
Do not push in the lock switch or apply excessive force to it. This could cause deformation and prevent smooth feeding of the test strips.



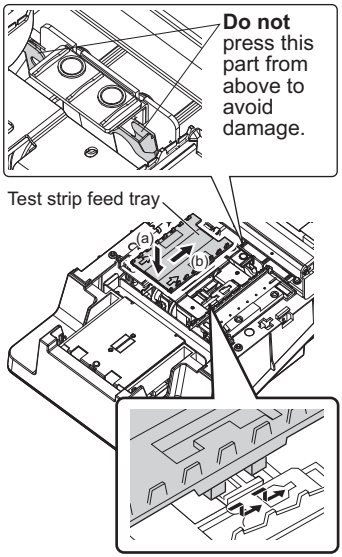
2 Attach the test strip feed tray.

❶ Hold the test strip feed tray in the orientation shown on the right.

NOTE:
Check that the two marks on the test strip feed tray are:
- on the top side
- facing toward the rear of the instrument.

❷ Insert the tabs on the bottom of the test strip feed tray into the holes in the instrument (a) and slide it firmly to the rear (b).

NOTE:
When aligning the tabs of the test strip feed tray with the holes of the unit, do not just lower the tray into place from directly above but also slide the tray to the rear.

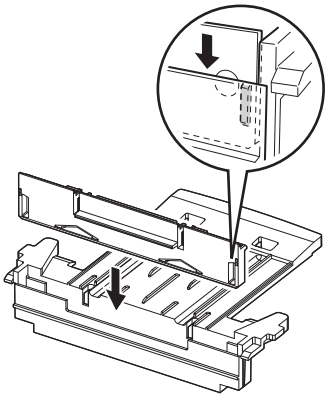


3 Attach the suction ports to the test strip tray.

❶ Insert the suction ports into the test strip tray.
- Push it in until it contacts the base perpendicularly.

❷ Make sure that the left and right grooves in the suction ports are completely covered.

NOTE:
If the suction ports are raised above the test strip tray, the test strips will not be fed correctly and may jam or cause other problems.

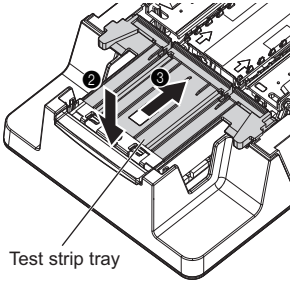


4 Attach the test strip tray.

❶ Make sure that the 2 tabs are on the bottom of the test strip tray.

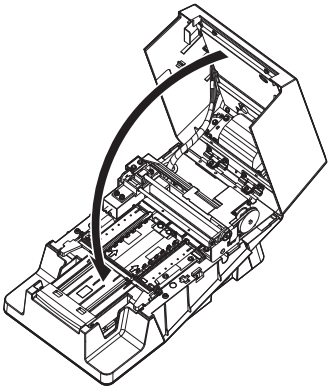
❷ Align the tabs on the test strip tray with the holes in the instrument and insert them into the instrument.

❸ Slide it to the rear until it clicks.



5 Close the maintenance cover.

❶ Slowly close the maintenance cover.
- Finally, press and lock the maintenance cover until it clicks closed.

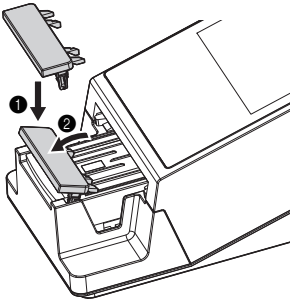


6 Attach the carrying arm.

❶ Insert the 2 black tabs of the carrying arm into the holes in the instrument.

❷ Push it in until a click sound is heard.

NOTE:
Make sure the carrying arm is not tilted.



4.2.2 Cleaning the Waste Box

At the end of measurement for the day, discard the used test strips and sterilize and clean the waste box.

- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used test strips and protective gloves from general waste and discard them in accordance with local regulations for biohazardous waste.

NOTE:
Do not sterilize and clean the waste box with an organic solvent such as thinners. Do not use ultrasonic cleaning. This could deform or discolor the waste box and make it unusable.

REFERENCE:
The waste box becomes full after approximately 100 measurements.

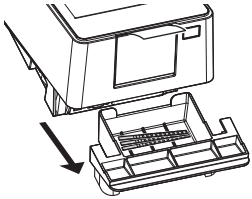
Items required: Alcohol, cloth, and protective gloves

1 Dispose of used test strips.

❶ Make sure the [Stand by] screen is displayed. Or, ensure that the power supply is turned OFF.

❷ Pull out the waste box horizontally and detach it.

❸ Dispose of the used test strips.

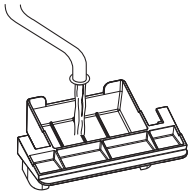


2 Sterilize and clean the waste box.

❶ Sterilize the waste box with alcohol.

❷ Rinse it with water.

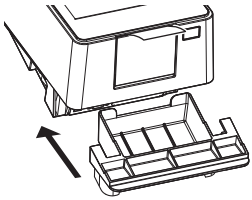
❸ Wipe away any moisture with a cloth and let it dry.



3 Attach the waste box.

❶ Install the waste box back into the instrument.

NOTE:
- Make sure that the waste box is installed correctly without any gaps.
- Do not lay tissue paper on the bottom of the waste box. It could cause problems.



4.3 Replacing the Thermal Recording Paper

Red lines appear along both edges of the thermal recording paper when the paper is near the end of the roll. Replace the paper roll as soon as possible. One roll of new thermal recording paper can print about 450 measurements.

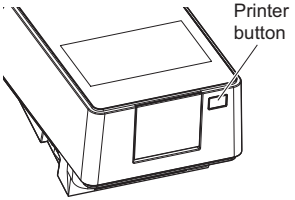
Items required: Thermal recording paper

1 Remove the remaining thermal recording paper.

❶ Make sure the [Stand by] screen is displayed.

❷ Press the printer button.
- The printer cover will open.

❸ Remove the remaining thermal recording paper and the old roll from the printer.

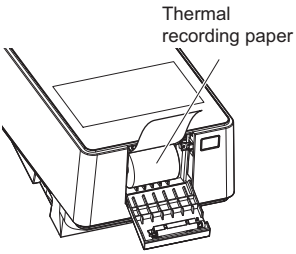


2 Load a new roll of thermal recording paper.

❶ Remove the sticker from the new thermal recording paper.

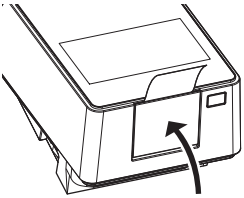
❷ Pull out the outer winding of the thermal recording paper about 10 cm.

❸ Install the new thermal recording paper in the paper compartment so that the paper unrolls from the top.

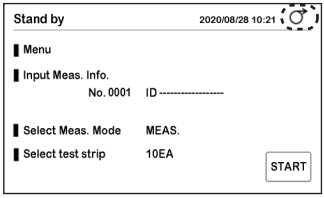


3 Close the printer cover.

❶ Close the printer cover.
- Push the cover until a click sound is heard.



4 Feed paper.



❶ Tap [FEED].
- The thermal recording paper will be fed.

NOTE:
If the thermal recording paper is not fed, the measurement result will not be printed.

4.4 Maintenance When the Instrument Will Not Be Used for a Long Period of Time

If the instrument will not be used for more than a week, follow the procedures below to clean it.

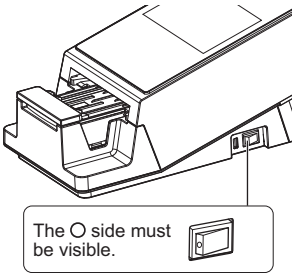
- Wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used test strips and protective gloves from general waste in accordance with local regulations for biohazardous waste.

Items required: Alcohol, cloth, and protective gloves

1 Turn OFF the power.

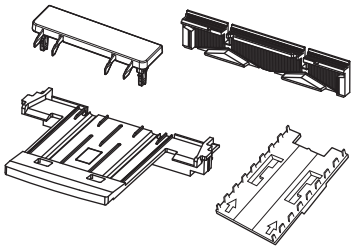
❶ Make sure the [Stand by] screen is displayed.

❷ Turn OFF the Power switch.



2 Clean the feeder.

❶ Clean the feeder.
- See “4.2.1. Cleaning the Feeder” on page 4-2.



3 Clean the waste box.

❶ Clean the waste box.
- See “4.2.2. Cleaning the Waste Box” on page 4-11.

4 Disconnect the power cord.

❶ Pull out the power cord from the outlet.

Chapter 5 Troubleshooting

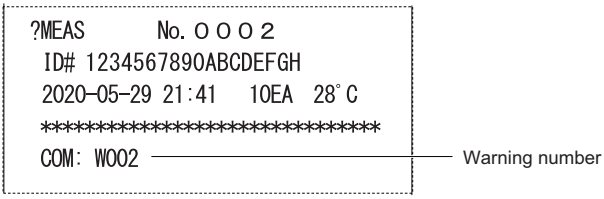
This chapter describes the action to take if a warning, error or trouble occurs. It also provides contact details in the event that the trouble cannot be resolved.

5.1 Measures If a Warning Occurs

5.1.1 When a Warning Occurs

A warning is issued if a normal measurement result was not obtained. If a warning occurs a measurement, the instrument continues measurement and prints the warning number in the measurement result.

● Sample print out



5.1.2 Causes of and Solutions to Warnings

- When taking measures that may involve touching the sample, wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used samples, test strips, and protective gloves from general waste and discard them in accordance with local regulations for biohazardous waste.

W001	Drift
Cause	The ambient light intensity changed suddenly due to ambient lighting or a camera flash.
Measures	● Perform measurement with constant light intensity around the instrument. ● Correctly mount the waste box. ● Change the orientation of the instrument.

W002	Abnormally high reflectance
Cause	An abnormal sample (e.g. a sample containing medicine) was measured.
Measures	● Check that the type of test strip specified in [Select test strip] is used. ● Check if the tested sample is abnormal or not.

W003	Incorrect test strip position
Cause	● The test strip was displaced from its correct position by vibrations. ● The test strip was incorrectly placed.
Measures	● Do not move or apply vibrations to the instrument during measurement. ● Correctly place the test strip.

W004	No dipping
Cause	● All or part of the test strip pad area was not dipped in the sample before measurement. ● The white plate is dirty.
Measures	● Fully dip the entire pad area of a new test strip and repeat the measurement. ● Clean the white plate (see page 4-2). ● If W004 occurs frequently, contact your distributor to control the occurrence of W004 (see page 3-29).

W005	Wrong test strip type
Cause	● A test strip other than the one specified was used. ● The test strip was not properly transferred to the photometric measurement position.
Measures	● Use the specified type of test strip. ● Use a new test strip and dip it in the sample. Be sure not to get the marker wet when dipping the test strip. ● Do not apply vibrations to the instrument during measurement.

W006	Transport error
Cause	A test strip was not transported correctly.
Measures	● Clean the test strip tray and suction ports (see page 4-2). ● Correctly mount the suction ports on test strip tray (see page 4-2). ● Clean the incoming strip sensor window.

W007	151 or more Operator ID registered
Cause	150 operator IDs are already registered.
Measures	Delete unnecessary operator IDs (see page 3-14).

W008	Elapse of QC deadline
Cause	A QC Lock-Out occurred.
Measures	Perform a control measurement (see page 2-20).

W009	Abnormal temperature in the instrument
Cause	Measurement was performed outside the ambient temperature range.
Measures	Adjust the room temperature so that it is within the ambient temperature range and repeat the measurement.

5.2 Measures If an Error Occurs

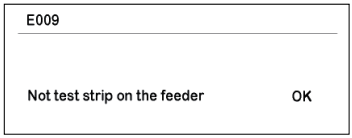
5.2.1 When an Error Occurs

An error occurs when the instrument is used or operated incorrectly.
An error is notified by a warning tone, error number, and error message.
The warning tone is a short beeping sound that continues for about 1 minute.

❶ Tap [OK].
- The warning tone stops.

❷ Take the appropriate measures.
- See "5.2.2. Causes of and Solutions to Errors" on page 5-3.

❸ If the error persists, turn OFF the instrument and contact your distributor.



Error number and message

5.2.2 Causes of and Solutions to Errors

- When taking measures that may involve touching the sample, wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used samples, test strips, and protective gloves from general waste and discard them in accordance with local regulations for biohazardous waste.

E001	**Power down**
Cause	The instrument was suddenly turned OFF during measurement.
Measures	Tap [OK] to cancel the error.

E002	**Backup memory error**
Cause	The backup battery spontaneously discharged because the instrument was not turned ON for more than 3 months.
Measures	(1) Tap [OK] to cancel the error. (2) Keep the instrument powered ON for at least 11 hours to charge the battery. (3) After charging the battery, tap [OK] to initialize the backup memory. (4) Correctly set the date and time (see page 3-3).

E004	No paper in the printer
Cause	● The thermal recording paper has run out. ● The thermal recording paper was not mounted correctly. ● Paper was not fed after mounting the thermal recording paper.
Measures	(1) If [OK] is displayed, tap [OK] to cancel the error. (2) Replace it with the new thermal recording paper (see page 4-12). If some thermal recording paper remains, mount it correctly. (3)Tap [FEED] to feed the paper.

E005	Waste box is full
Cause	The waste box is full of test strips (more than 90 samples have been measured).
Measures 	(1) Tap [OK] to cancel the error. (2) Discard the test strips in the waste box (see page 4-11). (3) Tap [OK] to initialize the counter.

E006	Surplus urine is full
Cause	Surplus urine is full (more than 190 samples have been measured).
Measures 	(1) Tap [OK] to cancel the error. (2) Turn OFF the instrument and open the maintenance cover. (3) Appropriately handle the surplus urine (see page 4-2).

E007	Data not found
Cause	No measurement results were found that match the search criteria.
Measures	(1) Tap [OK] to cancel the error. (2) Check that the specified criteria are correct.

E008	Auto start sensor error
Cause	● The test strip was placed while the carrying arm was moving to the suction ports. ● The detection window is dirty. ● The auto start sensor is defective.
Measures 	(1) Tap [OK] to cancel the error. (2) Remove the test strip or clean the detection window. (3) If the error persists, contact your distributor.

E009	Not test strip on the feeder
Cause	● The feed lever is not attached. ● The detection window is dirty. ● The incoming strip sensor is broken. ● There is a problem with the detection level adjustment.
Measures 	(1) Tap [OK] to cancel the error. (2) Turn OFF the power and open the maintenance cover. (3) Attach the feed lever if it is not attached (see page 4-2). (4) Clean the detection window if it is dirty (see page 4-2). (5) If the error persists, contact your distributor.

E011	Elapse of QC deadline
Cause	A QC Lock-Out occurred because no control measurement was performed over a certain period of time or during a certain number of measurements.
Measures	(1) Tap [OK] to cancel the error. (2) Perform a control measurement (see page 2-20).

5.3 Measures If Trouble Occurs

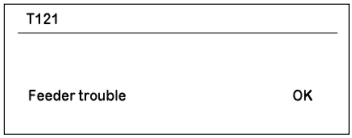
5.3.1 When Trouble Occurs

Trouble occurs when there is an issue with the instrument that forces operation to stop. Trouble is notified by a warning tone, error number, and error message. The warning tone is a long beeping sound that continues for about 1 minute.

❶ Tap [OK] to cancel the warning tone.

❷ Take the appropriate measures.
- "5.3.2. Causes of and Solutions to Troubles" on page 5-6.

❸ If the trouble persists, turn OFF the instrument and contact your distributor.



Trouble number and message

REFERENCE:
- If trouble occurs during measurement
  Perform the measurement again. Check the measurement results of the samples before and after the sample where the trouble occurred. Repeat the measurement if something seems wrong.

5.3.2 Causes of and Solutions to Troubles

- When taking measures that may involve touching the sample, wear protective gloves to prevent exposure to pathogenic microorganisms.
- Separate used samples, test strips, and protective gloves from general waste and discard them in accordance with local regulations for biohazardous waste.

T101	**EEPROM trouble**
Cause	● The EEPROM is defective.
Measures	(1) Tap [OK] to cancel the trouble. (2) Turn OFF the instrument and contact your distributor.

T102	**Changed version**
Cause	● The program was updated. ● A backup memory error occurred.
Measures	(1) Tap [OK] to cancel the trouble. (2) Tap [OK] to initialize the backup memory. (3) If the trouble persists, turn OFF the instrument and contact your distributor.

T110	No calibration curve
Cause	No calibration curve has been input, or the information is inadequate.
Measures	(1) Tap [OK] to cancel the trouble. (2) Tap [OK] to initialize the mechanism. (3) If the trouble persists, turn OFF the instrument and contact your distributor.

T120	Inlet error
Cause	● The carrying arm hit something, causing a time-out. ● The feed motor did not operate.
Measures 	(1) Tap [OK] to cancel the trouble. (2) Open the maintenance cover. (3) Remove any obstacle in the instrument or the test strips that are scattered. (4) Check that the carrying arm, test strip tray, suction ports, and feeder are not damaged. (5) Close the maintenance cover. (6) Tap [OK] to initialize the mechanism. (7) If there is damage or the trouble persists, contact your distributor.

T121	Feeder trouble
Cause	● The feed lever hit something, causing a time-out. ● The feed motor did not operate.
Measures 	(1) Tap [OK] to cancel the trouble. (2) Open the maintenance cover. (3) Remove any obstacle in the instrument or the test strips that are scattered. (4) Check that the carrying arm, test strip tray, suction ports, and feeder are not damaged. (5) Close the maintenance cover. (6) Tap [OK] to initialize the mechanism. (7) If there is damage or the trouble persists, contact your distributor.

T123	Incoming strip sensor trouble
Cause	● The incoming strip sensor window is dirty. ● The incoming strip sensor window is covered by the test strip. ● The incoming strip sensor is defective.
Measures 	(1) Tap [OK] to cancel the trouble. (2) Open the maintenance cover. (3) Remove any test strips that are scattered in the feeder. (4) Clean the feeder, including the incoming strip sensor window, if it is dirty (see page 4-2). (5) Check for damaged parts in the feeder. (6) Close the maintenance cover. (7) Tap [OK] to initialize the mechanism. (8) Discard any test strips that overflow from the waste box. (9) If there is damage or the trouble persists, contact your distributor.

T130	Photometric section initialization trouble
T131	**Photometric section driving trouble**
Cause	● An error occurred in the drive mechanism of the photometric section or the position detection sensor. ● Test strips overflowing from the waste box hindered the drive of the photometric section.
Measures 	(1) Tap [OK] to cancel the trouble. (2) Open the maintenance cover. (3) Remove any test strips that are scattered in the feeder. (4) Check that the photometric section is not damaged. (5) Close the maintenance cover. (6) Tap [OK] to initialize the mechanism. (7) Discard any test strips that overflow from the waste box. (8) If there is damage or the trouble persists, contact your distributor.

T132	A/D overflow
T133	**A/D range over**
T134	**A/D range under**
T135	**A/D range dark over**
Cause	● Ambient light entered the instrument. ● The white plate is dirty. ● An error occurred in the electrical circuits. ● An error occurred in the photometric section.
Measures 	(1) Tap [OK] to cancel the trouble. (2) Open the maintenance cover. (3) Remove any test strips that are scattered in the feeder. (4) Clean the white plate if it is dirty (see page 4-2). (5) Close the maintenance cover. (6) Check that the waste box is mounted correctly. Discard any overflowing test strips. (7) Adjust the instrument orientation so that no direct light enters. (8) Tap [OK] to initialize the mechanism. (9) If the trouble persists, contact your distributor.

T137	Black mark not found
Cause	● An error occurred in the test strip feeder. ● Test strips are overflowing from the waste box. ● An error occurred in the electrical circuits. ● Incorrect orientation setting for mounting test strips
Measures 	(1) Tap [OK] to cancel the trouble. (2) Open the maintenance cover. (3) Remove any test strips that are scattered in the feeder. (4) Close the maintenance cover. (5) Check that the waste box is mounted correctly. Discard any overflowing test strips. (6) Tap [OK] to initialize the mechanism. (7) If the trouble persists, contact your distributor.

T138	Test strip feeding trouble
Cause	● A test strip was not transported correctly. ● Test strips are overflowing from the waste box. ● An error occurred in the electrical circuits.
Measures	(1) Tap [OK] to cancel the trouble. (2) Open the maintenance cover. (3) Remove any test strips that are scattered in the feeder. (4) Clean the feeder, including the incoming strip sensor window, if it is dirty (see page 4-2). (5) Check that the suction ports are not damaged. (6) Close the maintenance cover. (7) Discard any test strips that overflow from the waste box. (8) Tap [OK] to initialize the mechanism. (9) If there is damage or the trouble persists, contact your distributor.

T160	Unable to initialize
Cause	● An error occurred in the drive system. ● An electrical error occurred in the position detection sensor.
Measures	(1) Tap [OK] to cancel the trouble. (2) Tap [OK] to initialize the mechanism. (3) If the trouble persists, turn OFF the instrument and contact your distributor.

T161	Temperature sensor error
Cause	● An error occurred in the temperature sensor. ● An error occurred in the electrical circuits.
Measures	(1) Tap [OK] to cancel the trouble. (2) Tap [OK] to initialize the mechanism. (3) If the trouble persists, turn OFF the instrument and contact your distributor.

T170	External output initialization trouble
Cause	An electrical error occurred in the circuit board.
Measures	(1) Tap [OK] to cancel the trouble. (2) Tap [OK] again. (3) Turn OFF the instrument. (4) Contact your distributor.

T171	Two-way communication trouble
Cause	● The cable is disconnected. ● The communication settings are incorrect.
Measures	(1) Tap [OK] to cancel the trouble. (2) Check if the external communication cable is disconnected. (3) Tap [OK] to initialize the mechanism. (4) If the trouble persists, contact your distributor.

T180	Automatic adjustment error
Cause	An electrical error occurred in the sensors, photometric section LEDs, or circuit board.
Measures	■ **If the error occurs during the optical adjustment** (1) Tap [OK] to cancel the trouble. (2) Clean the white plate (see page 4-2). (3) Perform optical adjustment again. (4) If the trouble persists, contact your distributor. ■ **In other cases** (1) Tap [OK] to cancel the trouble. (2) Turn OFF the instrument. (3) Contact your distributor.

T999	Unknown trouble
Cause	An unknown error occurred.
Measures	Hold onto the printout on the thermal recording paper and contact your distributor.

Chapter 6 Appendix

6.1 Performance characteristics

6.1.1 Analytical Performance

Item	Specifications (Product specifications)
Accuracy	Within 2 ranks of semi-quantitative sign
Reproducibility	System: SD of all items shall be equal to or less than 2.5% (reflectance around 50%).

For the information on sensitivity, specificity and interferences, please refer to reagent package inserts.

6.1.2 Clinical Performance

In the AutionIDaten AE-4070 system, the measurement results of pH, Creatinine and Specific Gravity are used to assist the judge of other measurement items. The measurement result of ALB is used clinically using the calculation result A / C ratio with CRE. Therefore, Positive Percent Agreement, Negative Percent Agreement, Overall Percent Agreement about pH, Creatinine, Specific Gravity and Albumin are not described.

Analyte	Positive Percent Agreement	Negative Percent Agreement	Overall Percent Agreement
Glucose	100	99	99
Protein	94	100	98
Bilirubin	100	100	100
Urobilinogen	99	100	100
Blood	100	99	99
Ketones	100	100	100
Nitrite	100	100	100
Leukocytes	91	97	96
P/C ratio	74	97	85
A/C ratio	89	100	93

[P/C ratio, A/C ratio] vs. AUTION ELEVEN AE-4021
[Other than P/C ratio, A/C ratio] vs. AUTION MAX AX-4280

6.2 Index

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V

W

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Rev.: 2024.06.28
84-08685C


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