Semi-automatic Urine Analyzer

AUTION ELEVEN™

AE-4020 | Operating Manual

arkray,inc.

1 Premise

Thank you for purchasing our semi-automatic urine analyzer, the AUTION ELEVEN AE-4020.

This manual contains important information on the functions of the AUTION ELEVENTM AE-4020.
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.

■ Intended Purpose

The AUTION ELEVEN AE-4020 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.
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 operating manual gives an outline of the system and the proper procedures for operation and maintenance. Follow instructions in this operating manual in order not to impair the protection by 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 microbes 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 and spare parts in accordance with local regulations for biohazardous waste.
- This instrument may become infectious in the course of use. Discard the instrument in accordance with local regulations for biohazardous waste.

Each measurement result includes a patient ID so that the result can be associated with its personal health information.
Measurement results should be viewed, printed, output or deleted by authorized persons only and always handled with extreme care by every operator. The authorized persons mentioned above do not require any special IT skills or training, but should read the operating manual before first use for a proper understanding.

3 Symbols

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

■ Personal injury

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

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

■ Damage to the product or its performance

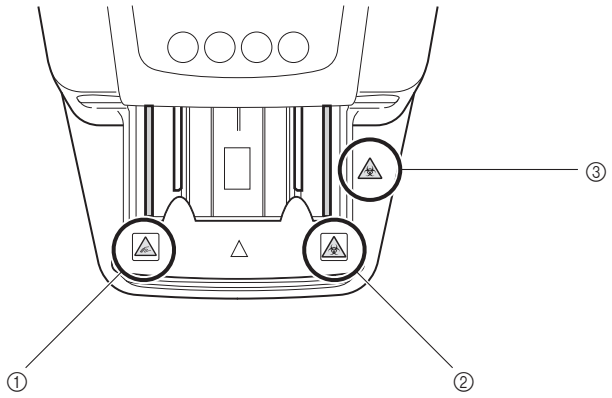
IMPORTANT:
Follow the instructions given here to obtain accurate measurement results.

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 potential dangers warned by each label and observe the precautions described below.



①Carrying arm

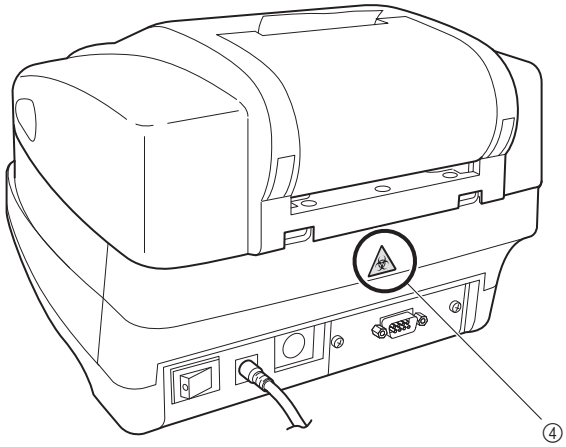
The carrying arm moves during measurement. While the carrying arm is moving, **do not** put your hand close to the arm so as to avoid being caught or pinched.

②Carrying arm

Never touch with unprotected hands the carrying arm, where the sample may adhere. During cleaning or maintenance of the carrying arm, wear protective gloves to prevent exposure to pathogenic microbes.

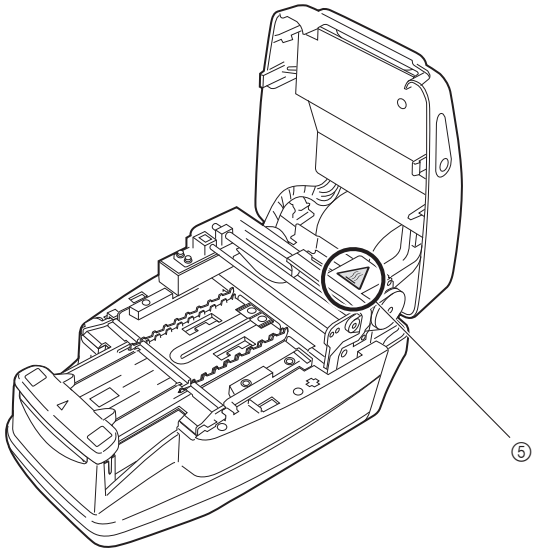
③Maintenance cover and inside the instrument

Never touch with unprotected hands the maintenance cover and inside the instrument, where the sample may adhere. During cleaning or maintenance of these parts, wear protective gloves to prevent exposure to pathogenic microbes.



④**Waste box**

Never touch with unprotected hands the waste box, where the sample may adhere. During cleaning or maintenance of the waste box, wear protective gloves to prevent exposure to pathogenic microbes.



⑤**Motor**

Do not touch the motor and its surrounding area, which may be hot and cause burn on the hand, especially during operation and just after the instrument is turned off.

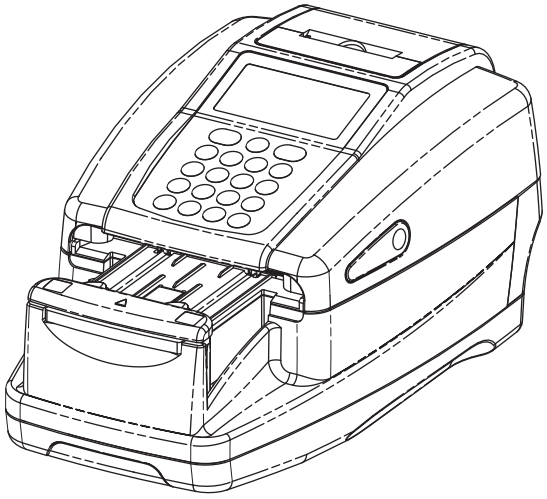
5 Table of Contents

Chapter 3. Supplementary Operations 3-1

Chapter 1 Before Using the AE-4020

1.1 Outline of the AE-4020

The AUTION ELEVEN AE-4020 is a semi-automatic urine analyzer that uses test strips.
This compact instrument is capable of performing a variety of functions.



1.1.1 AE-4020 Features

- Compact and lightweight, with simple structure

The instrument has a minimal installation footprint of just the area of an A4-size sheet of paper. It can be installed in various locations and can be carried easily, thanks to its lightweight construction and minimal weight of approx. 3.6 kg. Despite its compactness, the device 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 measurements.

- 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 vessels. Small volume samples can also be measured easily.

- Dipping timing signal

A buzzer can be set to signal the optimum dipping timing. The user can then dip all test strips for the correct period of time by paying attention to the buzzer, which keeps the test strip reaction time constant.

- Measurement of one sample every seven seconds

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

- Measurement auto-stop

When the instrument detects that no test strip is placed on the test strip tray, it automatically stops measurement.

- Auto start, and non-directional test strip placement

The instrument automatically detects a test strip when placed on the test strip tray and starts measurement. Measurement can be performed regardless of the test strip orientation (pointing right or left).

● Test strip type auto-detection

The instrument automatically identifies the type of test strips (assuming they have auto-classification marks) and performs the appropriate measurements. However, the instrument does not automatically detect the test strip when selected test strip type is “Uriflet S 11UA”.

● Temperature correction

The optimum ambient temperature range for AUTION ELEVEN measurements using test strips is from 20 to 25°C. However, even when the ambient temperature is out of this range, at temperatures from 10 to 30°C, the instrument’s temperature correction function compensates for any deviation caused by temperature. For ambient temperatures outside the 10 to 30°C range, the instrument may not obtain proper measurement results for certain measurement items.

● Color tone determination

In addition to the measurement of each measurement item, the instrument measures the color tone of samples. The instrument measures shading and hue, and obtains finely graduated urine color tone data corresponding to 23 categories.

(See “■ Color tone correction” on page 1-7)

● Specific Gravity correction by pH

Highly accurate measurements can be performed by automatically correcting S. G. values according to pH values.

● Abnormal color detection

The instrument automatically detects urine containing medicine, and prints a “!” mark with the measurement result (only applicable to measurement items KET, BIL, and URO)

● Prints measurement results in bold

The instrument prints measurement results with other data emphasizing the results by using bold-type and larger characters for easy and fast reading.

(See “2.5. How to read the measurement results” on page 2-34)

● 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.

● Store up to 520 measurement results

The instrument can store up to 520 measurement results. When the number of measurement results exceeds 520, the instrument automatically deletes the oldest sample data. The measurement results are stored in categories of measurement types and result types (normal and abnormal).

● Optional hand-held barcode reader

A hand-held barcode reader (optional) can be mounted. Each barcode scanned by the barcode reader is allocated a patient ID number.

● Ethernet connection

An Ethernet device (optional) can be installed.

1.1.2 Measurement types

● Normal measurement

In the normal measurement mode, samples are measured consecutively. Measurements in this mode are allocated MEAS No. * * * *. After the measurement number of the first sample is entered, the system automatically increments the number by one for each subsequent measurement. When measuring another batch after returning to the [Standby screen] (see the Note below), the system allocates consecutive MEAS Nos. Even when the instrument is switched to a different operating mode, consecutive MEAS Nos. will be allocated until the instrument is turned OFF.

● STAT measurement

In the STAT measurement mode, the instrument also measures samples consecutively, just as it does in the normal measurement mode. The instrument can be switched to the STAT measurement mode by pressing  during normal measurement, when you need to make urgent sample measurements. The measurement mode can be returned to the normal mode by pressing  after this work is completed. Measurements in this mode are allocated STAT No. * * * *. After the measurement number of the first STAT sample is entered, the system automatically increments the STAT measurement number by one for each subsequent measurement. When measuring another batch after returning to the [Standby screen] (see Note below), the system continuously allocates consecutive STAT Nos. until the instrument is turned OFF.

● Control measurement

The Control measurement mode is used for the periodical measurement of Controls, to check the accuracy of the instrument. Controls can be measured consecutively. Measurements in this mode are allocated CONTROL No. * * * *.

● Check measurement

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

NOTE:

One batch is a group of samples that will be measured consecutively (from automatic start or after pressing the  button, until the display returns to the [Standby screen]). This system can measure up to 100 samples as one batch. (When the number of samples measured exceeds 90, a message appears advising the user to discard the previously used test strips.) When measuring a group of more than 100 samples consecutively, divide them into two or more batches.

1.1.3 Specifications

Sample	Urine
Test Strip / Reagent pack	AUTION Sticks / Uriflet S / AUTION SCREEN
Measurement item	GLU, KET, BIL, NIT, PRO, URO, pH, BLD, LEU, ALB, CRE, Specific Gravity, color tone
Measurement range	Test strip: Rank table (See “1.1.5. Rank tables” on page 1-8) Color tone: Color tone classification chart (See “■ Color tone correction” on page 1-7)
Measurement method	Test strip method Dual-wavelength reflection photometric method (single wavelength for BLD)
Measurement wavelength	4-wavelength LED (430, 565, 635, and 760 nm)
Test strip reaction time	60 seconds
Processing speed	514 samples per hour (maximum processing mode: 7-second interval)
Display	Custom LC display (icons are used)
Built-in printer	32-digit thermal printer (58 mm width)
External output	Conforms to RS-232C standard (serial) Option: Ethernet
Memory capacity	520 measurement results
Temperature correction	Auto-correction by the internal temperature sensor (between 10 to 30°C)
S. G. correction	Auto-correction by pH values
Chromaturia correction	Auto-correction by the color tone correction section on test strips
Operating environment	Temperature: 10 to 30°C; Humidity: 20 to 80% R.H. (non-condensing)
Measurement environment	Temperature: 10 to 30°C; Humidity: 30 to 60% R.H. (non-condensing) *Temperature correction function used
Storage environment	Temperature: 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)
Sound pressure level	Less than 85 dB
Site location	Indoor use only
Altitude	Up to 2000 m/ 6560 feet
Pollution degree	2
DC power requirements (To instrument)	12 Vdc 3 A
AC power requirements (To AC adapter)	100-240 Vac 50-60 HZ ,1200 mA Voltage fluctuation allowance is ±10%
Power consumption	Max. 45 VA
Overvoltage category	II
Dimensions	210 (width) × 328 (depth) × 164 (height) mm
Weight	Approx. 3.6 kg
Expected life	5 years from first use (installation) of the instrument (according to company data). The manufacturing date is included in the serial number as shown below. • 2nd and 3rd digits of the serial number: The last 2 digits of the manufacturing year • 4th and 5th digits of the serial number: The manufacturing month

1.1.4 Measurement principles

Measurements using double or single wavelength reflection are made, using test strips designed for the AE-4020.

■ Measuring with 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. Reagents in the test strip react and change color within 60 seconds after dipping, and the reflectance is measured in the photometric section. 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, 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 adjust for variability in the amount of reflected light and sample coloring.

The reflectance is obtained using the following equation.

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

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

The BLD measurement 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.

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

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

● Measurement wavelength of each measurement item

Measurement item	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

Concerning sample illumination, 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 at the right.

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

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

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

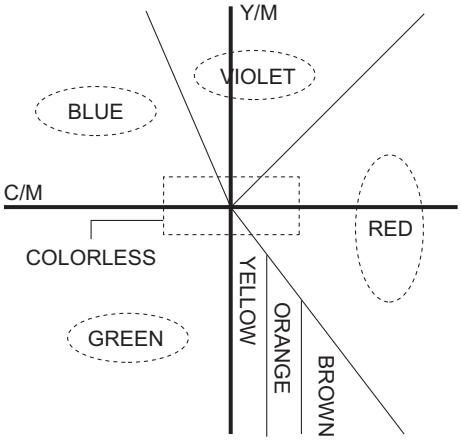
Y: Reflectance of 430 nm beam
M: Reflectance of 565 nm beam
C: Reflectance of 635 nm beam
R: Reflectance of 760 nm beam

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

● Color tone classification chart



1.1.5 Rank tables

● 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

● 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

● 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

● 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

● 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

● 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

● 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

● A/C (Ratio of Albumin to 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 of Protein to Creatinine)

Rank No.	1	2	3	4	5	6
Qualitative value	DILUTE	NORMAL	1+		2+	
Semiquantitative value (mg/gCr)		<80*	200	400	>500	OVER

* This value can be changed to "<150". To change the setting, contact your local distributor.

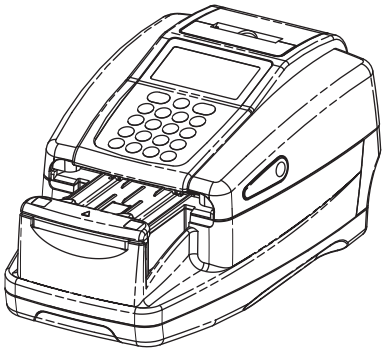
IMPORTANT:

In the rank tables above, measurement results in the range of values shown in gray cells will be printed with abnormal marks. None of PH, S.G., ALB or CRE measurement results will have abnormal marks.

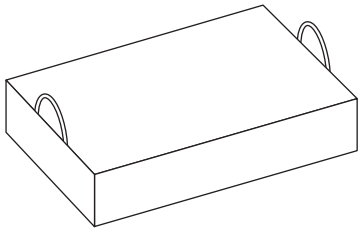
1.2 Confirm the items included in the package

NOTE:
Test strips and controls are not included with the instrument. These items are underlined in the “Prepare:” sections on the later pages.

1.2.1 Items in the package



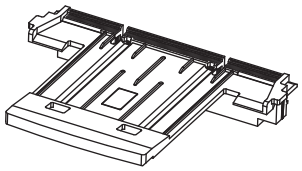
① Instrument



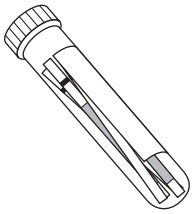
② Accessory kit box

No.	Name	Description	Qty.
①	Instrument	AE-4020	1
②	Accessory kit box	See the next page	1

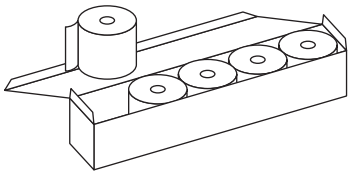
■ Accessory kit box



① Test strip tray



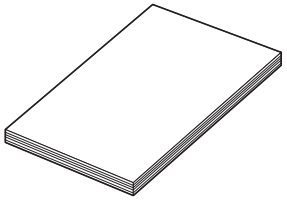
② Check strip set



③ Thermal recording paper

④ AC adapter

⑤ Power cords

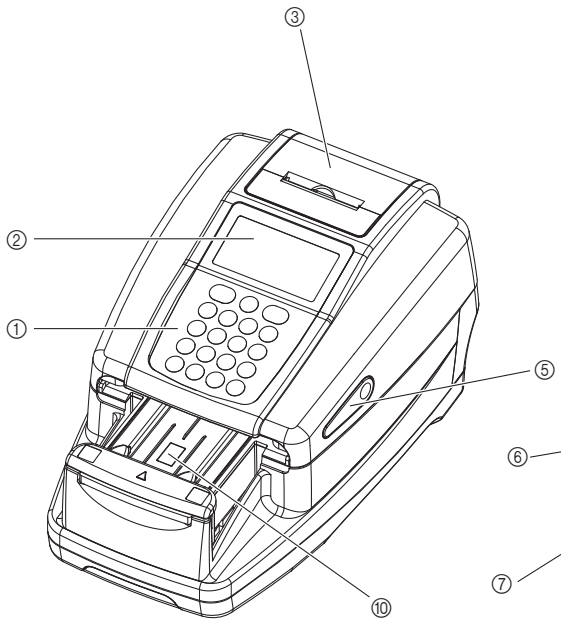


⑥ Operating manual

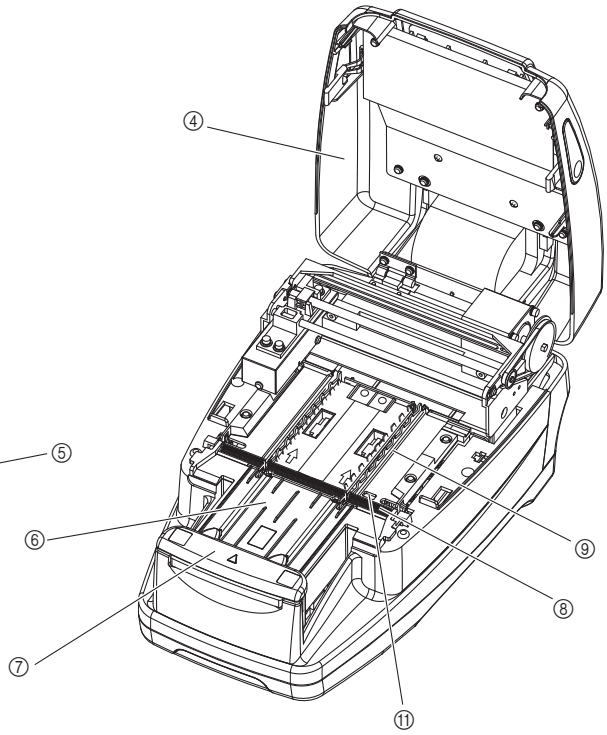
No.	Name	Description	Qty.
①	Test strip tray	-	1
②	Check strip set	2 check strips (white)	1
③	Thermal recording paper	58 mm width, 5 rolls	1
④	AC adapter	-	1
⑤	Power cords	Rating: 125V 7A (A type plug) and 250V 2.5A (C type plug) Please use the appropriate power cord for your region's power voltage.	2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

1.3 Name and function of each part

1.3.1 Front side



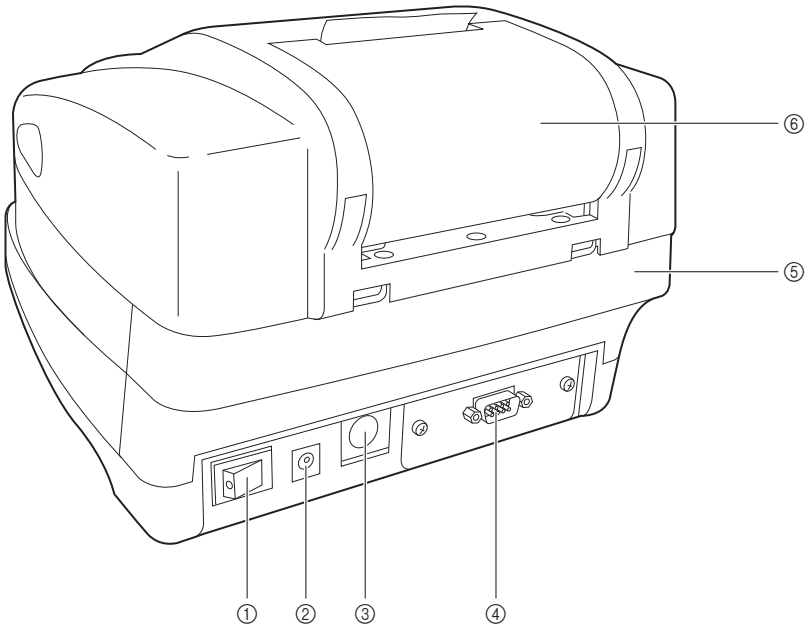
The maintenance cover closed



The maintenance cover opened

No.	Name	Function
①	Display	Displays information such as operating status and error messages.
②	Operator panel	Used to start and stop measurement as well as to input numeric values.
③	Built-in printer	Thermal line printer for printing measurement results and parameter setting details.
④	Maintenance cover	Prevents any light from entering the instrument. Is opened only when installing the instrument or performing internal maintenance.
⑤	Cover open buttons (left/right)	Press the left and right buttons at the same time to open the maintenance cover.
⑥	Test strip tray	Place the test strip on this tray after dipping it in the sample to be measured.
⑦	Carrying arm	Carries the test strip placed on the test strip tray to the suction ports while the tray rails adjust the position.
⑧	Suction ports	They absorb surplus sample urine adhering to the test strip.
⑨	Test strip feed mechanism	Transfers the test strips to the photometric section after the surplus urine is removed. This mechanism also discards the used test strips into the waste box.
⑩	Test strip detection window (auto start sensor)	Detects when a test strip is placed on the test strip tray.
⑪	Incoming strip sensor windows	The incoming test strip is detected here, and is allocated a measurement number and a patient ID number.

1.3.2 Rear side

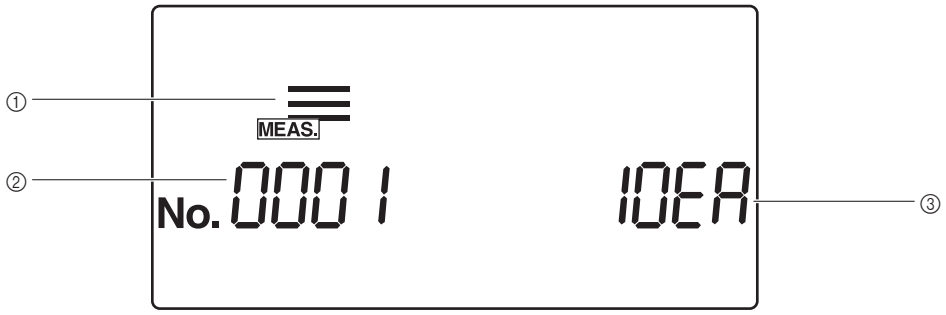


No.	Name	Function
①	Power switch	Turns the instrument ON/OFF.
②	Power input terminal	For connection with the supplied AC adapter.
③	B.C.R.	Terminal for the optional hand-held barcode reader.
④	RS-232C	Terminal for an external device.
	Ethernet (optional)	For connection to an Ethernet device.
⑤	Waste box	Used test strips are discarded in this box.
⑥	Printer cover	Open this cover to replace the thermal recording paper.

1.3.3 Display

■ Standby screen

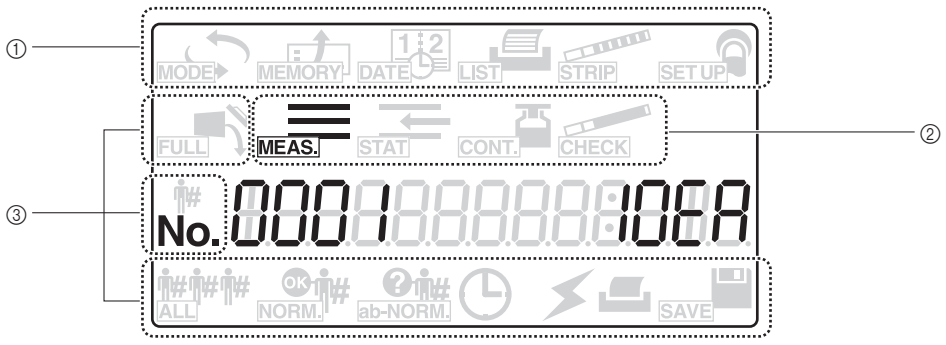
When the instrument is turned ON, the [Standby screen] appears.



No.	Name	Function
①	Measurement mode	The currently selected measurement mode is shown with an icon. To change the measurement mode, press ◀ or ▶ when the [Standby screen] is displayed.
②	Measurement number	The measurement number is displayed, except in the check measurement mode. Different information is displayed depending on the present measurement operation, operational status, and menu.
③	Test strip type	The test strip type for the current setting is displayed. (In the check measurement mode, the current time is displayed.) To set the test strip type, see “3.6. STRIP (selecting the test strip type)” on page 3-14.

■ Details of each icon

The icons indicate the present measurement mode, menu, and operational status.



No.	Name	Function
①	Menu icon area	Area for menu icons. Press ◀ or ▶ to select a menu icon.
②	Measurement mode icon area	Area for measurement mode icons. Press ◀ or ▶ to change the measurement mode.
③	Operational status icon areas	Areas for operational status icons. Different icons are displayed to indicate the current operational status and settings.

The function of each icon is noted below.

Icon	Name	Function	See page
	MODE icon	Selected to change the measurement mode.	3-4
	MEMORY icon	Selected to reprint or resend measurement results.	3-6
	DATE icon	Selected to set the date and time.	3-10
	LIST icon	Selected to print an abnormal measurement results list.	3-12
	STRIP icon	Selected to change the test strip type setting.	3-14
	SETUP icon	Selected to change the user settings.	3-16
	FULL icon	Flashes when the number of measurements has exceeded the set amount. When this icon flashes, discard the collected used test strips and surplus urine.	–
	MEAS. icon	Selected to perform normal measurement. This icon appears during normal measurements and while normal measurement settings are changed.	3-4
	STAT icon	Selected to perform STAT measurement. This icon appears during STAT measurements and while STAT measurement settings are changed.	3-4
	CONT. icon	Selected to perform Control measurement. This icon appears during Control measurements and while Control measurement settings are changed.	3-4
	CHECK icon	Selected to perform CHECK measurement. This icon appears during CHECK measurements and while CHECK measurement settings are changed.	3-4
	ID# icon	Appears when a patient ID number is input or displayed.	3-8
No.	No. icon	Appears when a measurement number is input or displayed. Also appears while an item number is entered or displayed when changing user settings.	3-8
	ALL icon	Selected to extract all data for reprinting and resending.	3-8, 3-9
	NORM. icon	Selected to extract only normal results for reprinting and resending.	3-9
	ab-NORM. icon	Selected to extract only abnormal measurement results for reprinting and resending.	3-9
	CLOCK icon	Appears when a measurement process is started, and flashes when measurement is interrupted or when a measurement process is ending. When this icon is appearing or flashing, the instrument will not accept key input.	–
	Communication icon	Appears during a communication process, and flashes to indicate a communication error.	3-6
	Print icon	Appears during a printing process, and flashes to indicate a printing error (e.g. insufficient thermal recording paper).	3-6
	SAVE icon	Appears when data are sent to and stored in the EEPROM.	–

1.3.4 Operator panel

Key	Name	Function
	START	Press to start measurement.
	STOP	Press to interrupt measurement, a menu function, setting, or to cancel an input operation.
	FEED	Thermal recording paper is fed to the built-in printer while this key is pressed.
	MENU	Press to move between menus or to change pages.
	ENTER	This “Enter” key selects a menu or item to be set, or confirms the input value.
	– (hyphen)	Press to select an item to be set, or to input a “– (hyphen)” character.
0 – 9	0 to 9 (numeric keys)	Use these numeric keys to select a menu or to input values.
	ID#	Press before inputting a patient ID number.
/	Left/right	Press to change the measurement mode and to move the cursor.

1.4 Installing the instrument

1.4.1 Precautions for installation

Before installing the instrument, read the following items and always take proper safety precautions.

- Install the instrument at least 20 cm away from walls. Inadequate clearance between the instrument and walls may cause overheating of the instrument or undesirable load on cable connections, thus resulting in fire or incorrect measurement results.
- Apply the correct voltage to the instrument. The wrong voltage may result in fire or damage to the instrument and consequently lead to personal injury.
- **Do not** disassemble or modify the instrument without our approval. This may result in fire, damage to the instrument and consequently personal injury.
- Install the instrument on a level, vibration-free sturdy platform. Operation of the instrument in an unstable place may cause trouble or malfunction of the instrument resulting in personal injury. **DO NOT** install the instrument where it may fall off or topple over.
- **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 fire or damage to the instrument and consequently lead to personal injury, or may otherwise cause incorrect measurement results.
- Install the instrument in a place not exposed to direct sunlight, condensation or wind. These factors may cause incorrect measurement results, as well as deformation of or damage to the instrument.
- Use an RS-232C cable to connect an external device to the instrument. Connection using other than an RS-232C cable may cause electric shock and fire. For more information, contact your distributor.
- Use an external communication cable shorter than 30 m. External communication cables are for indoor use only.
- Install the instrument where temperature and humidity can be maintained in the following ranges.
  Temperature: 10°C - 30°C
  Humidity: 20% - 80% R.H.
  Installation in measurement environments outside these ranges may result in incorrect measurement results.

1.4.2 Installation of the instrument

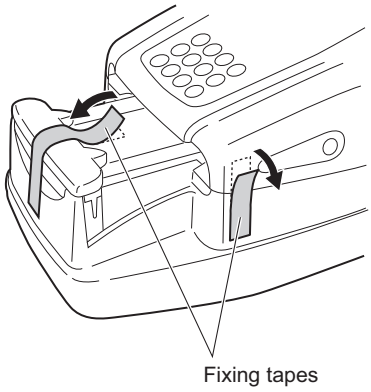
Certain components are held securely using fixing tape to protect the instrument from damage during transportation. The tapes must be removed and these security measures released to install the system and prepare the instrument for use.
Before installation, read “1.4.1. Precautions for installation” on page 1-17.

> ⚠ Use an RS-232C 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 details, contact your local distributor.

Prepare: AC adapter, power cord, carrying arm, and connection cable (sold separately) when communicating with an external device.

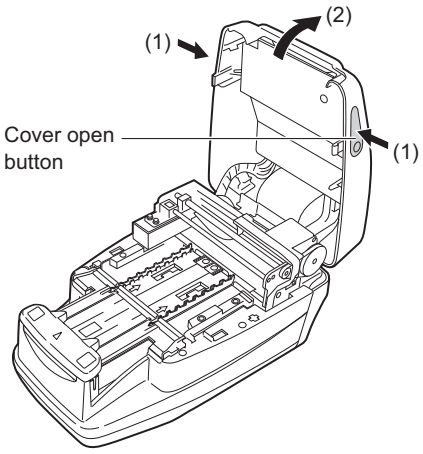
1 Release the carrying arm and maintenance cover.

❶ Remove the fixing tapes from the carrying arm and maintenance cover.



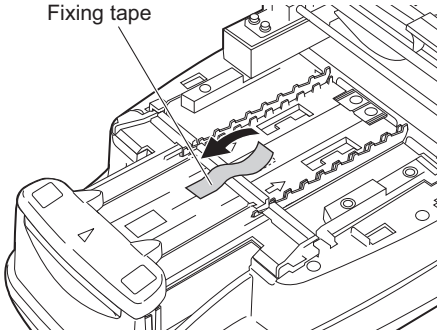
2 Open the maintenance cover

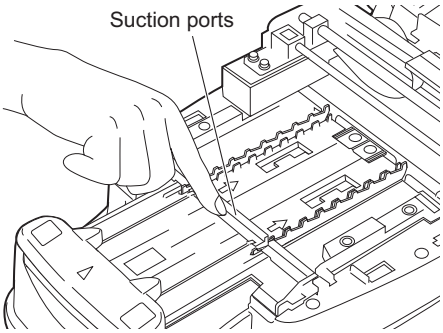
❶ Press and hold the two cover open buttons on either side of the instrument at the same time ((1) in the right figure) and open the maintenance cover ((2) in the right figure).



3 Release the suction ports

❶ Remove the fixing tape from the suction ports.

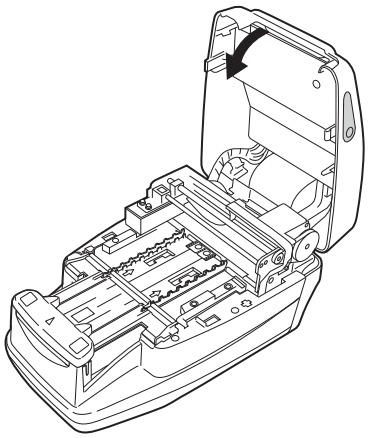




NOTE:
After removing the fixing tape, press the suction ports with your finger and ensure that the part is securely fixed in its proper position.

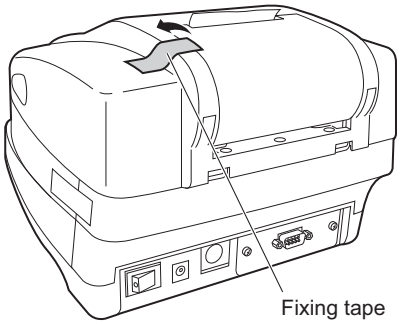
4 Close the maintenance cover

❶ Close the maintenance cover until it clicks closed.



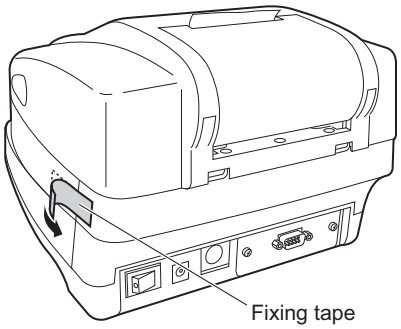
5 Release the printer cover

❶ Remove the fixing tape from the printer cover on the back of the instrument.



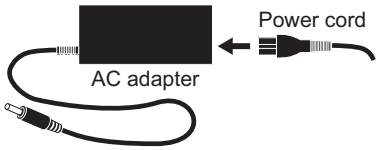
6 Release the waste box

❶ Remove the fixing tape from the waste box on the back of the instrument.



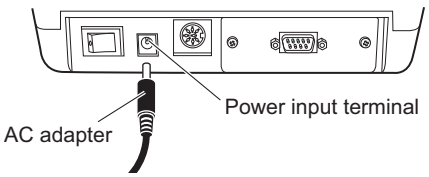
7 Connect the power cord

❶ Connect the power cord to the AC adapter.



❷ Check that the power switch at the back of the instrument is in the OFF position (the "◯" side of the ON/OFF switch should be visible).

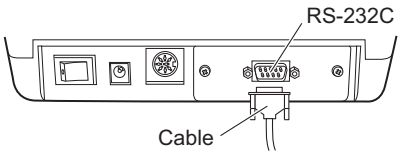
❸ Connect the AC adapter to the power input terminal on the back of the instrument and connect the plug of the power cord to a wall outlet.



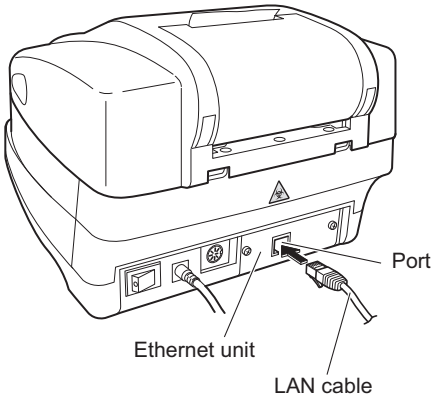
8 Connect an external device (if necessary)

REFERENCE:
Use an appropriate connection cable (option) when connecting an external device.

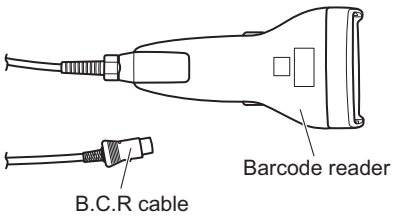
❶ Connect the cable from the external device to the RS-232C terminal on the back of the instrument. Tighten the terminal screws.



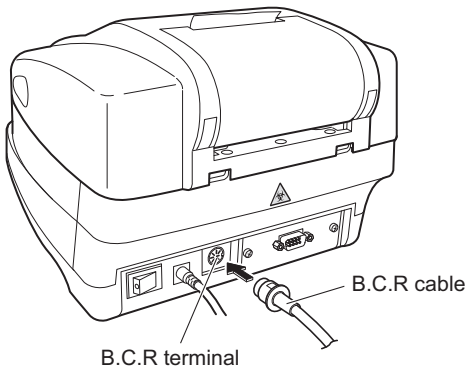
❷ To connect an external device using a LAN cable, ensure that an optional Ethernet unit is attached to the instrument, then connect the cable to the unit's LAN port.



9 Connect a handy barcode reader (if necessary)



❶ To use an optional handy barcode reader, connect the B.C.R. cable to the instrument's B.C.R. terminal.



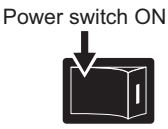
1.4.3 Starting and ending operation after installation

This section describes the startup process of the instrument, how to set the thermal recording paper, and how to set the date and time.

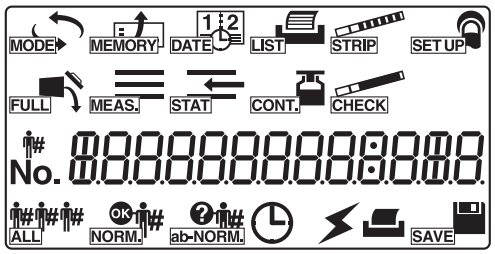
NOTE:
When the instrument is turned ON, the carrying arm repeats the test strip feeding movement. Ensure that nothing on the test strip tray obstructs the carrying arm movement.

1 Turn ON the instrument

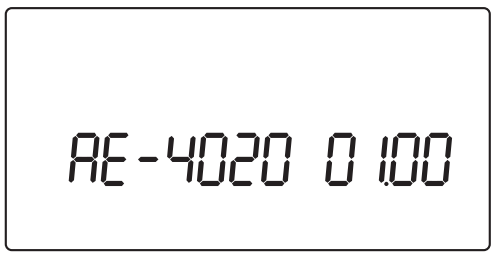
❶ Turn ON the power using the ON/OFF switch at the back of the instrument. When the switch is in the ON position, the " | " side of the ON/OFF switch will be visible.



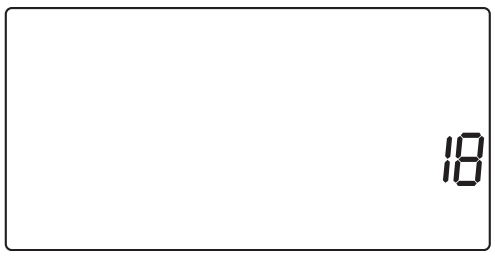
- All the icons and characters appear on the display screen for approximately 1 second.



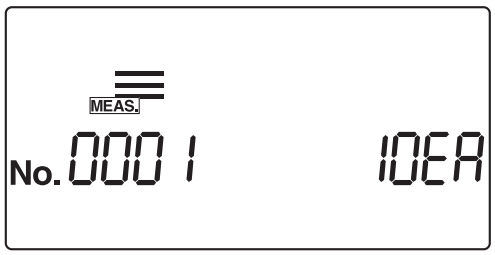
- The product name and system version (1.00 in the right figure) are displayed on the screen, and the system starts a self-diagnosis routine after approximately 2 seconds.
  The backup memory is checked for any abnormality.



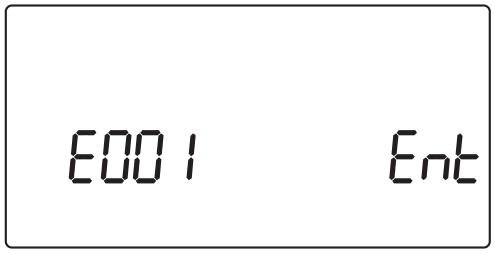
- The time is counted down (for 20 seconds) until the initialization of each mechanism in the instrument is completed. During the countdown, the carrying arm repeats the test strip feeding movement and the test strip feed mechanism makes feeding operations.



❷ After 20 seconds, the warm-up process ends, and the [Standby screen] appears.
The currently selected measurement mode, test strip type, and measurement number appear on the display screen.



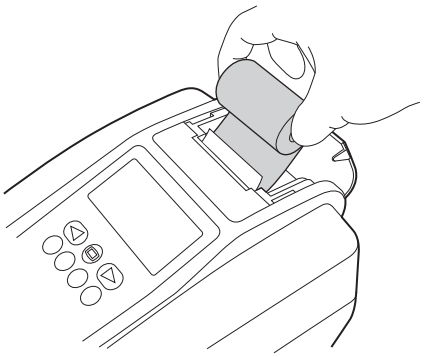
NOTE:
An error or problem is indicated by a buzzer alarm and a message on the screen, as shown in the right figure.
See “Chapter 5. Troubleshooting” to solve the error or problem.



2 Set the thermal recording paper

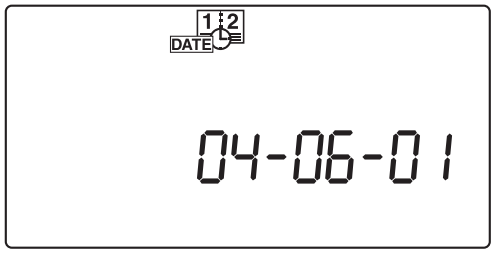
❶ Set a roll of the supplied thermal recording paper, referring to “4.2. Replacing the thermal recording paper” on page 4-12.

NOTE:
Always press the ☞ button after setting a new roll of thermal recording paper.
If you **do not** fully feed the thermal recording paper through the unit by pressing the ☞ button, the printer will fail to print the measurement results.



3 Set the date and time

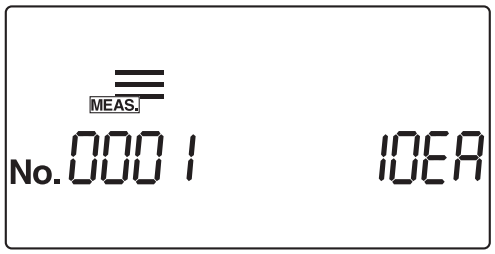
REFERENCE:
The time is displayed on the screen in the check measurement mode only.
In other measurement modes, the date and time are not displayed, but they are printed with the measurement results.



❶ Set the current date and time, referring to “3.4. DATE (setting the date and time)” on page 3-10.

4 Turn OFF the instrument

❶ At the end of work, or when you will not be performing measurements or making settings, turn OFF the instrument after first checking that the [Standby screen] is displayed.

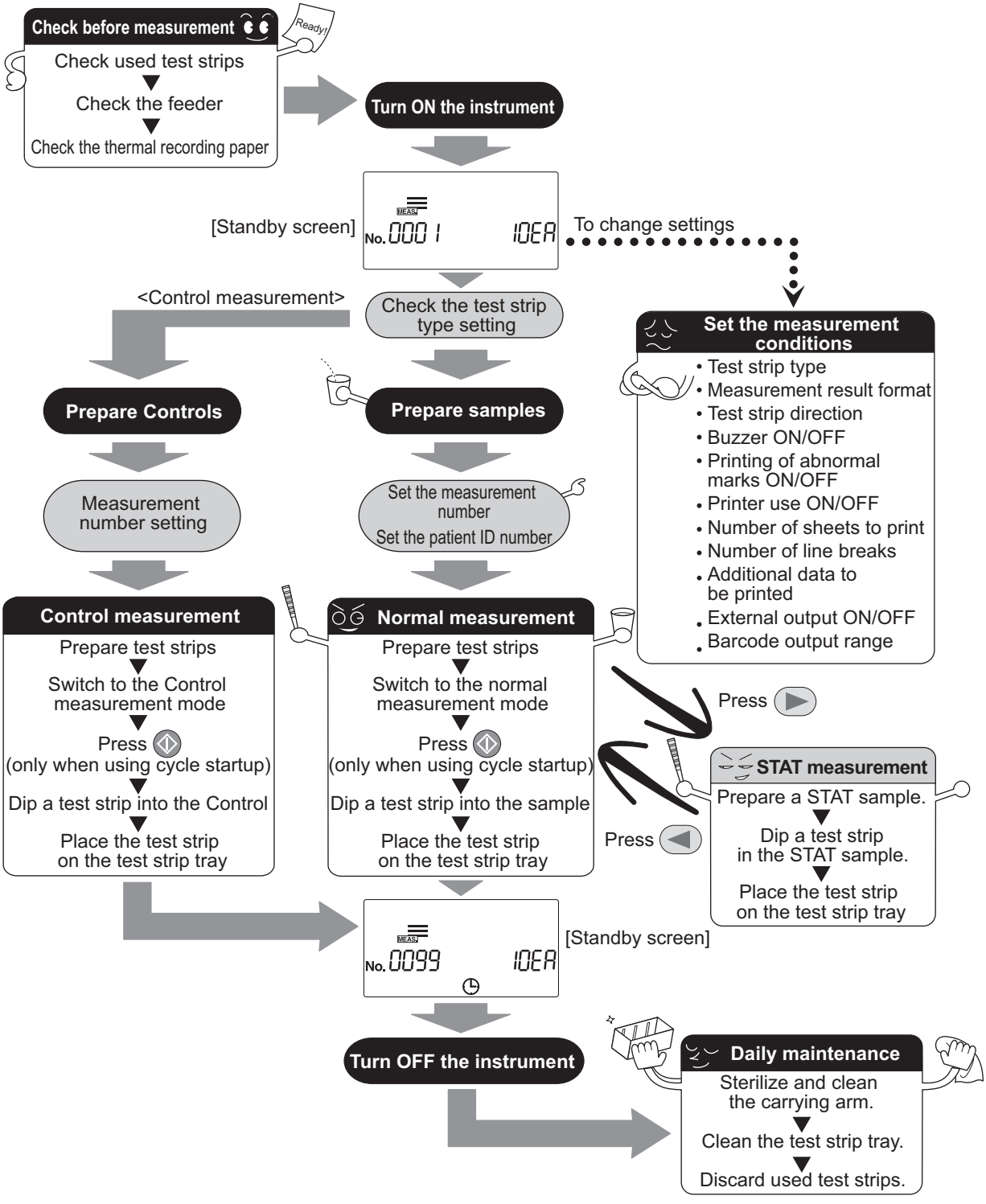


Chapter 2 Measurement Operation

2.1 Outline of measurement operation

This instrument measures samples and Controls. This chapter describes the operational flow and outline of each measurement mode.

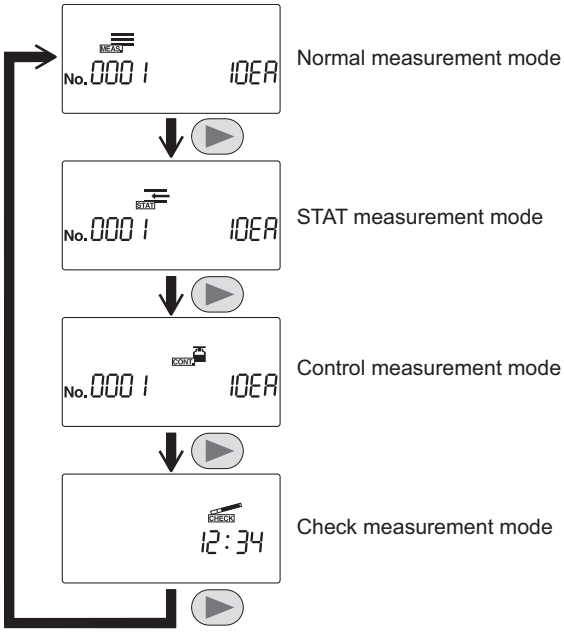
2.1.1 Measurement operational flow



2.1.2 Measurement

■ Measurement mode

This instrument has four types of measurement modes: “Normal measurement”, “STAT measurement”, “Control measurement” and “Check measurement”. Press ▶ on the [Standby screen] to change the measurement mode. The figures below show the appearance of the [Standby screen] for each of the four measurement modes.



■ Operational mode

Two operational modes are available, which affect the starting of measurements and operations during measurement.

● Auto start

When a dipped test strip is placed on the inlet, it will be detected by the auto start sensor in the section, and fed to the photometric section in 7-second intervals. You **do not** need to press the ◇ button to start a measurement. When a test strip is sensed, a short beep sounds. Subsequently placed test strips will be detected and measured in 7-second intervals. The timing buzzer can be set to “OFF” using the procedure explained in “3.7.9. No.006: Buzzer sound ON/OFF” on page 3-26.

● Cycle start

Press the ◇ button to start measurement from the standby status. The timing buzzer signals the test strip dipping timing to the user. After each test strip is placed on the inlet, it is fed to the photometric section in 7-second intervals. The inlet lever operates in 7-second intervals continuously regardless of whether a test strip is placed on the inlet section, and both the timing buzzer and the lever operate in the same interval. The timing buzzer can be set to “OFF” using the procedure explained in “3.7.9. No.006: Buzzer sound ON/OFF” on page 3-26.

REFERENCE:

The operational mode in effect when the instrument is turned ON can be selected. The standard setting is “auto start” (See “3.7.8. No.005: Operational mode when turning ON” on page 3-25). The timing buzzer signals the user the period (approx. 2 seconds) for dipping test strips in samples.

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 operating environment. Before turning ON the instrument, check that the “1.4.1.Precautions for installation” explained on page 1-17 have been followed.
- In the ambient temperature range of 10 to 30 °C, the temperature correction function operates to give the most accurate measurement results possible. However, for more precise results, we recommend that you perform measurement using the optimum operating environmental conditions, an ambient temperature of between 20 and 25 °C, and a relative humidity between 30 and 60 %.
- If you feel that the system 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 result in fire or damage to the instrument and consequently lead to personal injury.
- In case of instrument trouble, contact your local distributor for repairs. Unauthorized servicing or modification can damage the instrument and consequently lead to personal injury.
- Do not place a collection cup or any other vessel containing sample or other liquid on the unit. Sample or other liquid that gets inside the instrument may cause trouble.
- Any vibration during measurement may cause a malfunction and prevent accurate measurement. Vibration may also cause test strips to clog inside the instrument.
- Dip test strips in samples for approximately 2 seconds, following the beep sounds emitted by the instrument. Insufficient dipping of test strips may cause insufficient color change, while dipping too long may cause reagents to drain out of the test strip, either of which will prevent correct measurement.
- When dipping a test strip into sample, dip the whole the test strip pad area at once, but do not dip past the black mark on the test strip. If the black mark is wet, a correct measurement may not be obtained.

2.2.2 Precautions for handling samples

- TAKE THE UTMOST CARE WHEN HANDLING URINE. This system uses urine as sample and as an ingredient of Control. Urine may be contaminated by pathogenic microbes that can cause infectious diseases. Improper handling of urine may cause infection to the user or other individuals by pathogenic microbes.
- Discard used samples, parts and liquid waste in accordance with local regulations for biohazardous waste.

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 at a low temperature. When using samples that have been stored at low temperatures, allow them come to room temperature before making measurements.
- Stir samples well before measurement, but avoid subjecting them to centrifugation. Centrifugal force may cause undesirable sedimentation of blood cells and prevent obtaining proper measurements of certain items that need to be measured.
- Prepare sufficient volumes of samples so that each test strip pad area can be dipped entirely.
- Measure collected samples directly from collection. **Do not** add any antiseptic, anti-microbial agent, or detergent.
- **Do not** expose samples to direct sunlight. Exposure to direct sunlight may change their properties and prevent correct measurement.
- Sample containing ascorbic acid may give lower measurement results for GLU and BLD than actual values.
- **Do not** measure bloody urine, which may give incorrect measurement results.

2.2.3 Precautions for handling test strips

IMPORTANT:

- Use only ARKRAY's test strips designed for the AUTION ELEVEN
  The AUTION ELEVEN works with special test strips designed and made by ARKRAY, Inc. Thoroughly read the test strip package insert and use them by the expiry date.
- Check before use
  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. Measurements using such test strips will give incorrect results.
- Prepare test strips just before measurement
  Take out from the bottle only the number of test strips required for measurement. Unused test strips exposed to the air will absorb moisture or be contaminated with dust or dirt, which will cause incorrect measurements. After taking out the test strips, immediately close the bottle cap securely.
- **Do not** touch the test strip pad area
  Never touch the test strip pad area. Touching this with bare hands may cause sebum (skin oil) to adhere, which will cause incorrect measurements.
- Select the type of test strip
  Before measurement, select the correct type of test strip to use. Using test strips of a different type from that which the instrument is set to use will cause incorrect measurement results.
- **Do not** discard desiccant
  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 from the air, which would change their properties and cause incorrect measurements.

2.3 Preparation for measurement

Before starting measurement, check the waste box, feeder, and thermal recording paper.

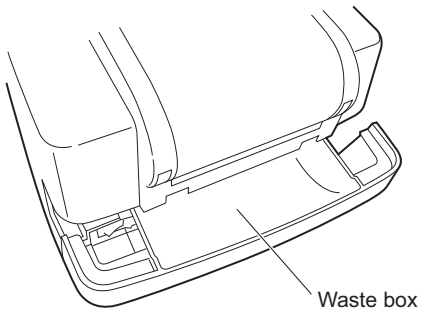
- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used test strips in accordance with local regulations for biohazardous waste.

NOTE:
The special test strips for the AUTION ELEVEN **do not** come with the instrument. Please purchase a sufficient supply before starting measurement.

2.3.1 Check before measurement

1 Check for used test strips

❶ Pull out the waste box to see if it is filled with used test strips.
If the waste box is full of test strips, discard them.

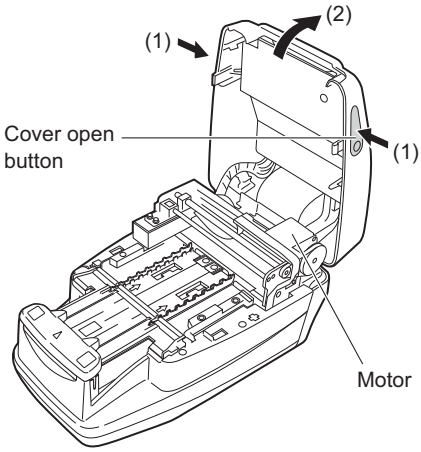


2 Open the maintenance cover

❶ Press and hold the two cover open buttons on either side of the instrument, ((1) in the right figure) to open the maintenance cover ((2) in the right figure).

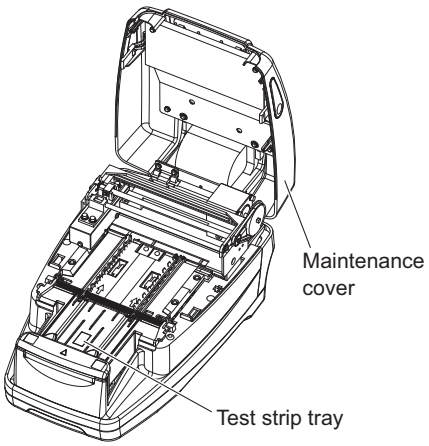
NOTE:
When the maintenance cover is opened, the power is automatically turned OFF.

Do not touch the motor, which may be hot.



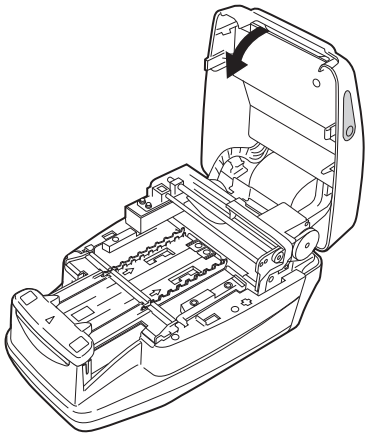
3 Check the feeder

❶ Check for the presence of crystallized surplus urine adhering to the test strip tray.
If you find any, wipe it off and clean the area.



4 Close the maintenance cover

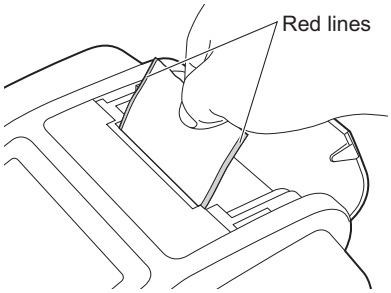
❶ Close the maintenance cover until it clicks closed.



5 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, referring to “4.2. Replacing the thermal recording paper” on page 4-12.

REFERENCE:
If measurement is started without the thermal recording paper set correctly, an error message appears.



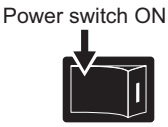
2.3.2 Starting the instrument

This section describes the instrument's operation from the time it is turned ON until the [Standby screen] is displayed.

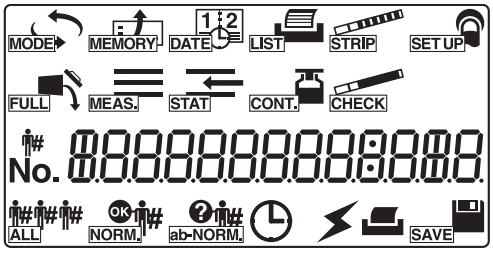
NOTE:
When the instrument is turned ON, the carrying arm repeats the test strip feeding movement. Ensure that nothing on the test strip tray obstructs the carrying arm movement.

1 Turn ON the instrument

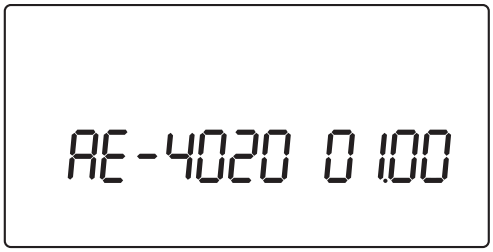
❶ Turn ON the power switch at the back of the instrument. When the power is turned ON, the " | " side of the ON/OFF switch will be visible.



- All the icons and characters fully appear on the screen for approximately 1 second.

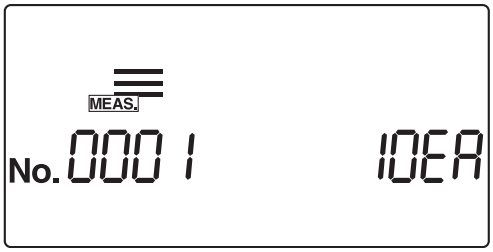


- The product name and system version (1.00 in the right figure) are displayed on the screen, and the system starts a self-diagnosis routine after approximately 2 seconds.
  The backup memory is checked for any abnormality.



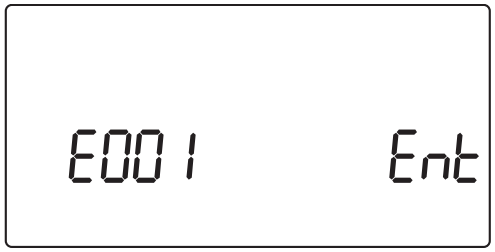
- The time is counted down (for 20 seconds) until the initialization of each mechanism in the instrument is completed. During the countdown, the carrying arm repeats the test strip feeding movement and the test strip feed mechanism makes feeding operations.

- After 20 seconds, the warm-up process ends, and the [Standby screen] appears.
  The currently selected measurement mode, test strip type, and measurement number appear on the display screen.



NOTE:

An error or problem is indicated by a buzzer alarm and a message on the screen, as shown in the right figure. See “Chapter 5. Troubleshooting” to solve the error or problem.



2.3.3 Setting measurement conditions

Before starting measurement, set the measurement conditions as required. If you wish to use the same measurement conditions as the last time, you need not set them again. See “Chapter 3. Supplementary Operations” for explanations concerning how to set individual items.

The currently selected conditions can be printed (See “3.7.4. No.001: Printing of parameters” on page 3-19) for checking.

Item No	Setting item	Description	Standard value	See pages
No.002	Test strip type	Specifies the test strip type for each measurement mode.	10EA*1	3-20
No.003	Measurement result format	Specifies the format of measurement results (semiquantitative value or reflectance) for each measurement.	0	3-22
No.004	Test strip placing direction	Specifies which direction test strips should be placed on the test strip tray.	0	3-24
No.005	Operational mode when turning ON	Specifies the operational mode used when the instrument is turned ON.	0	3-25
No.006	Buzzer sound ON/OFF	Specifies whether to sound the timing notification buzzer.	1	3-26
No.007	Printing of abnormal marks	Specifies whether to apply (when printing or communicating with an external device) an abnormal mark to the measurement result when an abnormal value is detected in a sample.	1	3-27
No.008	Initialization of measurement number when turning ON	Specifies whether the system initializes the measurement number when the instrument is turned ON.	1	3-28
No.009	Printer use	Specifies whether the built-in printer is used.	1	3-29
No.010	Number of sheets to print	Specifies the number of sheets to print when printing measurement results.	1	3-30
No.011	Number of line breaks	Specifies the number of line breaks between each measurement result.	1	3-31
No.012*2	Additional data	Specifies whether to output data to an external device.	1	3-32
No.013	External output ON/OFF	Selects whether or not to output data to an external source.	0	3-33
No.014	Barcode output range setting	Specifies the first digit to read.	1	3-34
		Specifies the number of digits to read.	13	

*1 For devices with 10V specifications, the default display is "10V", as shown at the right. 

*2 For measurement using several types of test strips, set the additional data to be printed to “1: Measurement number + Status (Date and time + Test strip type + Temperature)” or “2: Measurement number + Status (Date and time + Test strip type + Temperature + ID number)”. If you select “0: Only measurement number”, the test strip type will not printed, so you will not be able to distinguish which type of test strip was used.

2.3.4 Sample preparation

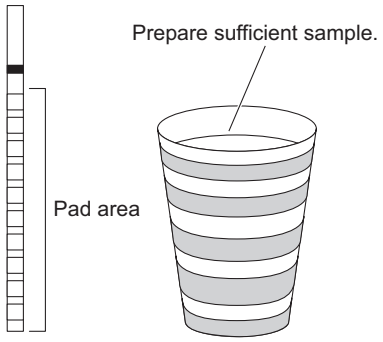
Prepare samples according to the following steps, referring to “2.2.2. Precautions for handling samples” on page 2-5.

> Wear protective gloves to prevent exposure to pathogenic microbes.

1 Preparing samples

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

❶ Prepare the samples in their collection cups.



2 Stirring the sample

❶ Stir each sample well in its collection cup.

IMPORTANT:
Do not centrifuge samples.
Centrifugal force may cause undesirable sedimentation of blood cells and/or other sample contents, thus causing several measurement items to have incorrect results.

2.3.5 Entering patient ID numbers

Each patient ID number can have up to 13 digits of numeric figures and "–" characters entered. The patient ID number entered is uniquely allocated to the measurement made just after this entry is made. After a group of measurements is completed, the patient ID numbers are automatically deleted.

REFERENCE:

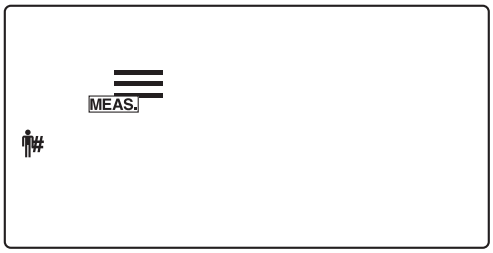
- In addition to the patient ID number, a measurement number is also allocated to each sample. The measurement number is automatically incremented by one for each successive measurement from the start of measurement until the instrument is turned OFF.
- When using a hand-held barcode reader (optional), you need not manually enter the patient ID number. Follow the procedures in "■ To enter a patient ID number using a barcode" on page 2-14.

■ To manually input a patient ID number

1 Call up the screen

❶ With the [Standby screen] displayed, press .

• The [Patient ID number input screen] appears.

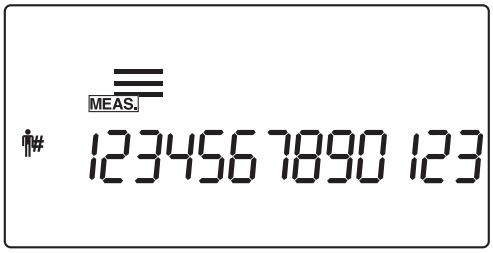


2 Enter a patient ID number

❶ Enter a patient ID number.

• You can enter up to 13 digits using the numeric and (−) keys.

NOTE:
If the input value exceeds 13 digits, the first digit (the leftmost digit) will be deleted.

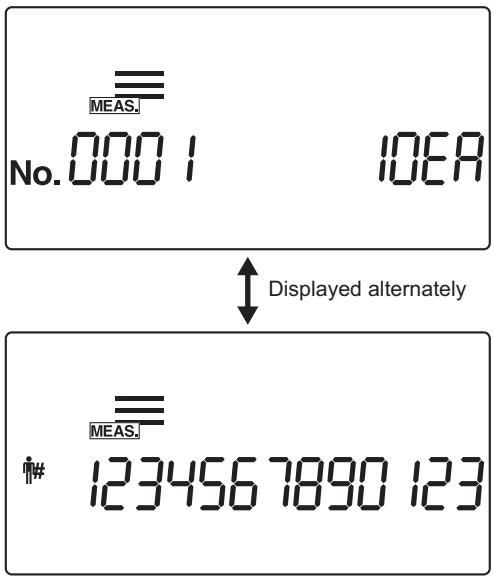


REFERENCE:

- If a patient ID number has already been set, the highest-order digit (leftmost digit) flashes. If you then input a number or "–", the next digit to the right flashes. The flashing digit accepts key input.
- If you press (▽) during input, the currently input patient ID number is cancelled and the instrument returns to the [Standby screen].

❷ Press .

- The recorded patient ID number is stored and the display returns to the [Standby screen].
- Once the patient ID number is set, the “measurement number + test strip type” and “patient ID number” are displayed alternately on the [Standby screen].

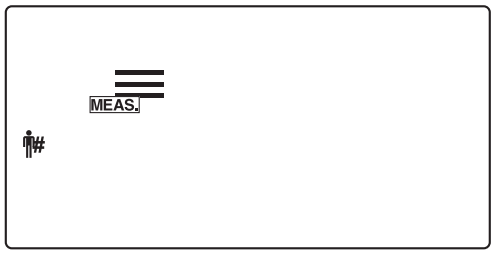


■ To enter a patient ID number using a barcode

1 Call up the screen

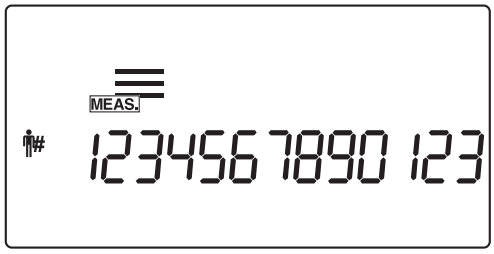
❶ With the [Standby screen] displayed, press .

- The [Patient ID number input screen] appears.



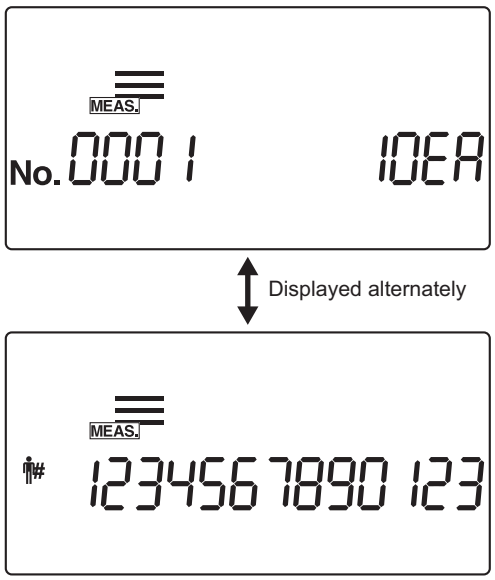
2 Enter patient ID number by reading its barcode

❶ Use a hand-held barcode reader to scan the barcode on the label, which will enter the ID number when the [Patient ID number input screen] is displayed.



❷ Press ↵ .

- The entered patient ID number is stored and the display returns to the [Standby screen].
- Once the patient ID number is set, the “measurement number + test strip type” and “patient ID number” are displayed alternately on the [Standby screen].



REFERENCE:

To cancel a patient ID number after pressing ↵ , press and hold # for about 2 seconds.

2.4 Measurement operation

2.4.1 Normal measurement

Normal measurement mode is used for consecutive measurement of samples. To measure one or more urgent samples immediately during a normal measurement process, press ◀ or ▶ to switch to the STAT measurement mode.

Wear protective gloves to prevent exposure to pathogenic microbes.

1 Prepare the samples

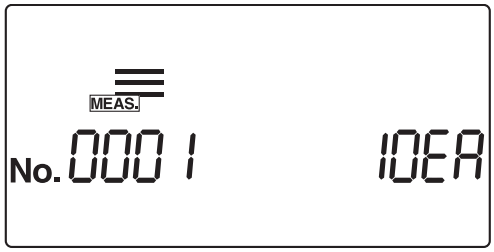
❶ Prepare the samples, referring to “2.3.4. Sample preparation” on page 2-12.

2 Set the measurement number

After the first sample is allocated a 4-digit measurement number, the system automatically increments the measurement number by one. These measurement numbers are stored in the system until the power is turned OFF. To set the first measurement number to “0001”, **do not** enter a measurement number, but follow the procedure in step **3** below.

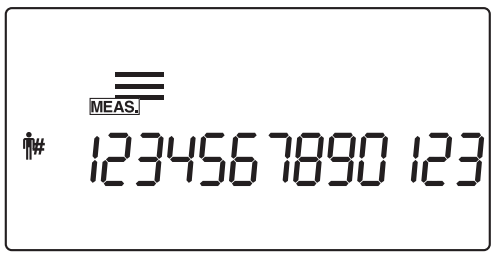
❶ Enter a measurement number using the numeric keys and press ↵.

- You can enter any value from 0 to 9999. When the measurement number “9999” is incremented, the sequence will begin again from “0000”.



3 Set the patient ID number (when required)

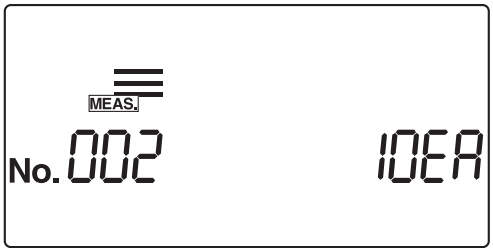
❶ Enter the patient ID number, referring to “2.3.5. Entering patient ID numbers” on page 2-13.



4 Prepare test strips

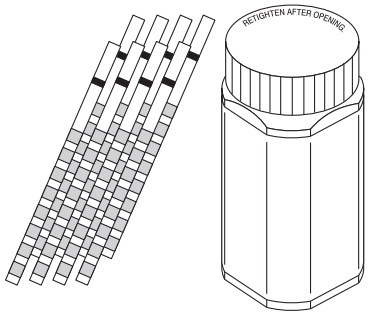
REFERENCE:

The currently set test strip type is displayed on the [Standby screen]. To change the test strip type, please refer to “3.7.5. No.002: Test strip type” on page 3-20.



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

❷ Close the test strip bottle cap securely.

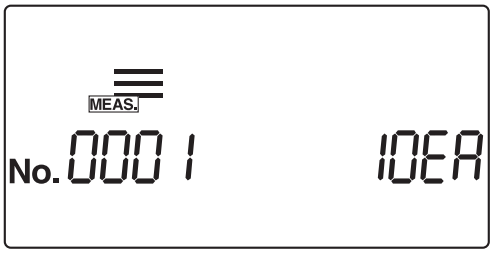


IMPORTANT:

After taking the test strips out of the bottle, immediately close the cap or the test strips in the bottle will absorb moisture or dirt in the air, which may deteriorate reagents and make the test strips useless.

5 Start normal measurement

❶ Confirm that the icon (MEAS.) for normal measurement appears on the [Standby screen].

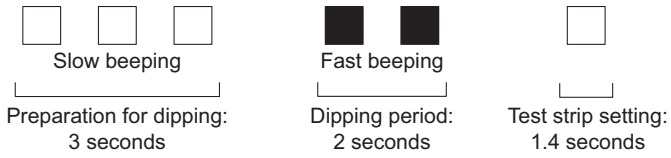


IMPORTANT:

Different procedures at this stage are required, depending on the setting of the “operational mode when turning ON” parameter. (See “■ Operational mode” on page 2-3.)
The standard setting is “Auto start” mode. To change the “operational mode when turning ON” parameter, see “3.7.8. No.005: Operational mode when turning ON” on page 3-25.

REFERENCE:

When the buzzer setting is ON, the buzzer sounds in the following intervals to signal the dipping timing for the test strips.



- When using the “Auto start” mode, go to step **6**.
- When using the “Cycle start” mode, press ◇ and go to step **6**.

6 Dip a test strip in the sample for 2 seconds

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

IMPORTANT:

- Dip the entire test strip pad area in the sample at once. **Do not** allow the black mark shown in the figure to become wet. If the test strip is dipped too deeply and the black mark is moistened, correct measurement may not be obtained.

- After dipping the test strip in the sample, remove excess urine using the edge of the collection cup.
- In the “Auto start” mode, the buzzer does not sound for the first measurement. Always dip the test strip for 2 seconds. Insufficient dipping of test strips may cause insufficient color change, while dipping too long may cause reagents to drain out of the test strip, either of which will prevent correct measurement.

REFERENCE:

When the buzzer setting is ON, the buzzer sounds for 2 seconds to signal the dipping timing.

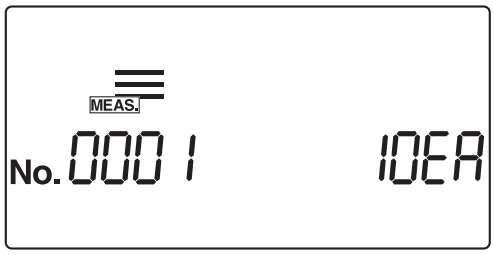
7 Place the test strip on the test strip tray

❶ Place the test strip on the test strip tray.

In the auto start mode, the instrument makes a beep sound when detecting a test strip.

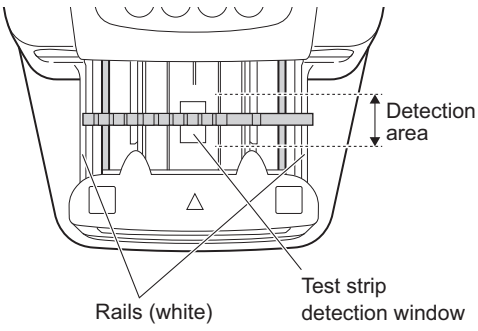
Then the carrying arm moves the test strip to the suction ports.

After surplus urine has been removed, the test strip is fed through the test strip feed mechanism to the photometric section.



NOTE:

Place a test strip in the detection area of the test strip detection window as shown in the right figure. If the system does not detect the test strip in the auto start mode, remove and replace it in the center of the test strip detection widow. At this time, the test strip must cross both of the white rails in the detection area. If the test strip is not placed in the correct position, it may not be transported properly, leading to a strip jam or inaccurate measurement result.

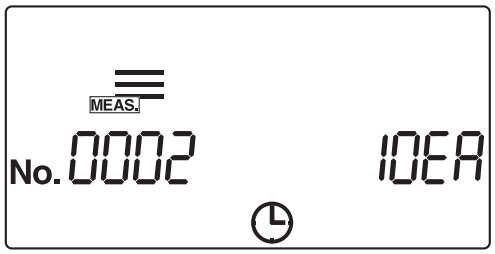


Pay attention to the carrying arm when it moves, so as not to have your fingers caught or pinched.

8 Prepare the next sample and test strip

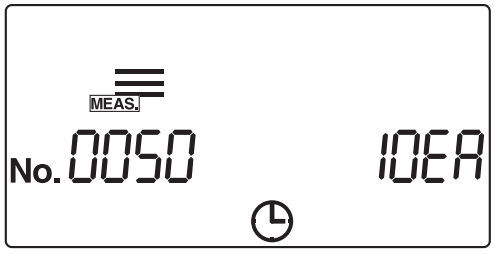
❶ Repeat steps **6** and **7** for dipping and setting subsequent test strips.

- When a test strip is placed, the system automatically starts the measurement of the next sample.



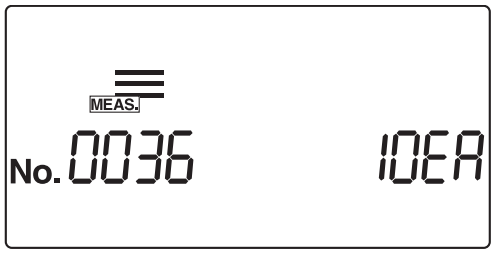
REFERENCE:

- The measurement number can be changed during the measurement process. To change the measurement number from “0005” to “0050”, for example, input (5) (0) and press (↵) .
  After displaying “---”, the system changes the measurement number to the input number and then the screen returns to the [Measurement screen].
- To interrupt measurement, press (▽) . The system then stops measurement and the display returns to the [Standby screen].
  The measurement and patient ID numbers for the next measurement are displayed on the [Standby screen].



9 Finish normal measurement

❶ When the normal measurement finishes, the display returns to the [Standby screen].
The measurement and patient ID numbers for the next measurement are displayed on the [Standby screen].



2.4.2 STAT measurement

The STAT measurement mode, like the normal measurement mode, measures samples consecutively. The STAT measurement mode can also be used for measuring urgent samples during normal measurement.
With the [Standby screen] or [Measurement screen] displayed, press ◀ or ▶ to switch to the STAT measurement mode.

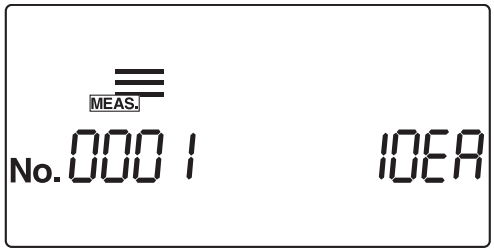
Wear protective gloves to prevent exposure to pathogenic microbes.

1 Prepare the samples

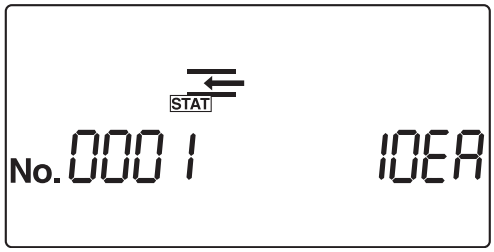
❶ Prepare the samples for STAT measurement, referring to section "2.3.4. Sample preparation" on page 2-12.

2 Change the measurement mode

❶ Check that the [Standby screen] or [Measurement screen] is displayed.



❷ Press ◀ or ▶ to switch to the STAT measurement mode.
- On the [Standby screen], the STAT icon is displayed and the mode changes to the STAT measurement mode. When the measurement mode is switched, the measurement number restarts from "0001".

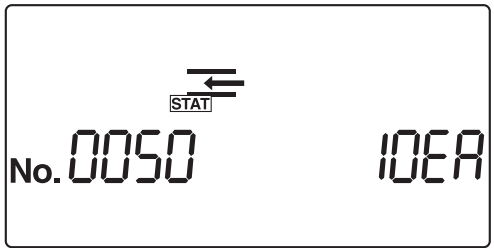


3 Set the measurement number

After the first sample is allocated a 4-digit measurement number, the system automatically increments the measurement number by one. The measurement numbers are stored in the system until the power is turned OFF. To set the first measurement number to "0001", **do not** enter a measurement number, but follow the procedure in step **4** below.

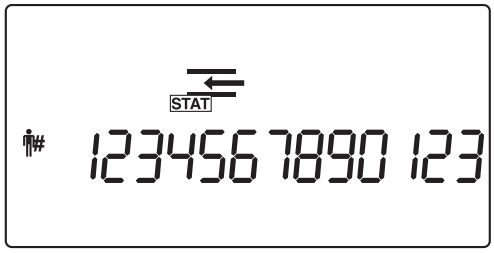
❶ Enter a measurement number using the numeric keys and press  .

- Your can enter any value from 0 to 9999. When the measurement number "9999" is incremented, the sequence will begin again from "0000".



4 Set the patient ID number (when required)

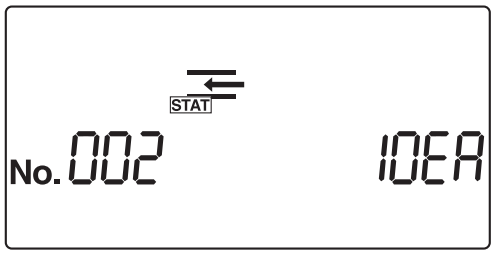
❶ Enter the patient ID number, referring to "2.3.5. Entering patient ID numbers" on page 2-13.



5 Prepare test strips

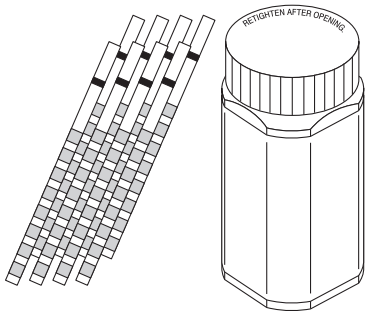
REFERENCE:

The currently set test strip type is displayed on the [Standby screen]. To change the test strip type setting, see "3.7.5. No.002: Test strip type" on page 3-20.



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

❷ Close the test strip bottle cap securely.



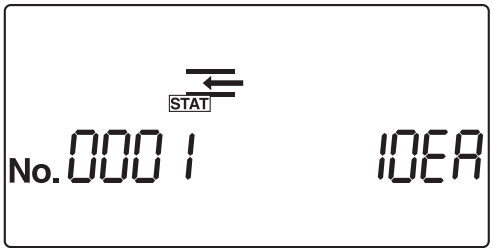
IMPORTANT:

After taking the test strips out of the bottle, immediately close the cap, or the test strips in the bottle will absorb moisture or dirt in the air, which may deteriorate reagents and make the test strips useless.

6 Start the STAT measurement

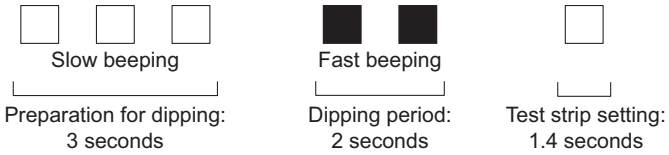
IMPORTANT:

Different procedures at this stage are required, depending on the setting of the “operational mode when turning ON” parameter. (See “■ Operational mode” on page 2-3.)
The standard setting is “Auto start” mode. To change the “operational mode when turning ON”, see “3.7.8. No.005: Operational mode when turning ON” on page 3-25.



REFERENCE:

When the buzzer setting is ON, the buzzer sounds in the following intervals to signal the dipping timing for the test strips.



- When using the “Auto start” mode, go to step **7**.
- When using the “Cycle start” mode, press ◇ and go to step **7**.

7 Dip a test strip in the sample for 2 seconds

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

IMPORTANT:

- Dip the entire test strip pad area in the sample at once. **Do not** allow the black mark shown in the figure to become wet. If the test strip is dipped too deeply and the black mark is moistened, correct measurement may not be obtained.

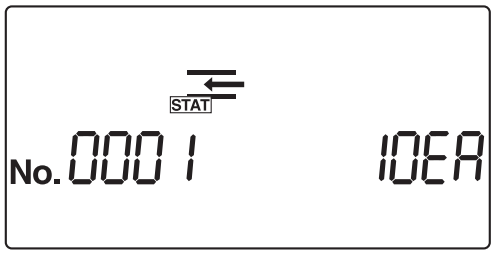
- After dipping the test strip in the sample, remove excess urine using the edge of the collection cup.
- In the “Auto start” mode, the buzzer does not sound for the first measurement. Always dip the test strip for 2 seconds. Insufficient dipping of test strips may cause insufficient color change, while dipping too long may cause reagents to drain out of the test strip, either of which will prevent correct measurement.

REFERENCE:

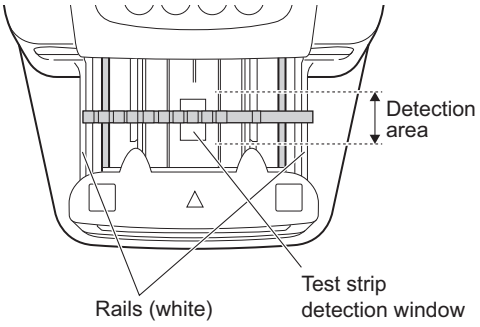
When the buzzer setting is ON, the buzzer sounds for 2 seconds to signal the dipping timing.

8 Place the test strip on the test strip tray

❶ Place the test strip on the test strip tray.
In the auto start mode, the instrument makes a beep sound when detecting a test strip.
Then the carrying arm moves the test strip to the suction ports.
After surplus urine has been removed, the test strip is fed through the test strip feed mechanism to the photometric section.



NOTE:
Place a test strip in the detection area of the test strip detection window as shown in the right figure. If the system does not detect the test strip in the auto start mode, remove and replace it in the center of the test strip detection widow. At this time, the test strip must cross both of the white rails in the detection area. If the test strip is not placed in the correct position, it may not be transported properly, leading to a strip jam or inaccurate measurement result.

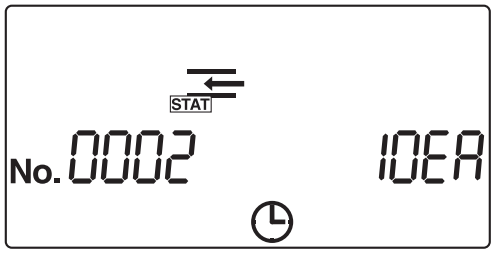


Pay attention to the carrying arm when it moves, so as not to have your fingers caught or pinched.

9 Prepare the next sample and test strip

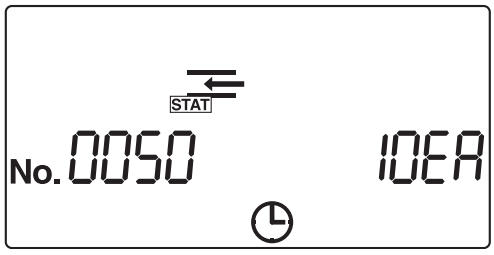
❶ Repeat steps **6** and **7** for dipping and setting subsequent test strips.

- When a test strip is placed, the system automatically starts the measurement of the next sample.



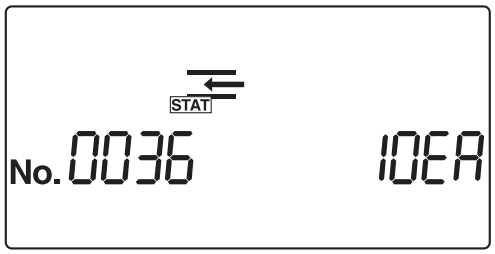
REFERENCE:

- The measurement number can be changed during the measurement process. To change the measurement number from “0005” to “0050”, for example, input 5 0 and press ↵ .
  After displaying “---”, the system changes the measurement number to the input number and then the screen returns to the [Measurement screen].
- To interrupt measurement, press ▽ . The system then stops measurement and the display returns to the [Standby screen].
  The measurement and patient ID numbers for the next measurement are displayed on the [Standby screen].



10 Finish STAT measurement

❶ When the STAT measurement finishes, the display returns to the [Standby screen].
The measurement and patient ID numbers for the next measurement are displayed on the [Standby screen].



2.4.3 Control measurement

Conduct Control measurement periodically to check the precision of the instrument.

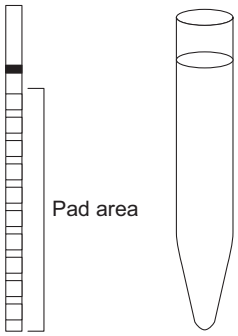
Wear protective gloves to prevent exposure to pathogenic microbes.

Prepare: Controls that are commercially available,laboratory or manufactured by ARKRAY*
*AUTION CHECK PLUS manufactured by ARKRAY are recommended.
*For information on Contorol manufactured by ARKRAY, contact your distributor.

1 Prepare the Control

IMPORTANT:
Prepare a sufficient volume of Control in a vessel so that the entire test strip pad area can be dipped at once.

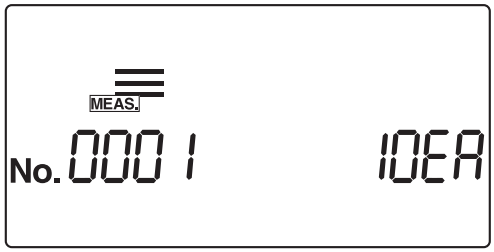
NOTE:
Before using a Control, read carefully its package insert.



❶ Prepare the Control.

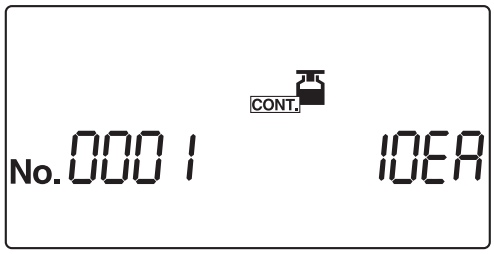
2 Change the measurement mode

❶ Check that the [Standby screen] is displayed.



❷ Press ◀ or ▶ to switch to the Control measurement mode.

- On the [Standby screen], the CONT. icon is displayed and the mode changes to the Control measurement mode. When the measurement mode is switched, the measurement number restarts from “0001”.

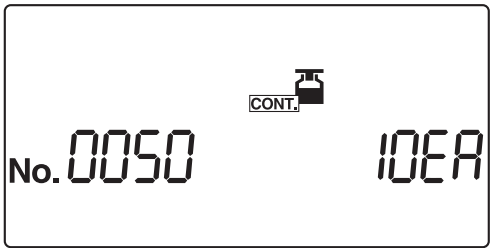


3 Set a measurement number

After the first sample is allocated a 4-digit measurement number, the system automatically increments the measurement number by one. The measurement numbers are then stored in the system until the power is turned OFF. To set the first measurement number to "0001", **do not** enter a measurement number, but follow the procedure in step **4** below.

❶ Enter a measurement number using the numeric keys and press ↵ .

- Your can enter any value from 0 to 9999. When the measurement number "9999" is incremented, the sequence will begin again from "0000".



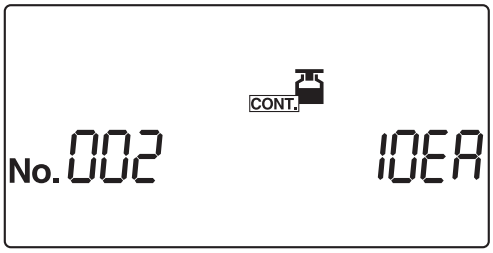
REFERENCE:

Patient ID number setting is disabled in the Control measurement mode.

4 Prepare the test strips

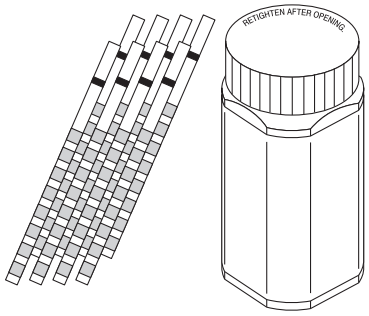
REFERENCE:

The currently set test strip type is displayed on the [Standby screen]. To change the test strip type, refer to "3.7.5. No.002: Test strip type" on page 3-20.



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

❷ Close the test strip bottle cap securely.



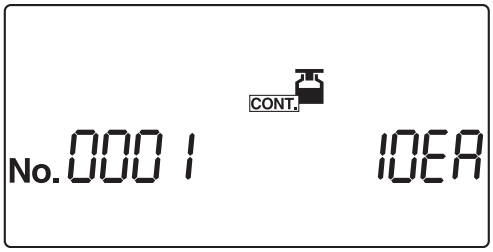
IMPORTANT:

After taking the test strips out of the bottle, immediately close the cap, or the test strips in the bottle will absorb moisture or dirt in the air, which may deteriorate reagents and make the test strips useless.

5 Start the Control measurement

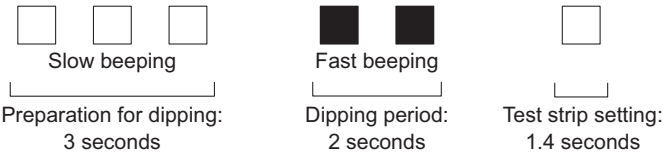
IMPORTANT:

Different procedures at this stage are required, depending on the setting of the “operational mode when turning ON” parameter. (See “■ Operational mode” on page 2-3.)
The standard setting is “Auto start” mode. To change the “operational mode when turning ON”, see “3.7.8. No.005: Operational mode when turning ON” on page 3-25.



REFERENCE:

When the buzzer setting is ON, the buzzer sounds in the following intervals to signal the dipping timing for the test strips.



- When using the “Auto start” mode, go to step **6**.
- When using the “Cycle start” mode, press ◇ and go to step **6**.

6 Dip a test strip in the sample for 2 seconds

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

IMPORTANT:

- Dip the entire test strip pad area in the sample at once. **Do not** allow the black mark shown in the figure to become wet. If the test strip is dipped too deeply and the black mark is moistened, correct measurement may not be obtained.

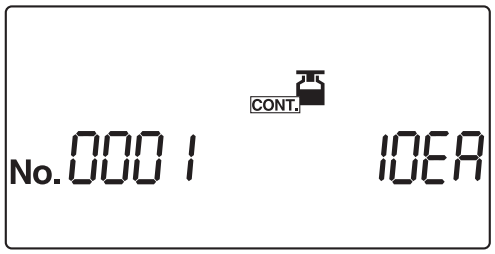
- After dipping the test strip in the sample, remove excess urine using the edge of the collection cup.
- In the “Auto start” mode, the buzzer does not sound for the first measurement. Always dip the test strip for 2 seconds. Insufficient dipping of test strips may cause insufficient color change, while dipping too long may cause reagents to drain out of the test strip, either of which will prevent correct measurement.

REFERENCE:

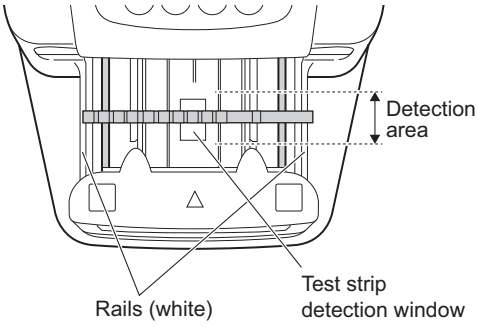
When the buzzer setting is ON, the buzzer sounds for 2 seconds to signal the dipping timing.

7 Place the test strip on the test strip tray

❶ Place the test strip on the test strip tray.
In the auto start mode, the instrument makes a beep sound when detecting a test strip.
Then the carrying arm moves the test strip to the suction ports.
After surplus urine has been removed, the test strip is fed through the test strip feed mechanism to the photometric section.



NOTE:
Place a test strip in the detection area of the test strip detection window as shown in the right figure. If the system does not detect the test strip in the auto start mode, remove and replace it in the center of the test strip detection widow. At this time, the test strip must cross both of the white rails in the detection area. If the test strip is not placed in the correct position, it may not be transported properly, leading to a strip jam or inaccurate measurement result.

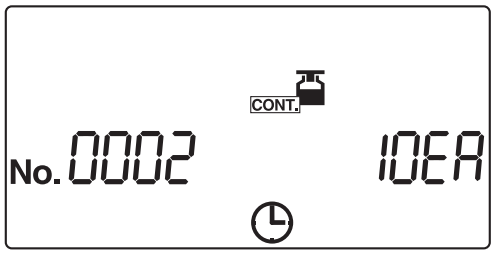


Pay attention to the carrying arm when it moves, so as not to have your fingers caught or pinched.

8 Prepare the next Control and test strip

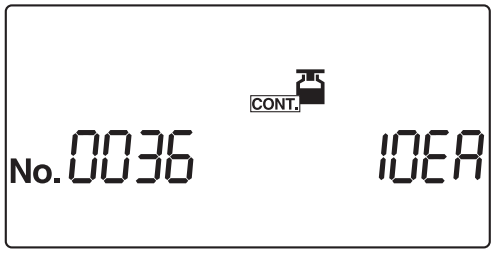
❶ Repeat steps **6** and **7** for dipping and setting subsequent test strips.
- When a test strip is placed, the system automatically starts the measurement of the next Control.

REFERENCE:
To interrupt the measurement, press . The system stops measurement and the display returns to the [Standby screen]. The measurement number for the next Control and test strip type appears on the [Standby screen].



9 End Control measurement

❶ When the Control measurement finishes, the display returns to the [Standby screen].
The measurement and patient ID numbers for the next measurement are displayed on the [Standby screen].



2.4.4 Check measurement

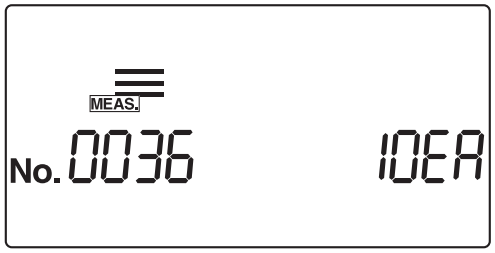
Check measurement is conducted using the check strips that are included with the instrument, to confirm the system status. The check strip bottle contains two gray and two white check strips. Use one test strip of each color for this measurement procedure.

IMPORTANT:
Do not touch the check strip surfaces. Sebum (skin oil) adhered on the surface may result in incorrect measurements.

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

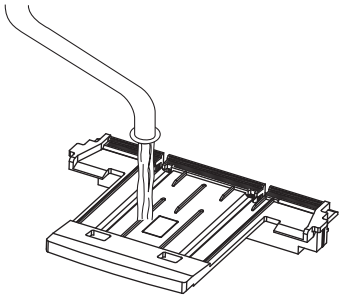
1 Clean each section

❶ After confirming that the [Standby screen] is displayed, turn OFF the instrument.



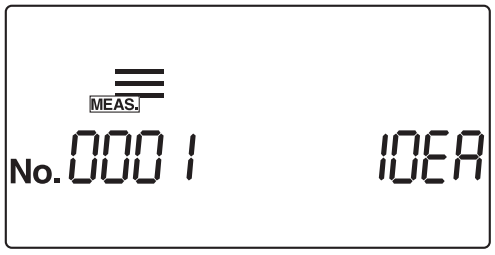
❷ Thoroughly clean the feeder and the waste box, referring to pages 4-2 to 4-10.

NOTE:
Unless these cleaning procedures are properly carried out before the check measurement, the check strips may become soiled and be ruined.

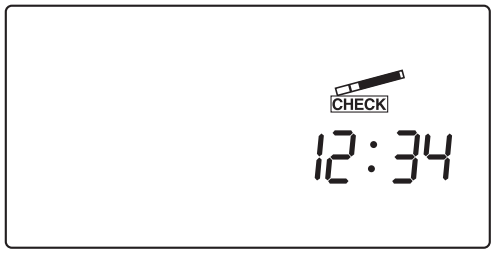


2 Change the measurement mode

❶ Turn ON the instrument.

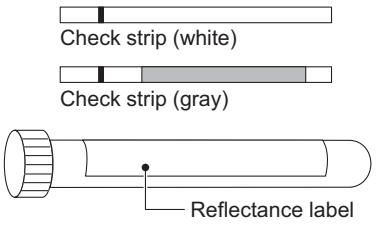


❷ Press ◀ or ▶ to switch to check measurement mode.
- On the [Standby screen], the CHECK icon is displayed, and the measurement mode is switched to the Check measurement mode.



3 Prepare the check strips

❶ Prepare the check strips. The check strip bottle has a reflectance label on it, which must be used when evaluating reflectance after the check measurement. Keep this labeled bottle in an easily accessible place.



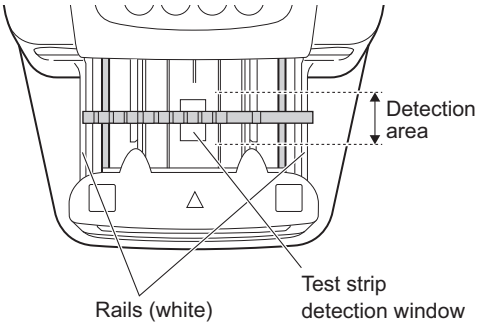
NOTE:
500 nm is not used as a measurement wavelength for the AUTION ELEVEN AE-4020. Thus, check measurement results printout will not include a 500 nm result. The description of 500 nm in the reflectance label on the check strip bottle is for other types of devices.

4 Start the check measurement

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

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

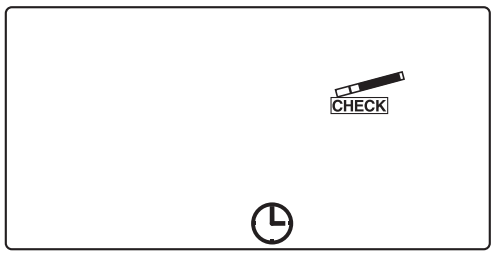
NOTE:
Place a test strip in the detection area of the test strip detection window as shown in the right figure. If the system does not detect the test strip in the auto start mode, remove and replace it in the center of the test strip detection widow. At this time, the test strip must cross both of the white rails in the detection area. If the test strip is not placed in the correct position, it may not be transported properly, leading to a strip jam or inaccurate measurement result.



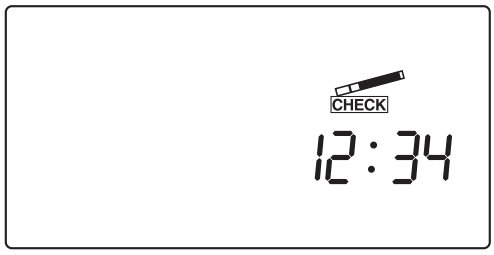
Pay attention to the carrying arm when it moves, so as not to have your fingers caught or pinched.

IMPORTANT:
Different procedures at this stage are required, depending on the setting of the “operational mode when turning ON” parameter. (See “■ Operational mode” on page 2-3.)
The standard setting is “Auto start” mode. To change the operational mode when turning ON, see “3.7.8. No.005: Operational mode when turning ON” on page 3-25.

- When using the “Cycle start” mode, press to start the check measurement of the first strip.
- In the “Auto start” mode, the system automatically starts the check measurement of the first strip when placement of the check strip is detected.

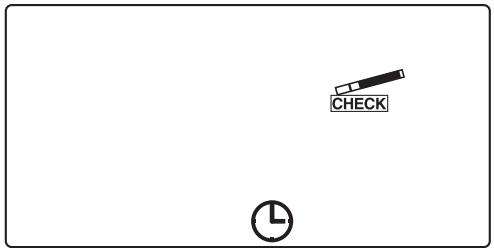


❷ The check strip is fed to the photometric section through the test strip feed mechanism.
- After the check measurement is complete, the display returns to the [Standby screen].
  The check measurement result of the white check strip is printed.



5 Start the check measurement of the second strip

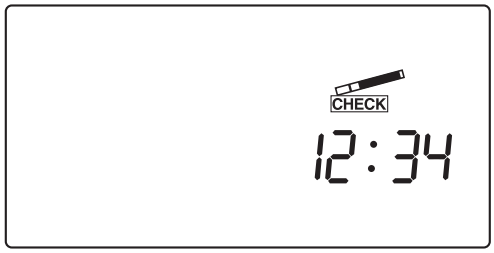
❶ Place a gray check strip on the test strip tray.
- When using the “Cycle start” mode, press to start the check measurement of the second strip.
- In the “Auto start” mode, the system automatically starts the check measurement of the second strip when placement of the check strip is detected.



❷ The carrying arm and test strip feed mechanism transport the check strip to the photometric section.

6 End the check measurement

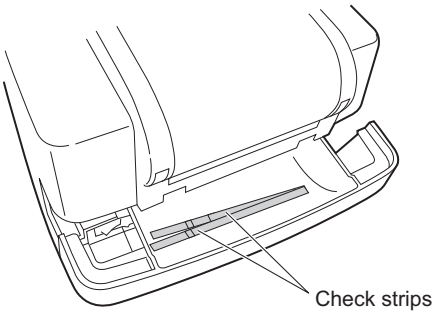
❶ When the check measurement finishes, the display returns to the [Standby screen].
  The check measurement result of the gray check strip is printed.



7 Remove the check strips

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

❷ Return the check strips to the check strip bottle for safekeeping.



8 Evaluate reflectance

See the samples of the printed check measurement results on the next page.

Check that the reflectance at each wavelength printed for the check measurement result is within the ranges written on the reflectance label.

NOTE:
500 nm is not used as a measurement wavelength for the AUTION ELEVEN AE-4020. 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.

● If the measurement results are within the ranges

The system is functioning normally, so the check measurement is finished.

● If any of the measurement results are outside the specified ranges

Either the check strip is defective or the system is not functioning properly.
Repeat the check measurement using the two other check strips remaining in the check strip bottle, and then go to step **9**.

IMPORTANT:
- If “COM: W001” is printed with the measurement results, this indicates that light entered the system and prevented proper measurement. After taking steps to remove the source of the intrusive light or mitigate its effects, repeat the check measurement using the same check strips.
- If “COM: W003” is printed with the measurement results, this indicates that the check strip was not placed in the correct position. Repeat the check measurement using the same check strip.

9 Reevaluation

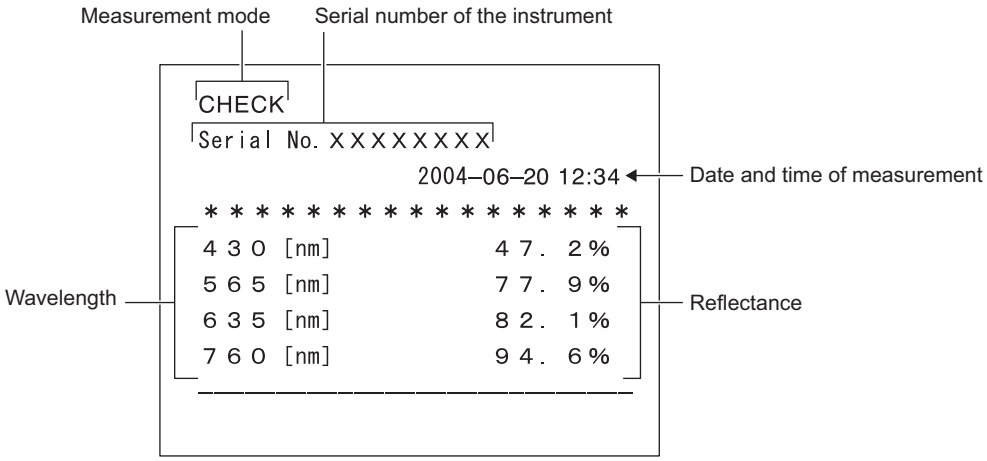
● If the measurement results are within the ranges

The check strips used for the first check measurement are faulty. **Do not** use these check strips again.

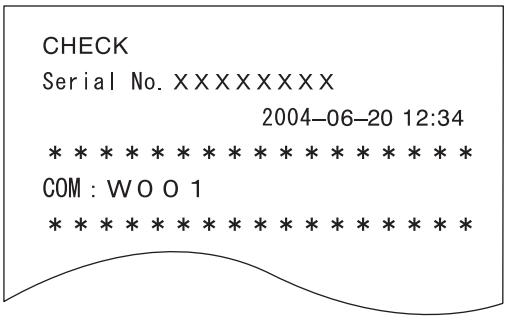
● If any of the measurement results are outside the specified ranges

The instrument is faulty.
Contact your local distributor.

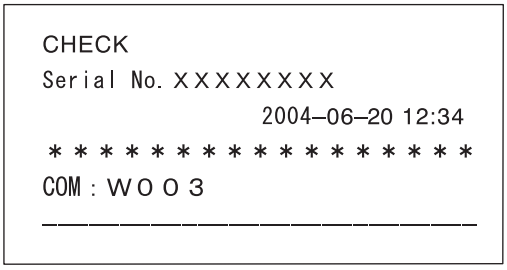
■ Check measurement results



- When unwanted light entered the instrument and prevented proper measurement

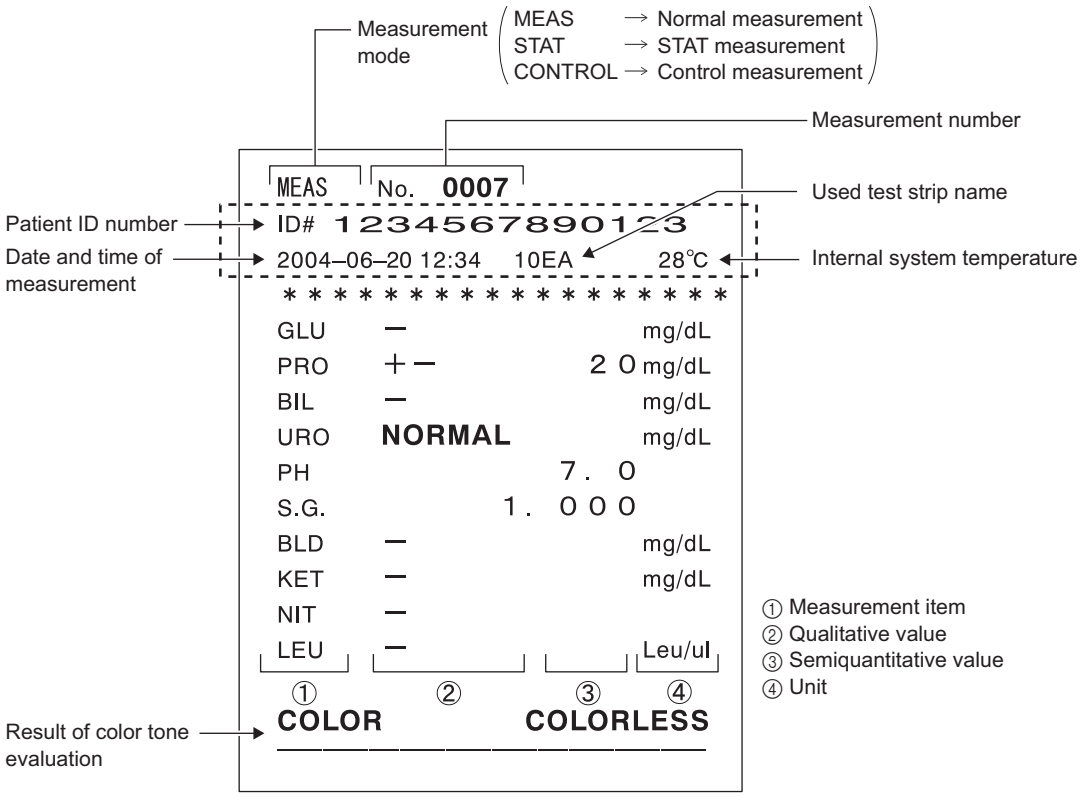


- When the check strip was not placed in the correct position and proper measurement was impossible



2.5 How to read the measurement results

- When the measurement result format is “semiquantitative”.

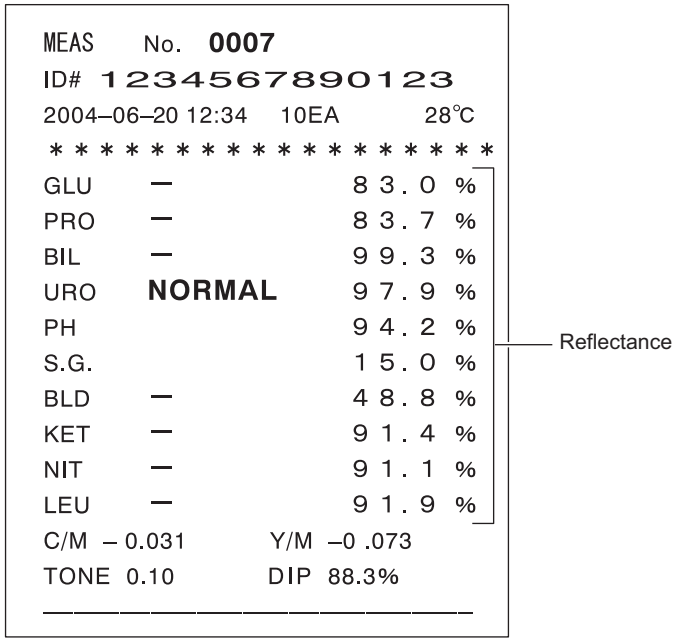


If a measurement result has any abnormality, a sample error mark “” is printed before the measurement mode.
*If the system has any abnormality, a measurement error mark “?” is printed before the measurement mode.
If any of the measurement items is abnormal, an abnormal mark “” or abnormal color mark “!” is added to the item.
*The items printed within the dotted rectangle illustrated vary according to the additional data printing parameter setting. To change this setting, see “3.7.15. No.012: Additional data” on page 3-32.
The system can extract results tagged with abnormal marks (or ?) and print them in a list. Details concerning this function are given in section “3.5. LIST (printing a list of abnormal measurement results)” on page 3-12.

REFERENCE:

If a warning message “W* * *” is printed with the measurement results, see “5.1. Warning messages” on page 5-2 for a description of the problem and measures that can be taken.

- When the selected measurement result format is “reflectance”:



Chapter 3 Supplementary Operations

3.1 Outline of menu screen

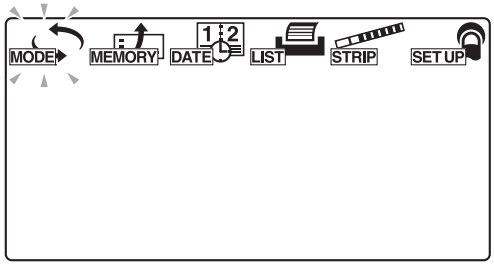
This system has six menus, each of which is represented by an icon displayed in a group at the top of the menu screen. By selecting the icon of the menu you wish to work with, you can switch to the setup screen for that menu and then make the appropriate settings.

3.1.1 How to operate the menu screen

Below is the operation method for the menu screen.

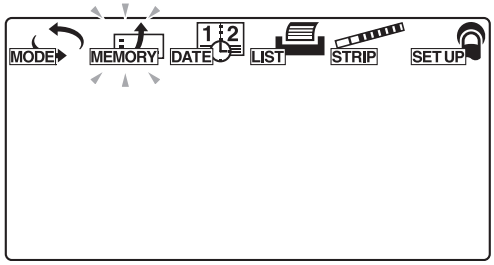
1 Call up the menu screen

❶ With the [Standby screen] displayed, press .
- The [Menu screen] then appears and MODE flashes.

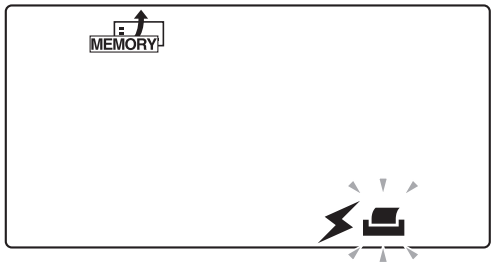


2 Select a menu

❶ Press ◀ or ▶ to choose the desired menu icon, which will flash.



❷ Press ↵ .
- The selected menu is confirmed, and the screen switches to the setup screen for that menu.



❸ Detailed settings can then be made using the selected menu's setup screen.

3.1.2 Menu list

The following lists the six menus and their purpose.

Menu	Icon	Description	Pages
MODE		Measurement mode selection	3-4
MEMORY		Reprinting and resending measurement results	3-6
DATE		Setting the date and time	3-10
LIST		Printing a list of abnormal measurement results	3-12
STRIP		Selecting the test strip type	3-14
SETUP		User settings	3-16

3.2 MODE (measurement mode selection)

Use the MODE menu to choose or change the measurement mode.
See section “2.4. Measurement operation” on page 2-16 for details concerning the measurement method for each mode.

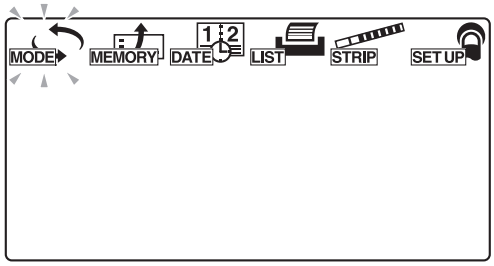
REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Menu screen].

1 Call up the menu screen

❶ With the [Standby screen] displayed, press ▭ .
• The [Menu screen] appears and MODE flashes.

2 Select the MODE (measurement mode selection) menu

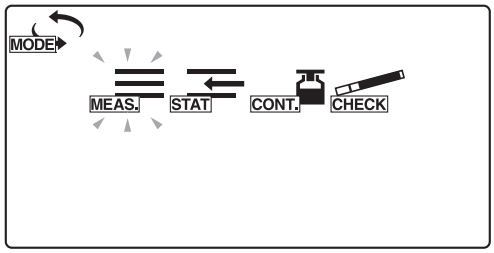
❶ Press ◀ or ▶ several times until MODE flashes.



❷ Press ↵ .
• The [MODE screen] appears.

3 Select the measurement mode

❶ Press ◀ or ▶ to select the desired measurement mode, which will flash.



• MEAS. : Normal measurement mode
STAT : STAT measurement mode
CONT. : Control measurement mode
CHECK : Check measurement mode

❷ Press ↵ .
• The selected measurement mode is confirmed and the display returns to the [Menu screen].

4 Quit the MODE menu (measurement mode selection)

❶ Press  .

- The display returns to the [Standby screen].

REFERENCE:

- When the [Standby screen] is displayed, you can change the measurement mode directly by pressing  or  .
- You can toggle between the Normal and STAT measurement modes by pressing  or  when in either of these two measurement modes.

3.3 MEMORY (reprinting and resending measurement results)

Use the MEMORY menu to reprint or resend measurement data (of up to 520 samples) stored in the instrument's memory. The stored measurement results are classified by measurement mode and by measurement result.
To reprint or resend the data, specify the "measurement period", "measurement mode", "sample", and "measurement result type" so that the desired measurement results will be selected for output.
The reprint/resend functions are available even if the settings for built-in printer use and external equipment use are set to "OFF".

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Menu screen].

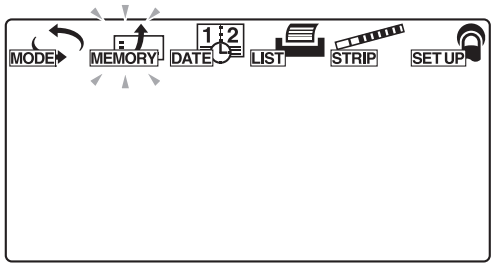
1 Call up the menu screen

❶ With the [Standby screen] displayed, press ▭ .
• The [Menu screen] appears and MODE flashes.

2 Choose MEMORY (to reprint or resend the measurement results)

❶ Press ◀ or ▶ several times until MEMORY flashes.

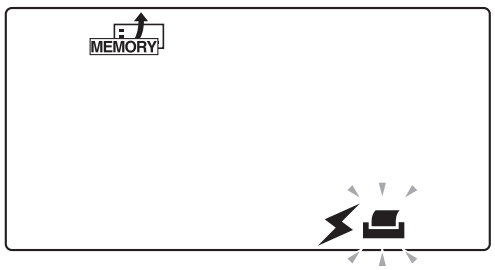
❷ Press ↵ .
• The [Output method selection screen] appears.



3 Select the desired output method

❶ Press ◀ or ▶ several times until the desired output method flashes.
• ⚡ : Resend
🖷 : Reprint

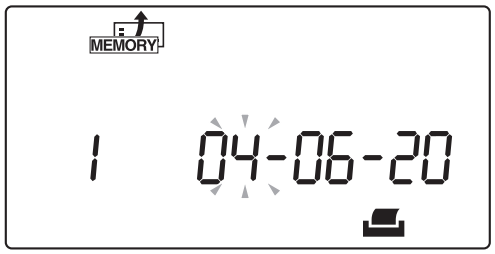
❷ Press ↵ .
• The output method is confirmed and the [Start date of measurement period input screen] appears.



4 Specify the start date of the measurement period

❶ Use (−) to move the flashing indicator, and use the numeric keys to enter the start date of the measurement period to be reprinted or resent.
- The digit for the year, month, or date accepting input flashes.

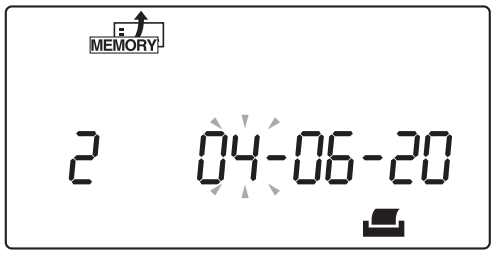
❷ Press (↵) .
- The start date of the measurement period is confirmed and the [Measurement period end date input screen] appears.



5 Specify the end date of the measurement period

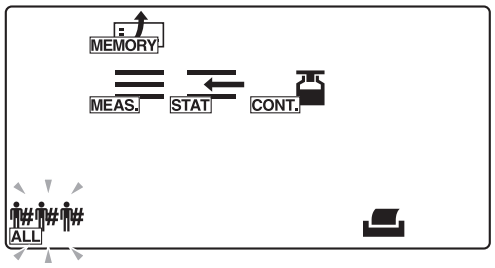
❶ Use (−) to move the flashing indicator, and use the numeric keys to enter the end date of the measurement period to be reprinted or resent.
- The digit for the year, month, or date accepting input flashes.

❷ Press (↵) .
- The end date of the measurement period is confirmed and the [Measurement mode selection screen] appears.



6 Select the measurement mode

❶ Press (◀) or (▶) several times until the desired measurement mode flashes.
- ALL : All three modes below
- MEAS. : Normal measurement mode
- STAT : STAT measurement mode
- CONT. : Control measurement mode

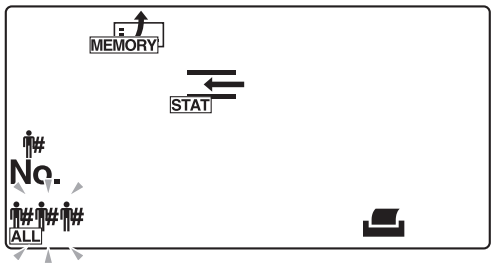


❷ Press (↵) .
- If ALL or CONT. is selected, the [Measurement result type selection screen] appears. Go to step **10**.
- If MEAS. or STAT is selected, the [Sample selection screen] appears. Go to step **7**.

7 Select the sample extraction method

❶ Press ◀ or ▶ several times until the desired method for extracting samples flashes.

- ALL : Extracts all samples
- : Extracts by patient ID number
- **No.** : Extracts by measurement number



❷ Press ↵ .

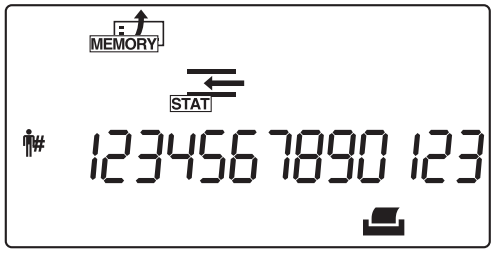
- If ALL is selected, the [Measurement result type selection screen] appears. Go to step **10**.
- If is selected, the [Patient ID number input screen] appears. Go to step **8**.
- If **No.** is selected, the [Measurement number input screen] appears. Go to step **9**.

8 Specify the patient ID number

❶ Enter a patient ID number using the numeric keys and − .

❷ Press ↵ .

- The entered patient ID number is confirmed and the [Measurement result type selection screen] appears.



REFERENCE:

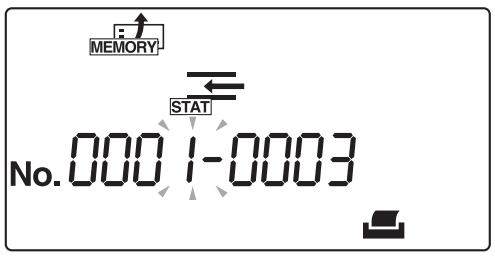
A patient ID number can be recalled from the memory using a hand-held barcode reader, if the ID number has previously been entered using a hand-held barcode reader.

9 Specify the measurement number range

❶ Press − to switch between the starting and ending measurement numbers, and enter these numbers using the numeric keys.

❷ Press ↵ .

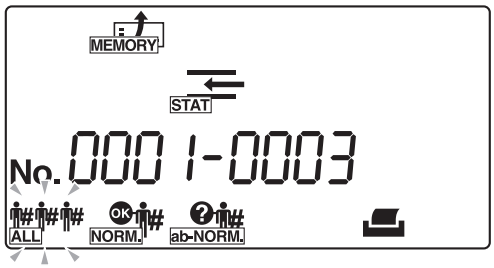
- The entered starting and ending measurement numbers are confirmed and the [Measurement result type selection screen] appears.



10 Select the search result type

❶ Press ◀ or ▶ several times until the desired measurement result type flashes.

- ALL : All the measurement results
- NORM. : Measurement results of normal samples
- ab-NORM. : Measurement results of abnormal samples



REFERENCE:

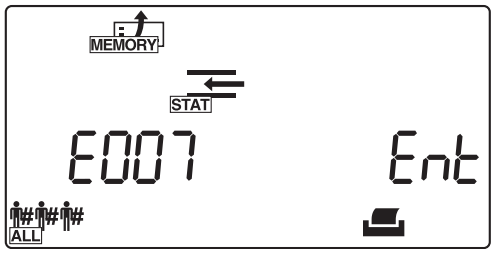
Different screens appear, depending on the sample data extraction method selected in step **7**. The screen to the right shows an example of data extraction by measurement number range.

❷ Press ↵ .

- The measurement results meeting the specified conditions are extracted and printed or transmitted. When the printing or data transmission is complete, the display returns to the [Menu screen].

REFERENCE:

- To interrupt the reprinting or resending of data, press ▽ . The system then stops reprinting or resending data and the display returns to the [Menu screen].
- If no measurement results meet the selected condi-tion(s), the [“Not found” error screen] appears, as shown in the figure. In this case, press ↵ to return to the [Menu screen].



11 Quit this menu

❶ Press ▽ .

- The display returns to the [Standby screen].

3.4 DATE (setting the date and time)

Use the DATE menu to set the date and time. After setting the date and time, you will not need to set them again until after a long period of use, when a deviation may indicate the need for adjustment.

REFERENCE:

If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Menu screen].

1 Call up the menu screen

❶ With the [Standby screen] displayed, press ▭ .

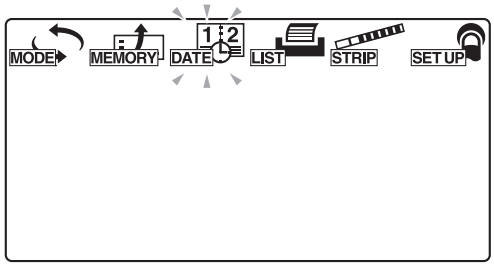
• The [Menu screen] appears and MODE flashes.

2 Select DATE (date and time setting)

❶ Press ◀ or ▶ several times until DATE flashes.

❷ Press ↵ .

• The [Date input screen] appears.



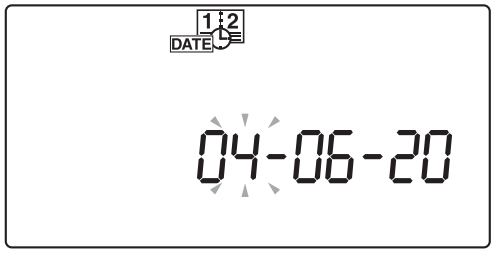
3 Set the date

❶ Use − to move the flashing indicator, and use the numeric keys to enter the current date.

• The digit for the year, month, or date accepting input flashes.

❷ Press ↵ .

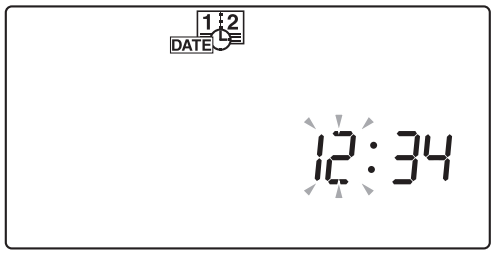
• The entered date is confirmed, and the [Time input screen] appears.



4 Set the time

❶ Use (−) to move the flashing indicator, and use the numeric keys to enter current time.
- Hour or minute that can be entered blinks.

❷ Press (↵) .
- The entered time is confirmed, and the [Menu screen] appears.



5 Quit the date and time setting menu

❶ Press (▽) .
- The display returns to the [Standby screen].

3.5 LIST (printing a list of abnormal measurement results)

Use the LIST menu to print a list of measurement results, along with sample error marks "*" and measurement error marks "?", extracted from the records of up to 520 samples stored in the system. See "2.5. How to read the measurement results" on page 2-34 for details concerning these error marks.

REFERENCE:

If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Menu screen].

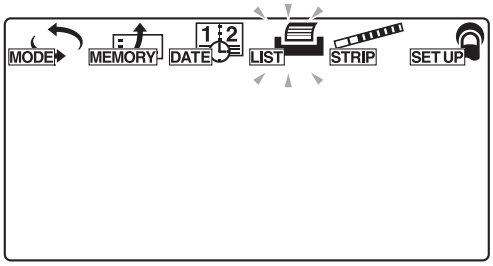
1 Call up the menu screen

❶ With the [Standby screen] displayed, press ▭ .

• The [Menu screen] appears and MODE flashes.

2 Select LIST (print abnormal measurement results list)

❶ Press ◀ or ▶ several times until LIST flashes.



❷ Press ↵ .

• The [Measurement date input screen] appears.

3 Specify the measurement date

❶ Use − to move the flashing indicator, and use the numeric keys to enter the date of the measurement results you want to print.

• The digit for the year, month, or date accepting input flashes.

❷ Press ↵ .

• The system starts searching, and then prints a list of the search results.

After the list is printed, the display returns to the [Menu screen].

REFERENCE:

- To interrupt printing, press ▽ . The system stops printing and the display returns to the [Menu screen].
- If no measurement results meet the selected condi-tion(s), the ["Not found" error screen] appears as shown in the right figure. In this case, press ↵ to return to the [Menu screen].

4 Quit the LIST setup menu

❶ Press  .

- The display returns to the [Standby screen].

3.6 STRIP (selecting the test strip type)

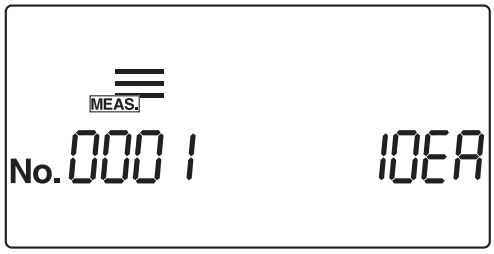
Use the STRIP menu to select the type of test strips to use in each measurement mode.

REFERENCE:

If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Menu screen].

1 Select the measurement mode

❶ With the [Standby screen] displayed, press ◀ or ▶ to switch the instrument to a measurement mode in which you wish to set the test strip type.



2 Call up the menu screen

❶ Press ▭ in the [Standby screen].

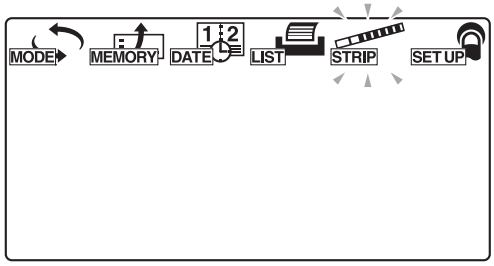
• The [Menu screen] appears and MODE flashes.

3 Select STRIP (select the test strip type)

❶ Press ◀ or ▶ several times until STRIP flashes.

❷ Press ↵ .

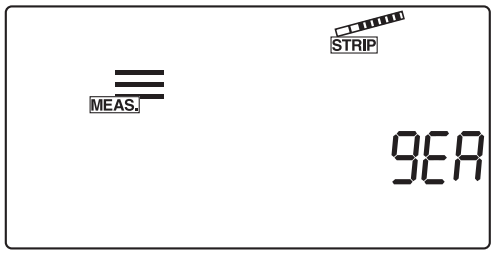
• The [Test strip type setting screen] appears.



4 Select which test strip to use

❶ Using (−), select the test strip type to be used in the current measurement mode.

❷ Press (↵) .
- The test strip type is confirmed, and the display returns to the [Menu screen].



5 Quit the STRIP setup menu

❶ Press (▽) .
- The display returns to the [Standby screen].

3.7 SETUP (user settings)

Use the SETUP menu to set the detailed conditions for measurements, printing, and external output.
To change the settings for a specific item, enter the desired user setting item number, using the [Item number input screen] to call up the setting screen for that particular item.

3.7.1 Operation of user settings

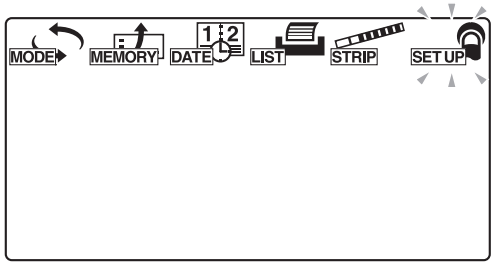
The following describes the method for inputting user settings.

1 Call up the menu screen

With the [Standby screen] displayed, press .
- The [Menu screen] appears and flashes.

2 Select the SETUP (user setting) menu

❶ Press or several times until flashes.



❷ Press .
- The [Item number input screen] appears.

3 Enter the item number

❶ Enter an item number using the numeric keys.

❷ Press .
- The input item number is confirmed and the display changes to the appropriate setting screen.

❸ Input settings for the desired item in the setting screen.
See “3.7.2. List of settable items” on page 3-17 for details concerning the items that can be set.

3.7.2 List of settable items

The details for each item number are as follows.

Item No.	Item	Description	Standard value	See page
No.000	Printing of parameter item numbers	Prints the parameter item number, parameter item, specified range, or selected item.	–	3-18
No.001	Printing of parameters	Prints the current settings for each item.	–	3-19
No.002	Test strip type	Specifies the test strip type for each measurement mode.	10EA	3-20
No.003	Measurement result format	Specifies the format of measurement results (semiquantitative value or reflectance) for each measurement mode.	0	3-22
No.004	Test strip placing direction	Specifies which direction test strips should be placed on the test strip tray.	0	3-24
No.005	Operational mode when turning ON	Specifies the operational mode used when the instrument is turned ON.	0	3-25
No.006	Buzzer sound ON/OFF	Specifies whether to sound the timing buzzer.	1	3-26
No.007	Printing of abnormal marks	Specifies whether to apply (when printing or communicating with an external device) an abnormal mark to the measurement result when an abnormal value is detected in a sample.	1	3-27
No.008	Initialization of measurement number when turning ON	Specifies whether the system initializes the measurement number when the instrument is turned ON.	1	3-28
No.009	Printer use	Specifies whether the built-in printer is used.	1	3-29
No.010	Number of sheets to print	Specifies the number of sheets to print when printing measurement results.	1	3-30
No.011	Number of line breaks	Specifies the number of line breaks between each measurement result.	1	3-31
No.012	Additional data	Specifies optionally printable items that can be added from the following: “measurement number”, “status (date and time + test strip type + temperature)” and “ID number”.	1	3-32
No.013	External output ON/OFF	Specifies whether to output data to an external device.	0	3-33
No.014	Barcode output range setting	• Specifies the first digit to read.	1	3-34
		• Specifies the number of digits to read.	13	
No.090	Printing of a trouble list	Prints out a trouble list of problems having occurred.	–	3-36
No.099	Initialization of parameters	Returns system parameter settings to their standard values.	–	3-37

3.7.3 No.000: Printing of parameter item numbers

Use this submenu item to print parameter item numbers, parameter items, specified ranges or selected items. Refer to the printed material to change the user settings.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the submenu screen

❶ Call up the [Item number input screen], referring to "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ When "No. 000" is displayed, press ↵ .

❸ If "No. 000" does not appear, press 0 0 and then press ↵ .
- The [Item number input screen] appears.

2 Print the parameter item numbers

❶ Press 1 .
- The parameter item numbers are printed.
- After the completion of printing, the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

3.7.4 No.001: Printing of parameters

Use this submenu item to print the current settings for each parameter item number, if you need to verify them.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

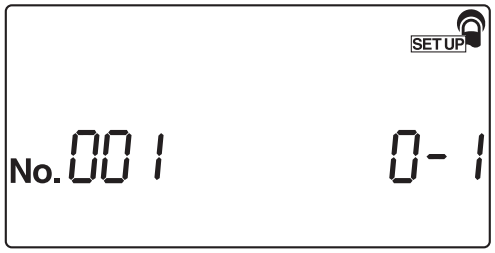
❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 1 .

❸ Press ↵ .
- The [Parameter print setting screen] appears.

2 Print the current settings

❶ Press 1 .
The system starts printing the parameters.
- After the completion of printing, the display returns to the [Item number input screen].



3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

3.7.5 No.002: Test strip type

Use this submenu to select the test strip type for each measurement mode. The sequence of measurement modes when making these settings is “Normal measurement”, “STAT measurement”, and “Control measurement”.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section “3.7.1. Operation of user settings” on page 3-16, if necessary.

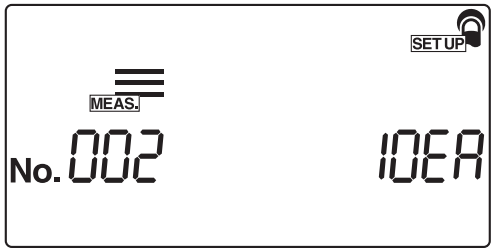
❷ Press 2 .

❸ Press ↵ .
- The [Test strip type setting screen] appears.

2 Select the test strip type to be used in the normal measurement mode

❶ Press − to display the desired test strip type to be used in the normal measurement mode.

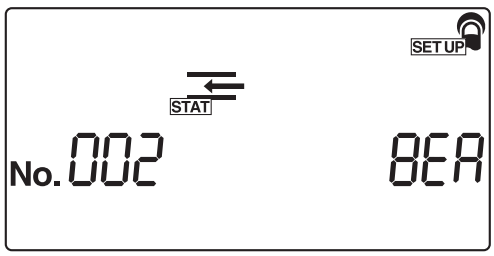
❷ Press ↵ .
- The test strip type used in the normal measurement mode is confirmed and the [Test strip type setting screen] for the STAT measurement mode appears.



3 Select the test strip type to be used in the STAT measurement mode

❶ Press − to display the desired test strip type to be used in the STAT measurement mode.

❷ Press ↵ .
- The test strip type used in the STAT measurement mode is confirmed and the [Test strip type setting screen] for the control measurement mode appears.

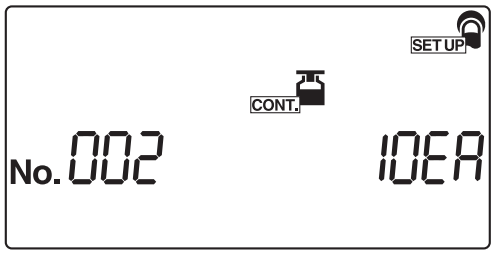


4 Select the test strip type to be used in the control measurement mode

❶ Press (−) to display the desired test strip type to be used in the control measurement mode.

❷ Press (↵) .

- The test strip type used in the control measurement mode is confirmed and the display returns to the [Item number input screen].



5 Quit the SETUP menu

❶ Press (▽) twice.

- The system returns to the [Standby screen].

3.7.6 No.003: Measurement result format

Use this submenu to select a measurement result format for each measurement mode, namely “semiquantitative value” or “reflectance”. The sequence of measurement modes when making these settings is “Normal measurement”, “STAT measurement”, and “Control measurement”.

REFERENCE:

If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section “3.7.1. Operation of user settings” on page 3-16, if necessary.

❷ Press 3 .

❸ Press ↵ .

- The [Measurement result format setting screen] for the normal measurement mode appears.

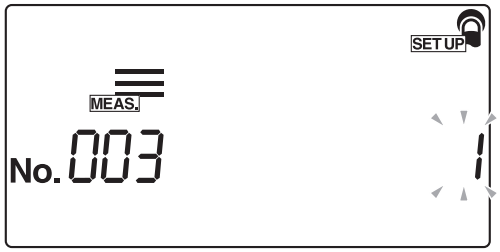
2 Select the measurement results format for the normal measurement mode

❶ Select the measurement results format for the normal measurement mode, using the numeric keys.

- 0: Semiquantitative value
  1: Reflectance

❷ Press ↵ .

- The measurement results format is confirmed and the [Measurement result format setting screen] for the STAT measurement mode appears.

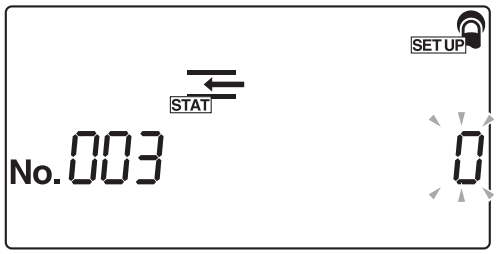


3 Select the measurement results format for the STAT measurement mode

❶ Select the measurement results format for the STAT measurement mode, using the numeric keys.

❷ Press ↵ .

- The measurement result format for the STAT measurement mode is confirmed and the [Measurement result format setting screen] for the control measurement mode appears.

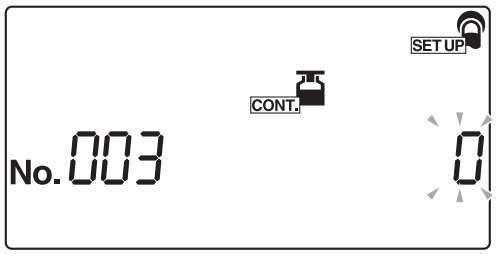


4 Select the measurement results format for the control measurement mode

❶ Select the measurement results format for the control measurement mode, using the numeric keys.

❷ Press ↵ .

- The measurement results format for the control measurement mode is confirmed and the display returns to the [Item number input screen].



5 Quit the SETUP menu

❶ Press ▽ twice.

- The display returns to the [Standby screen].

3.7.7 No.004: Test strip placing direction

Use this submenu to select the direction for placing test strips on the test strip tray.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 4 .

❸ Press ↵ .
- The [Test strip placing direction screen] appears.

2 Select the test strip direction

❶ Select the test strip direction, using the numeric keys.
- 0: Auto-detection
  1: Left
  2: Right

❷ Press ↵ .
- The test strip direction is confirmed and the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

3.7.8 No.005: Operational mode when turning ON

Use this submenu to set the operational mode when the instrument is turned ON.
See the explanation of the operational modes in the "■ Operational mode" on page 2-3.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 5 .

❸ Press ↵ .
• The [Operational mode setting screen] appears.

2 Specify the operational mode

❶ Select the operational mode to be used when the instrument is turned ON, using the numeric keys.
• 0: Auto start
1: Cycle start

❷ Press ↵ .
• The operational mode is confirmed and the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
• Then the display returns to the [Standby screen].

3.7.9 No.006: Buzzer sound ON/OFF

Use this submenu to select whether to sound the buzzer that indicates the dipping timing for test strips during measurement.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 6 .

❸ Press ↵ .
- The [Buzzer sound ON/OFF setting screen] appears.

2 Select the buzzer ON/OFF setting

❶ Select the buzzer sound ON/OFF setting, using the numeric keys.
- 0: OFF
  1: ON

❷ Press ↵ .
- The buzzer ON/OFF setting is confirmed and the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

3.7.10 No.007: Printing of abnormal marks

Use this submenu to select whether to print/output abnormal marks (the abnormal mark "*" or the abnormal color mark "!") with the measurement results when abnormal values are detected in samples.
Please note that the abnormal color mark will only print with the KET, BIL, and URO items when the measurement results are abnormal.

REFERENCE:
If you press ⓢ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

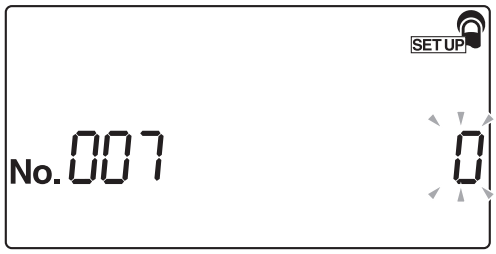
❷ Press 7 .

❸ Press ↵ .
- The [Printing of abnormal marks setting screen] appears.

2 Specify whether to print abnormal marks

❶ Select whether the abnormal marks should be printed, using the numeric keys.
- 0: OFF
  1: ON

❷ Press ↵ .
- The error mark printing setting is confirmed and the display returns to the [Item number input screen].



3 Quit the SETUP menu

❶ Press ⓢ twice.
- The display returns to the [Standby screen].

3.7.11 No.008: Initialization of measurement number when turning ON

Use this submenu to specify whether the measurement number is initialized when the instrument is turned ON.

REFERENCE:
If you press ⓒ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 8 .

❸ Press ↵ .
- The [Initialization of measurement number when turning ON setting screen] appears.

2 Select ON or OFF for the measurement number initialization function when the instrument is turned ON.

❶ Select ON or OFF for measurement number initialization, using the numeric keys.
- 0: OFF (no initialization)
  1: ON (initialization is performed)

❷ Press ↵ .
- The ON or OFF setting for the measurement number initialization function is confirmed and the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ⓒ twice.

The display returns to the [Standby screen].

3.7.12 No.009: Printer use

Use this submenu to specify whether to use the built-in printer. The measurement results stored in memory can be printed using the reprinting function, even if the built-in printer use is set to OFF.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 9 .

❸ Press ↵ .
• The [Printer use ON/OFF setting screen] appears.

2 Select ON or OFF for printer use

❶ Select whether to use the built-in printer, using the numeric keys.
• 0: OFF (the built-in printer is not used)
1: ON (the built-in printer is used)

❷ Press ↵ .
• The printer use ON or OFF setting is confirmed, and the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
The display returns to the [Standby screen].

3.7.13 No.010: Number of sheets to print

Use this submenu to set the number of sheets used to print the measurement results.

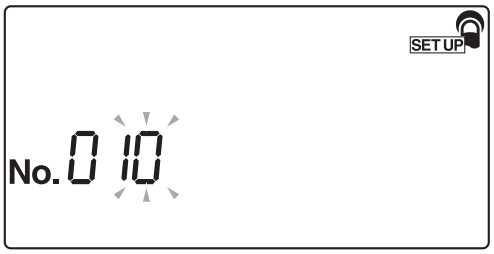
REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 1 0 .

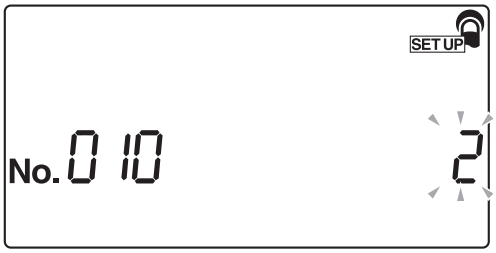
❸ Press ↵ .
- The [Number of sheets to print setting screen] appears.



2 Input the number of sheets to print

❶ Input the number of sheets to print, using the numeric keys. The acceptable number of sheets is from 1 to 3 (1 to 3 sheets).

❷ Press ↵ .
- The number of sheets to print is confirmed and the display returns to the [Item number input screen].



3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

3.7.14 No.011: Number of line breaks

Use this submenu to set the number of line breaks to be made between two printed measurement results. This setting adjusts the bottom margin (the number of breaks between the last line and the cutoff line).

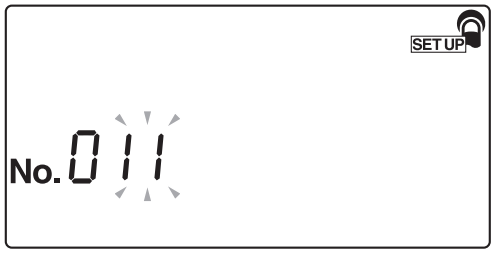
REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 1 1 .

❸ Press ↵ .
- The [Number of line breaks setting screen] appears.



2 Input the number of line breaks

❶ Input the desired number of line breaks, using the numeric keys. The acceptable input range is between 0 to 9 (0 to 9 line breaks).

❷ Press ↵ .
- The set number of line breaks is confirmed and the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
- Then the display returns to the [Standby screen].

3.7.15 No.012: Additional data

Use this submenu to specify additional data to be printed with the measurement results.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 1 2 .

❸ Press ↵ .
- The [Additional data setting screen] appears.

2 Select the additional data to be printed with measurement results

❶ Select the data to be printed, using the numeric keys.
- 0: Only measurement number
  1: Measurement number + Status (Date and time + Test strip type + Temperature)
  2: Measurement number + Status (Date and time + Test strip type + Temperature) + Patient ID number

❷ Press ↵ .
- The additional data to be printed is confirmed and the display returns to the [Item number input screen].

REFERENCE:
If you plan to use multiple types of test strip, set the additional data to be printed to "1: Measurement number + Status (Date and time + Test strip type + Temperature)" or "2: Measurement number + Status (Date and time + Test strip type + Temperature) + Patient ID number". If you select "0: Only measurement number", the test strip type will not be printed, so you will not be able identify which type of test strip was used.

3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

3.7.16 No.013: External output ON/OFF

Use this submenu to specify whether to output the measurement results to an external device.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 1 3 .

❸ Press ↵ .
- The [External output ON/OFF setting screen] appears.

2 Select external output ON/OFF

❶ Select ON or OFF for the external output, using the numeric keys.
- 0: OFF
  1: ON

❷ Press ↵ .
- The external output ON/OFF setting is confirmed and the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

3.7.17 No.014: Barcode output range setting

Before using the optional hand-held barcode reader, set “the first digit to read” and “the number of digits to read”. The hand-held barcode reader designed for this instrument can read 32-digit barcodes, but can store or output only up to 13 digits. Therefore, you need to set the first digit to read and how many digits (up to 13 digits) to output as patient ID numbers.

REFERENCE:

If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section “3.7.1. Operation of user settings” on page 3-16, if necessary.

❷ Press 1 4 .

❸ Press ↵ .

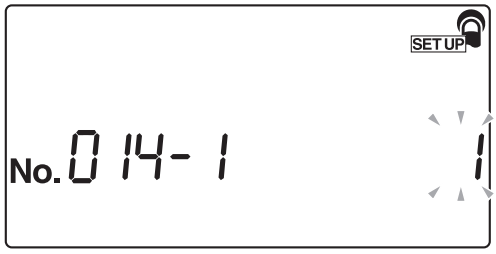
- The [First digit setting screen] appears.

2 Set the first digit to read

❶ Input the first digit number of barcode to read.
Input a number between 1 and 32.

❷ Press ↵ .

- The [number of digits setting screen] appears.

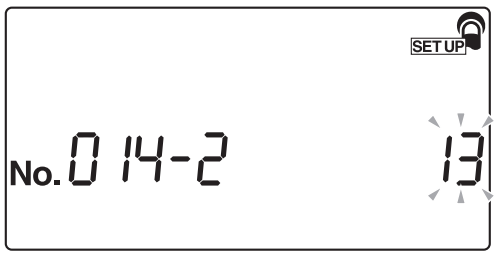


3 Set the number of digits to read

❶ Set the number of digits to read. Input a number between 1 and 13.

❷ Press ↵ .

- The barcode reading setting is confirmed and the display returns to the [Item number input screen].



4 Quit the SETUP menu

❶ Press  twice.

- The display returns to the [Standby screen].

3.7.18 No.090: Printing of a trouble list

Use this submenu to print the trouble history as a list.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section "3.7.1. Operation of user settings" on page 3-16, if necessary.

❷ Press 9 0 .

❸ Press ↵ .
- The [Trouble list printing setting screen] appears.

2 Print the trouble list

❶ Press 1 .
- The printer starts printing the trouble history as a list.
  After the list is printed, the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

3.7.19 No.099: Initialization of parameters

This submenu is used to return the parameter settings to their standard values. The standard values for the parameters are shown in “3.7.2. List of settable items” on page 3-17.

REFERENCE:
If you press ▽ during operation or input, the current setting is canceled and the display returns to the [Item number input screen].

1 Call up the screen

❶ Call up the [Item number input screen], referring to section “3.7.1. Operation of user settings” on page 3-16, if necessary.

❷ Press 9 9 .

❸ Press ↵ .
- The [Parameter initialization setting screen] appears.

2 Initialize the parameters

❶ Press 1 .
- The [Reconfirmation screen] appears.

❷ Press 2 .
- The system starts initializing the parameters.
  After the initialization is completed, the display returns to the [Item number input screen].

3 Quit the SETUP menu

❶ Press ▽ twice.
- The display returns to the [Standby screen].

Chapter 4 Maintenance

4.1 Daily maintenance

At the end of each working day, turn OFF the instrument, and then clean the feeder, and the waste box.

4.1.1 Cleaning the feeder

Sample residue often builds up on the test strip tray, carrying arm, suction ports, and test strip feed mechanism, as these parts carry test strips. After repeated measurements, significant sample residue may accumulate. Therefore, the test strip tray, carrying arm, suction ports, and test strip feed mechanism should be cleaned on a daily basis after use.

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

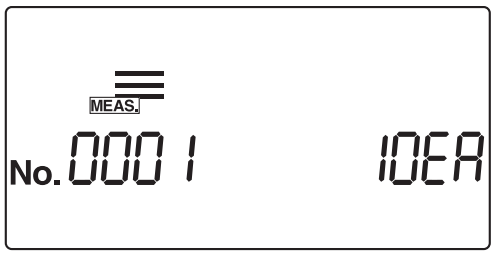
NOTE:

When cleaning the test strip tray, avoid the use of organic solvents such as alcohol and thinner or ultrasonic cleaning. These cleaning methods may deform or discolor the test strip tray and thus make it unserviceable for further testing.

Prepare: Alcohol, cloth, and protective gloves

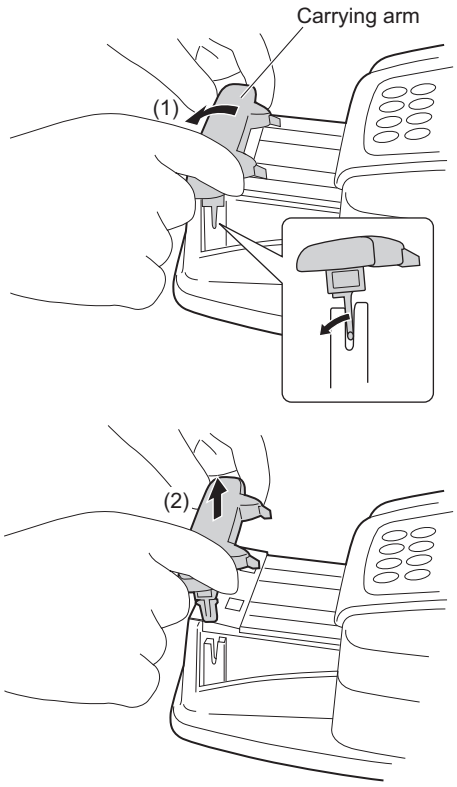
1 Turn OFF the instrument.

❶ Check that the [Standby screen] is displayed, and then turn OFF the instrument.



2 Detach the carrying arm

❶ Pull the carrying arm until a click sounds ((1) in the right figure), and lift it up to remove it ((2) in the right figure).

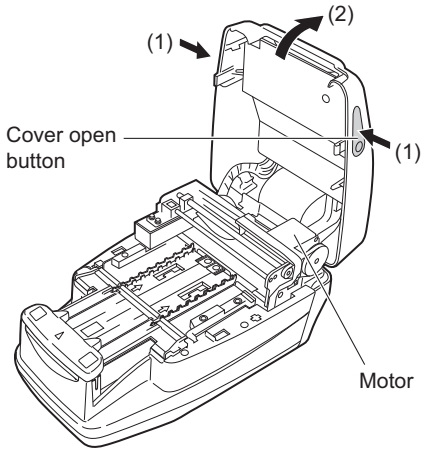


3 Open the maintenance cover

❶ Press and hold the two cover open buttons, one on either side of the instrument ((1) in the right figure) to open the maintenance cover ((2) in the right figure).

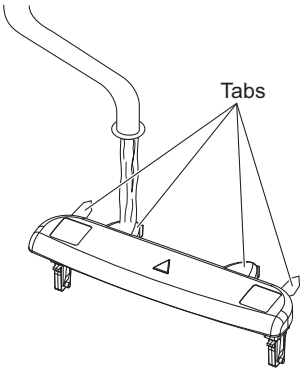
NOTE:
When the maintenance cover is opened, the power is automatically turned OFF.

Do not touch the motor, which may be hot.



4 Sterilize and clean the carrying arm

❶ Sterilize the carrying arm using alcohol and then wash it with water to remove any dirt present.



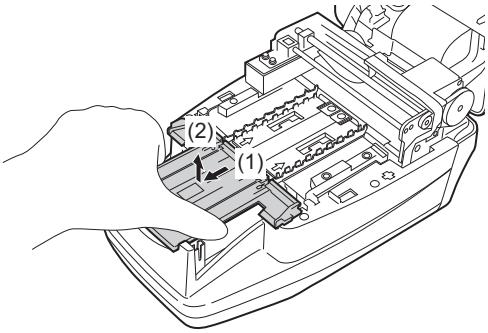
NOTE:
Carefully wipe and thoroughly clean the tabs shown in the right figure. Any dirt remaining on the tabs may prevent smooth feeding of test strips.

❷ Wipe moisture off with a cloth to dry the carrying arm.

5 Detach the test strip tray

❶ Check that no test strips are remaining on the test strip tray.

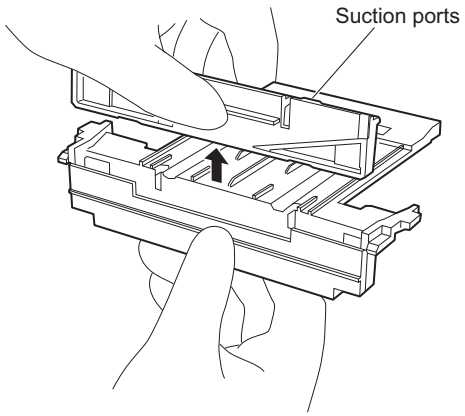
❷ Slide the test strip tray to the front ((1) in the right figure) and lift it up to detach it ((2) in the right figure).



NOTE:
When detaching the test strip tray, be careful to prevent any remaining urine from splashing around.

6 Detach the suction ports

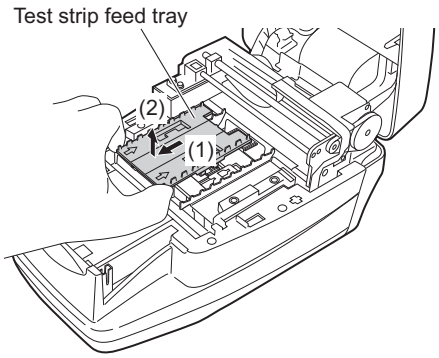
❶ Pull the suction ports straight up from the test strip tray, and detach the part.



NOTE:
When detaching the suction ports, be careful to prevent any remaining urine from splashing around.

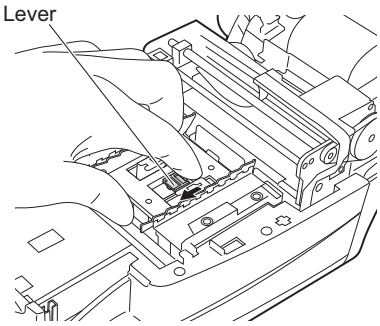
7 Detach the test strip feed tray

❶ Slide the test strip feed tray to the front ((1) in the right figure) and lift it up to detach it ((2) in the right figure).



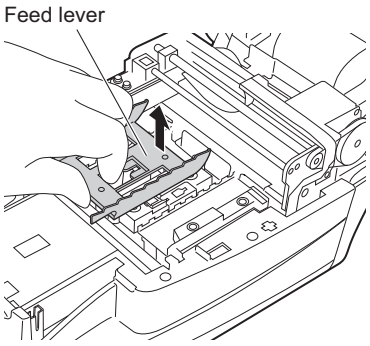
8 Detach the feed lever

❶ Slide the white lever in the center to the front.



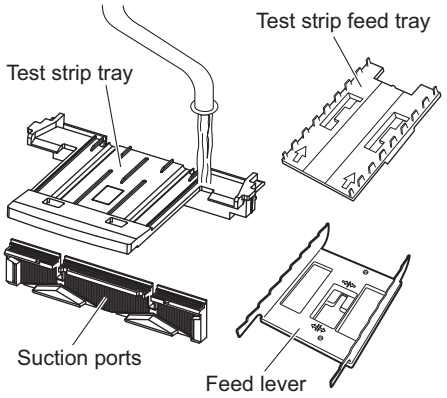
NOTE:
When sliding the lever, **do not** push or apply excessive force which might cause deformation of parts and prevent smooth feeding of test strips.

❷ Lift the feed lever up to detach it.



9 Clean the test strip tray, suction ports, test strip feed tray, and feed lever.

❶ Wash the test strip tray, suction ports, test strip feed tray, and feed lever with water to remove any dirt.



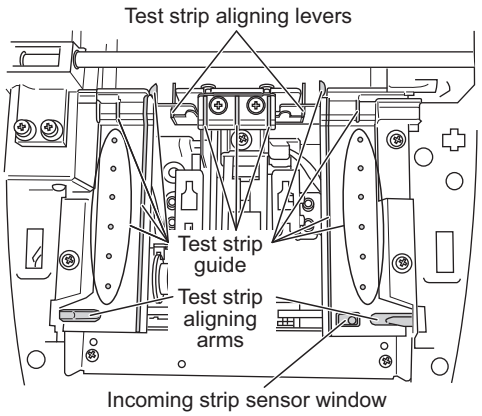
NOTE:

- **Do not** scratch or damage the test strip tray, suction ports, test strip feed tray, or feed lever. Any scratches or damage may prevent smooth feeding of the test strips.
- **Do not** sterilize the test strip tray with alcohol. If you use alcohol, the test strip detection window may become cloudy, resulting in a test strip detection error.

❷ Wipe moisture off with a cloth to dry the cleaned parts.

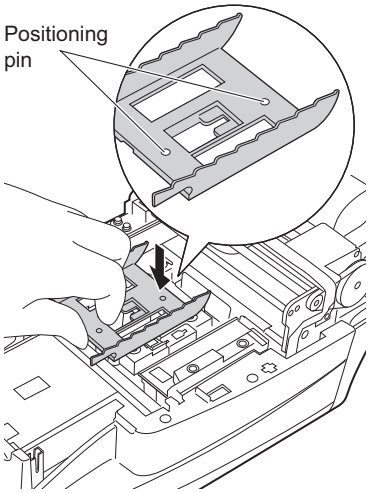
10 Clean the table

❶ Before attaching the feed lever, remove any dirt on the test strip guides on both sides and the three test strip guides on the photometric table, and also clean the incoming strip sensor window, test strip aligning levers and aligning arm.

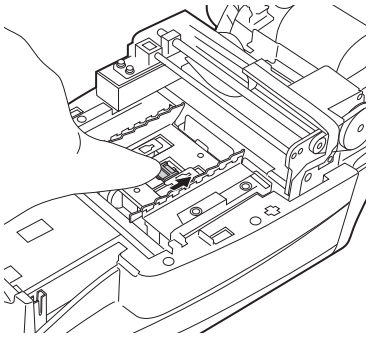


11 Attach the feed lever

❶ Place the feed lever inside the unit.
Set the feed lever to align with the two positioning pins.



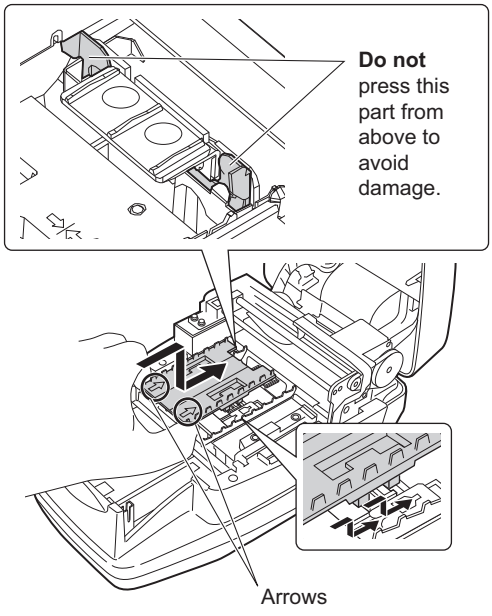
❷ Slide the lever at the center to the back until it audibly clicks into place.



NOTE:
When sliding the lever, **do not** push or apply excessive force, which might cause deformation of parts and prevent smooth feeding of test strips.

12 Attach the test strip feed tray

❶ As shown in the right figure, hold the test strip feed tray so that its arrows face up. Align the tabs of the test strip feed tray with the holes of the unit, and place the test strip feed tray in the unit. Insert the test strip feed tray completely.

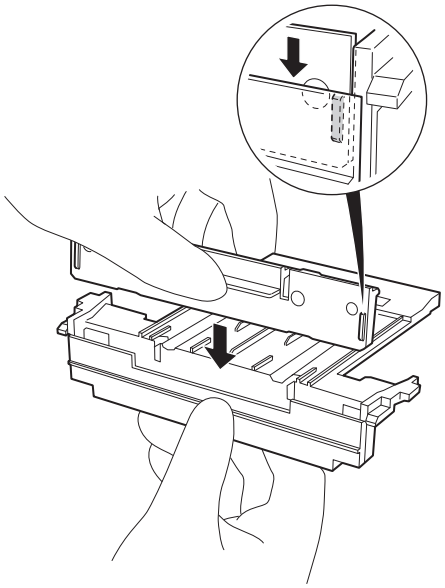


NOTE:
- Insert the test strip tray in the correct position.
- When aligning the tabs of the test strip feed tray with the holes of the unit, do not just lower the tray into place from directly above but also slide the tray to the rear.

13 Attach the suction ports to the test strip tray

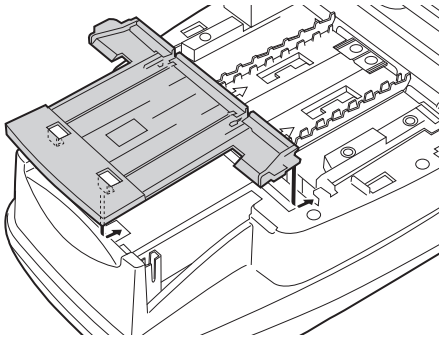
❶ Push the suction ports straight into the test strip tray until they come in contact with the bottom of the tray (until the protrusions on both sides are no longer visible).

NOTE:
If the suction ports are not correctly in contact with the bottom of the test strip tray, the test strip may not be transported properly, leading to a strip jam or trouble.



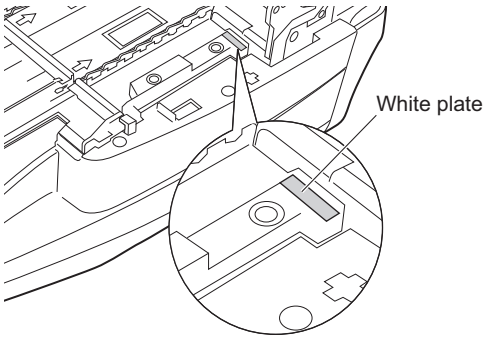
14 Mount the test strip tray

❶ Align the tabs of the test strip tray with the holes of the unit as shown in the right figure, and place the tray inside the unit. Then slide the test strip tray further inside.
Insert it until you hear a click.



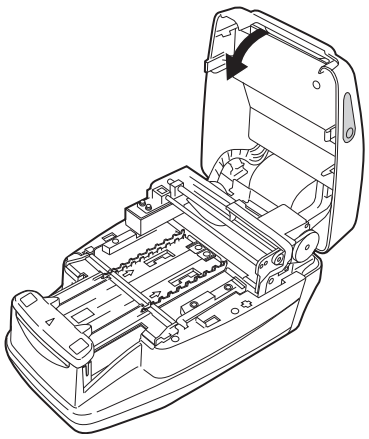
15 Clean the white plate

❶ Wipe any dirt off the white plate, using a clean cloth.



16 Close the maintenance cover

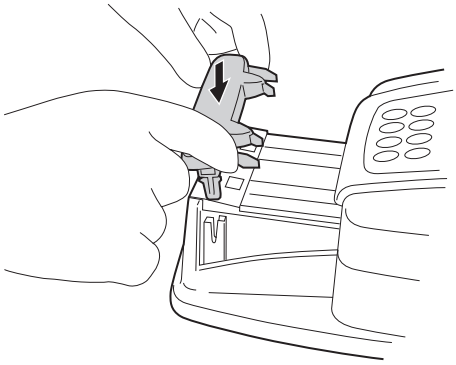
❶ Close the maintenance cover until it clicks closed.



17 Attach the carrying arm

❶ Insert the carrying arm into the bracket until you hear a click.

NOTE:
Insert carrying arm in the bracket in an upright position. Check that the carrying arm is not skewed against the bracket.



4.1.2 Cleaning the waste box

The waste box gets full after approximately 100 measurements. Discard the used test strips, and sterilize and clean the waste box.

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

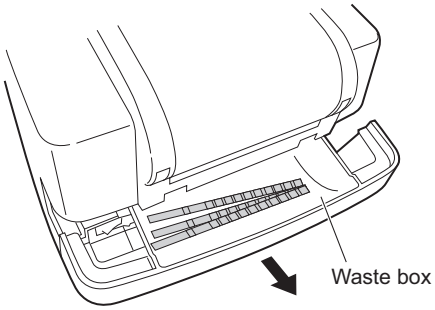
NOTE:
When sterilizing and cleaning the waste box, avoid the use of thinner, other organic solvents, or ultrasonic cleaning. These sterilizing/cleaning methods may deform or discolor the test strip tray and thus make it unserviceable for further testing.

Prepare: Alcohol, cloth, and protective gloves.

1 Discard used test strips

❶ Check that the [Standby screen] is displayed.

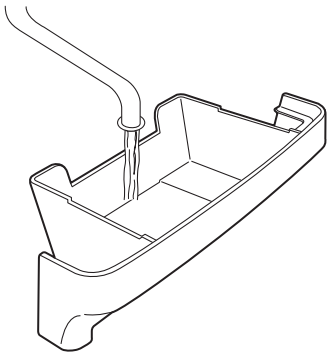
❷ Pull out the waste box and discard the used test strips.



2 Sterilize and clean the waste box

❶ Sterilize the waste box using alcohol and then wash with water to remove all traces of dirt.

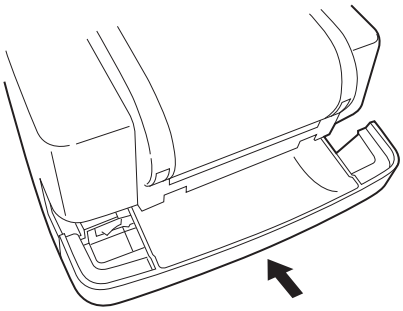
❷ Wipe all moisture off with a cloth to dry the part.



3 Attach the waste box.

❶ Attach the waste box to the unit.

NOTE:
When attaching the waste box to the unit, **do not** spread tissue paper (Kleenex) or anything else in the bottom of the box. Doing so may cause a problem later when disposing of waste.



4.1.3 Disinfection

For disinfection of the device, lightly wipe the device with a cotton swab or gauze moistened with disinfectant, then wipe off the disinfectant with a cotton swab or gauze moistened with water, and then wipe it dry. Use 70% isopropanol as the disinfectant. Contact your distributor if you use another disinfectant.

- Wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used cleaning tools and protective gloves in accordance with local regulations for biohazardous waste.

Prepare: 70% isopropanol, cotton swabs, and gauze

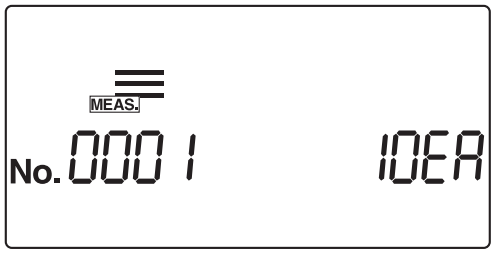
4.2 Replacing the thermal recording paper

When a red line appears on each side of the thermal recording paper, the paper will soon run out. Replace the depleted paper roll with a new one before it runs out. A new roll of thermal recording paper can be used for approximately 450 measurements.

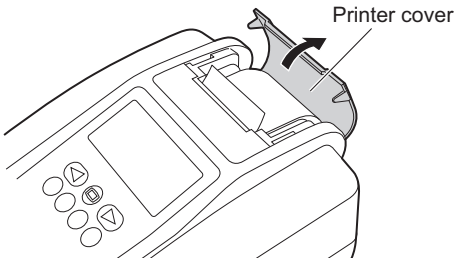
Prepare: New roll of thermal recording paper, scissors

1 Cut the thermal recording paper

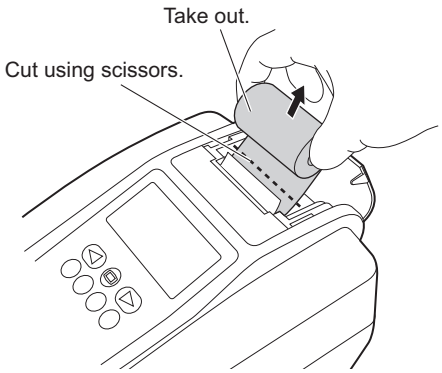
❶ Check that the [Standby screen] is displayed.



❷ Open the printer cover.

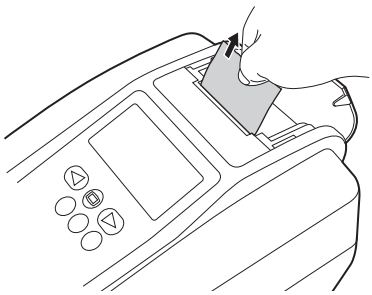


❸ If some thermal recording paper still remains in the printer, cut the remaining paper strip using scissors and remove the depleted roll's paper core.
If the paper has completely run out, remove the paper core from the paper holder and go to step **3**.



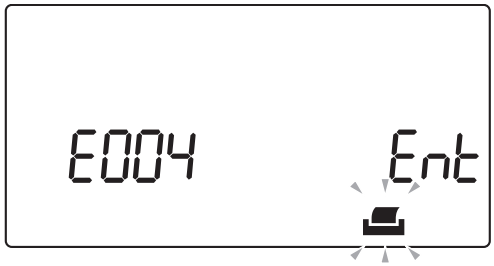
2 Remove the remaining thermal recording paper

❶ Press  . The thermal recording paper remaining in the printer is fed out. Remove the paper by holding it with your fingertips.



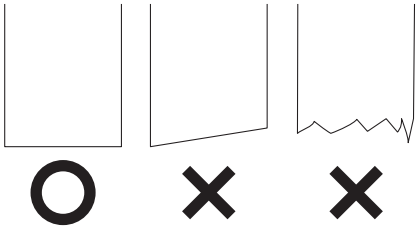
NOTE:

When the thermal recording paper is completely removed from the printer, the screen message shown in the right figure appears and a continuous beep sounds for approximately 1 minute. The alarm sound can be stopped by pressing ↵ .



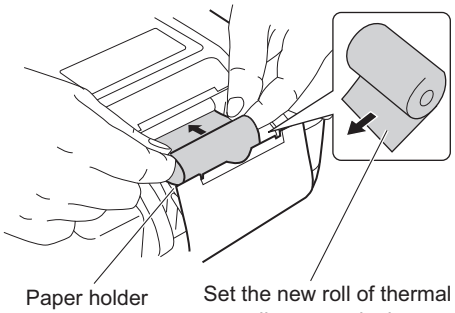
3 Prepare a new roll of thermal recording paper

❶ Cut the first (outermost) layer of a new thermal recording paper roll, and trim the end to make it straight. A skewed or odd-shaped end may cause the thermal recording paper to jam.



4 Set the new thermal recording paper roll

❶ Place the new roll of thermal recording paper in the paper holder, orienting it correctly so that the paper feeds from the bottom. Guide the trimmed end of the thermal recording paper into and through the slot that receives the recording paper.
The thermal recording paper is automatically wound forward and fed into the unit.



NOTE:

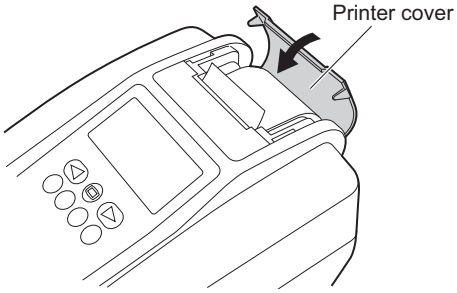
Always press the ☞ button after replacing the thermal recording paper.If you **do not** fully feed the thermal recording paper through the unit by pressing the ☞ button, the printer will fail to print the measurement results.

REFERENCE:

If the printer fails to properly wind and feed the thermal recording paper, press ☞ and verify that the paper feeds correctly.

5 Close the printer cover

❶ Close the printer cover.



4.3 Maintenance of the instrument when it will not be used for a long period

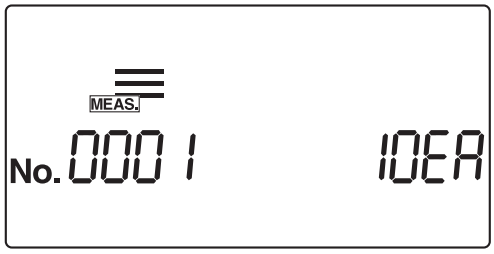
If the instrument will not be used for a period longer than one week, maintain it by following the procedures below.

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

Items required: Alcohol, cloth, and protective gloves

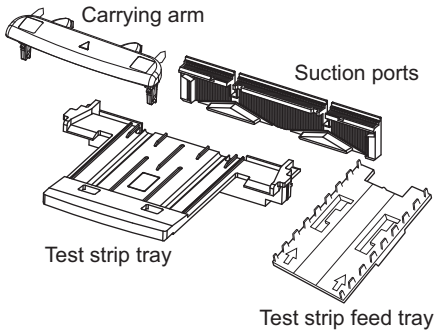
1 Turn the power switch OFF

❶ Check that the [Standby screen] is displayed, and then turn the power switch OFF.



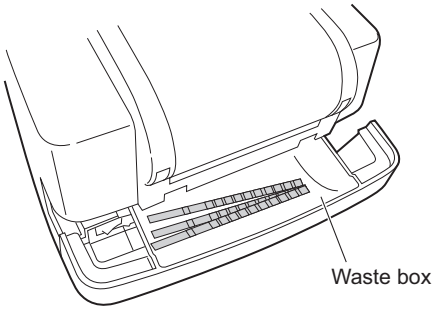
2 Clean the feeder

❶ Sterilize and clean the carrying arm, test strip tray, suction ports, and test strip feed tray, following the instructions in “4.1.1. Cleaning the feeder” on page 4-2.



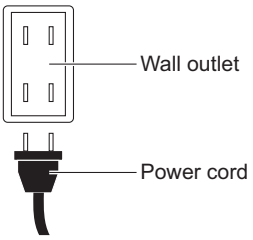
3 Clean the waste box

❶ Clean the waste box, following the instructions in “4.1.2. Cleaning the waste box” on page 4-10.



4 Unplug the instrument

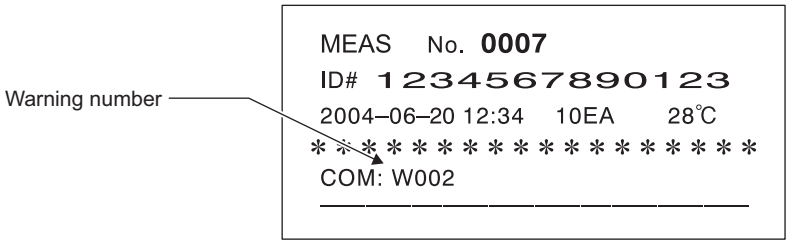
❶ Disconnect the power cord from the wall outlet.



Chapter 5 Troubleshooting

5.1 Warning messages

A warning message appears when a normal measurement result was not obtained.
When a problem occurs during measurement, the system continues measurement and prints warning messages with the measurement results.

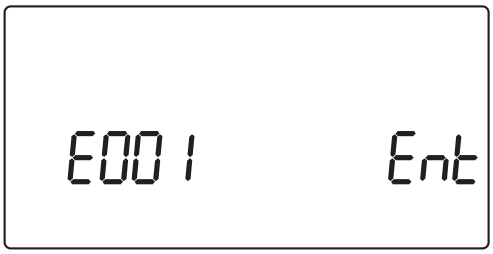


The table below explains the meaning of and measures to be taken for each warning number (message).

Message	Problem	Possible cause	Measures
W001	Drift	The ambient light level around the instrument changed rapidly, due to a photoflash or other reasons.	Maintain a constant level of illumination around the instrument during measurement.
W002	Abnormally high reflectance	An abnormal sample (e.g. a sample containing medicine) was measured.	Check if the tested sample is abnormal or not. If the sample is normal, test it again.
W003	Incorrect test strip position	• The test strip was displaced from its correct position due to vibration. • The test strips were incorrectly placed.	• **Do not** expose the instrument to any vibration during measurement. • Place the test strips correctly on the test strip tray. (See page 2-18.)
W004	No dipping	The entire pad section of the test strip was not dipped.	Dip a new test strip in the sample correctly and test again.
W005	Wrong test strip	A test strip other than that specified was used.	Only use ARKRAY's test strips designed for the AUTION ELEVEN.
W006	Transport error	The test strip may not have been transported properly.	• Clean the test strip tray and suction ports. • Attach the suction ports properly. • Clean the incoming strip sensor window.

5.2 Error messages

Errors may occur when you operate the instrument incorrectly or make a mistake during normal operation.
When an error occurs, an error message appears on the screen and an alarm (pi-pi-pi-pi) sounds for approximately 1 minute.



Press ↵ to cancel the error notice. The display returns to the [Standby screen] or the [Confirmation screen] shown below.

To prevent the error from recurring, take appropriate measures, referring to the table below. Alternatively, note the details of the situation at hand, turn OFF the instrument, and contact your local distributor.

Message	Error	Possible cause	Measures
E001	Power down	The instrument was suddenly turned OFF during measurement.	Retest the sample(s) currently being measured.
E002	Backup memory error	As the instrument was unused for a long period, the memory backup battery was exhausted and the measurement results stored in the memory were lost.	Cancel the error notice by pressing ↵ and then press 1. Keep the instrument powered for at least 11 hours to charge the backup battery. After charging the instrument, set the date and time. (See page 3-10.)
E004	No paper in the printer	• The thermal recording paper has run out. • The thermal recording paper roll was not properly installed.	• Install a new roll of thermal recording paper. (See page 4-12.) • Make sure the thermal recording paper is installed correctly.
E005	Waste box is full	At the end of the measurement, the test strip waste counter exceeded 90.	Cancel the error notice by pressing ↵. Empty the used test strips from the waste box, and press 1.
E006	Surplus urine is full	At the end of the measurement, the total number of measurements since turning ON the instrument exceeded 190.	Turn OFF the instrument and discard any surplus urine.
E007	Data not found	No data was found in the specified range.	Verify that the specified range for re-printing, re-sending, or list printing is appropriate.

Message	Error	Possible cause	Measures
E008	Auto start sensor error	• A test strip was placed while the carrying arm was moving to the suction ports. • The detection section of the auto start sensor was soiled with urine. • The auto start sensor is faulty.	• Remove the test strip. • Clean the detection section. • If you find no abnormality and the error recurs, contact your local distributor.
E009	No test strip on the feeder	• The feed lever is not attached. • The incoming strip sensor is faulty. • The sensor failed to detect a test strip.	• Turn OFF the instrument and open the maintenance cover. • Mount the feed lever. • If you find any obstacles or scattered test strips inside, remove them. • If you find no abnormality and the error recurs, contact your local distributor.

5.3 Trouble messages

A trouble message appears when the instrument itself has encountered trouble and must stop operation.
When trouble is detected, a message appears on the screen, as shown in the figure below. An alarm beep sounds for approximately 1 minute.

Cancel the alarm notice by pressing ↵ . The system displays the [System initialization confirmation screen].

Press 1 to initialize the system.
When initialization is complete, the system displays the [Standby screen].

To prevent the trouble from recurring, check that the [Standby screen] is displayed and take appropriate measures, referring to the table below. Alternatively, note the details of the trouble situation at hand, turn OFF the instrument, and contact your local distributor.

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

IMPORTANT:
If trouble occurs during measurement, perform the measurement again. The trouble may have affected several measurement results obtained before and after the trouble. If a measurement result seems to be incorrect, perform the measurement again.

Message	Description	Possible cause	Measures
XX XXXX XXXX XXXX	Unknown trouble	Trouble occurred due to unknown cause(s). (The message varies according to the trouble that has occurred.)	Note the displayed details, turn OFF the instrument, and contact your local distributor.
T101	EEPROM trouble	The EEPROM is malfunctioning.	Turn OFF the instrument and contact your local distributor.
T102	Changed version	The ROM has been upgraded.	
T110	No calibration curve	The calibration curve for the selected test strip was not entered, or else some test strip information was missing.	
T120	Inlet error	• There was an obstacle in the test strip inlet. • The motor-driven part malfunctioned.	Turn OFF the instrument and open the maintenance cover.If there are any obstacles or scattered test strips inside, remove them. Check for any damage to the carrying arm, test strip tray, suction ports, or test strip feed mechanism. If any of these parts show signs of damage or the trouble recurs, contact your local distributor.
T121	Feeder trouble	• The test strip feed mechanism encountered an obstacle. • Test strips are scattered inside the instrument. • The motor-driven part malfunctioned.	
T123	Incoming strip sensor trouble	• A test strip was blocked by the suction ports and was not transferred smoothly. • There was an obstacle in the sensing section (such as a misfed test strip) that desensitized the incoming strip sensor. • The incoming strip sensor malfunctioned.	• Turn OFF the instrument and open the maintenance cover. If there are any obstacles or scattered test strips inside, remove them. Check for any damage to the carrying arm, test strip tray, suction ports, or test strip feed mechanism. If any of these parts show signs of damage or the trouble recurs, contact your local distributor. • Check if any urine has adhered to the feeder, and clean it if necessary. • If the waste box is full of used test strips, empty the box.
T130	Photometric section initialization trouble	• The photometric section driving mechanism, or the position detection sensor of the photometric section driving mechanism malfunctioned. • The waste box was completely full of test strips, which prevented proper operation of the photometric section.	• Turn OFF the instrument and open the maintenance cover. If there are any obstacles or scattered test strips inside, remove them. Check for any damage to the photometric section. If the photometric section is damaged, or the trouble recurs with no identifiable cause, contact your local distributor. • If the waste box is full of used test strips, empty the box.
T131	Photometric section driving trouble		

Message	Description	Possible cause	Measures
T132	A/D overflow	• The white plate was dirty, or the photometric section malfunctioned. • The test strip feed system had a mechanical problem. • Direct sunlight entered the photometric section. • The photometric section malfunctioned electrically.	• Turn OFF the instrument and open the maintenance cover. • If the white plate is dirty, clean it. • If test strips are scattered inside, remove them. • Prevent direct sunlight from entering inside the instrument. • If you find no abnormality and the trouble recurs, contact your local distributor.
T133	A/D range over		
T134	A/D range under		
T135	A/D dark over		
T137	Black mark not found		• Turn OFF the instrument and open the maintenance cover. • Check whether a test strip has been wrongly placed in the photometric section. • If test strips are scattered inside, remove them. • Prevent direct sunlight from entering inside the instrument. • If you find no abnormality and the trouble recurs, contact your local distributor.
T138	Test strip feeding trouble	• A test strip was misfed and fell or moved to an incorrect position. • A test strip was misfed and rebounded, which was detected by the photometric section. • The photometric section detected test strips overflowing from the waste box. • The test strip sensor malfunctioned electrically. • The photometric section malfunctioned electrically.	• Turn OFF the instrument and open the maintenance cover. If there are any obstacles or scattered test strips inside, remove them. Check if the suction ports are damaged. If there are any signs of damage, or the trouble recurs, replace the suction ports and contact your local distributor. • Check whether the feeder is free from adhered urine. If the feeder is dirty, clean it. • If the waste box is full of used test strips, empty the box.
T160	Unable to initialize	• The optical motor malfunctioned. • The feed motor malfunctioned. • The position detection sensor malfunctioned electrically.	Contact your local distributor.
T170	External output initialization trouble	The PC board malfunctioned electrically.	
T171	Two-way communication trouble	• The external output settings were wrong. • There was a communication error.	

Chapter 6 Appendix

6.1 External output specifications

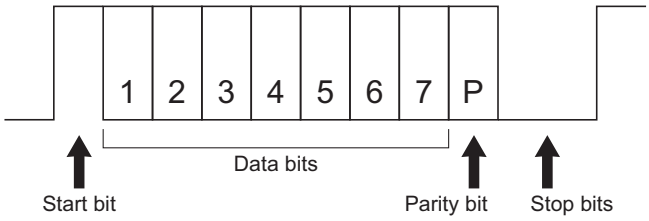
• External output: Bit serial output, RS-232C serial interface

• Communication system: Asynchronous communication

• Character structure:

(1) Standard format
Character length: 10 bits
Start bit: 1 bit
Data bits: 8 bits (ASCII code)
Parity bit: None
Stop bit: 1 bit

(2) AM/AJ/AX compatible format
Character length: 11 bits
Start bit: 1 bit
Data bits: 7 bits (ASCII code)
Parity bit: 1 bit (even parity)
Stop bits: 2 bits



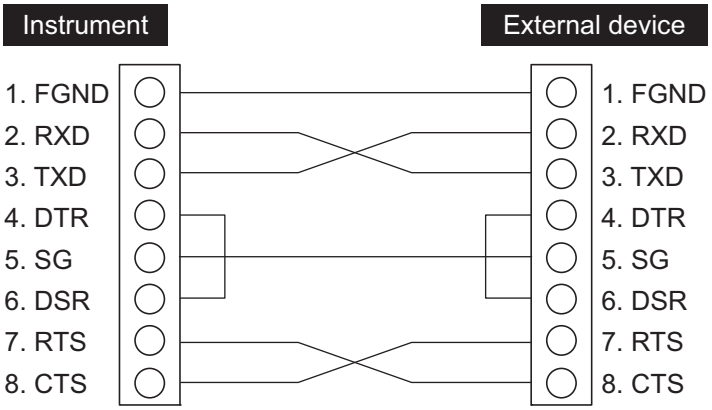
Time gap: 0.5 sec.

• Applicable connector: DB-9 9-pin connector (JIS X5103)

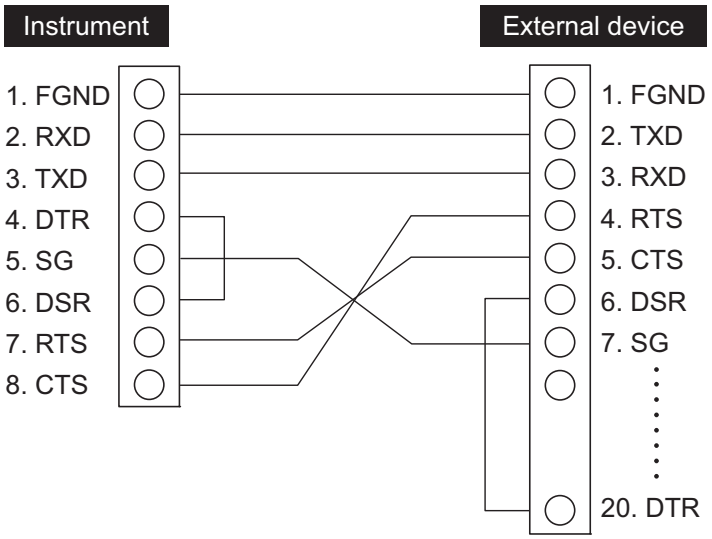
• Output timing: Data is output at the completion of a single sample measurement, or in response to a resend command.

● Connection diagram

<The external device has a 9-pin connector>



<The external device has a 25-pin connector>



6.2 Performance characteristics

6.2.1 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%).

6.2.2 Clinical Performance

In the AUTION ELEVEN AE-4020 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	99	98	99
Protein	99	92	97
Bilirubin	97	100	100
Urobilinogen	96	100	99
Blood	95	97	97
Ketones	94	100	99
Nitrite	100	100	100
Leukocytes	85	99	97
P/C ratio	96	88	94
A/C ratio	97	90	95

[A/C ratio] vs. Quantitative measurement system H7600
[Other than A/C ratio] vs. AUTION MAX AX-4280

ARKRAY Factory, Inc.
1480 Koji, Konan-cho, Koka-shi
Shiga 520-3306, JAPAN
https://www.arkray.co.jp/script/mailform/afc-contact_eng

EC REP ARKRAY Europe, B.V.
Prof. J.H. Bavincklaan 2
1183 AT Amstelveen, THE NETHERLANDS
If you need to obtain technical assistance,
please contact ARKRAY Europe, B.V.
TEL: +31-20-545-24-50
FAX: +31-20-545-24-59

84-07780

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