

Compact Urine Analyzer

PocketChemTM UA PU-4010 | Operating Manual

arkray,inc.

Premise

1

Thank you for purchasing our compact urine analyzer, the PocketChem UA PU-4010.

This manual contains important information on the functions of the PocketChem[™] UA PU-4010.

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 PocketChem UA PU-4010 is intended for the qualitative and/or semiquantitative 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 instrument is not intended for near-patient testing use.

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.



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 instruction 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.

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Read this manual thoroughly before using the instrument. This manual gives an overview of the instrument and the proper procedures for operation and maintenance. 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, contact your distributor.

- BE CAREFUL WHEN HANDLING URINE. This instrument uses urine as sample. 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 manual before use.

• Never touch the test strip holder or other parts where the 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 protective gloves 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.

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

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

For Your Safety

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3

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

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

For Optimal Performance

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

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

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

Before installation of the instrument, read the instructions in this section and always take proper safety precautions.



For the test strip holder to move freely, leave at least 7 cm (3 inches) of space to the right and left sides of the instrument.



If the instrument is subjected to sudden temperature changes, allow instrument to adjust to room temperature for 1 hour before testing.



To run the instrument on AC power, connect the instrument to an AC receptacle using the AC adapter that came with the instrument.



Remove old batteries. Also, remove batteries before long periods of non-use.



Use the instrument where temperature and humidity can be maintained between 10°C and 30°C and between 20% and 80% RH.



If you detect abnormal noise, odors or smoke, immediately turn off the power, unplug the AC adapter and contact your distributor.

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Install the instrument in a place not exposed to direct sunlight or wind.



DO NOT install the instrument near places that store chemicals or near equipment that generates corrosive gas or electrical noise.



Install the instrument on a level, vibration-free sturdy platform.



DO NOT disassemble or modify the instrument. Doing so may cause damage to the instrument and consequently lead to personal injury.



Remove the AC adapter when the instrument is not in use.



Keep the instrument away from liquids. Penetration inside may cause damage to the instrument.



Keep the instrument away from magnetic sources such as magnets and speakers.



DO NOT expose the instrument to physical shocks or impacts.

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1-1 Outline of the PocketChem UA

1-1-1 Features

• Compact, lightweight portable analyzer

The instrument alone weighs 180 g*. With the printer attached, it is a light 360 g*. The instrument can run on batteries.

*Not including batteries or printer paper.

• Simple operation. Just press the start button.

Measurement is performed by simply pressing the start button and placing a test strip. Test results can be simultaneously viewed on the display and printed out from the printer.

· Corrective features for obtaining accurate test results

Highly accurate readings can be obtained by eliminating the effects of chromaturia using the color correction test pad, by compensating measurements for the temperature of the surrounding environment using a built-in temperature sensor and by correcting specific gravity based on pH readings.

· Auto detection of test strip type

When using self-identifiable test strips, the instrument can automatically detect the type of strip during measurement.

Hassle-free daily maintenance

The only maintenance required on a daily basis is to wash the test strip holder. And the holder can be easily detached for cleaning without any special tools. The instrument also uses an LED light source, so there is no need to change lamps.

Store results for up to 100 samples. Output results to external devices.

Test results for up to 100 samples can be stored in memory. Stored results can be viewed, printed and sent to an external device using an RS-232C at any time after measurement. As results are recorded beyond the 100th entry, the new data overwrites the old data. For more information, contact your distributor.

Detachable printer

Attaching the printer to the instrument enables test results to be printed after measurement.

• Supports "AUTION Sticks" test strips for versatile urine testing

The instrument uses "AUTION Sticks" test strips that enable visual determination as well as a maximum of 10 simultaneous tests in a single measurement. You can select the type of test strip for the measurements you need to do.

1-1-2 Specifications

Product	Compact Urine Analyzer PocketChem UA PU-4010	
Configuration	Instrument (analyzer) and accessories	
Sample	Urine	
Test strips	AUTION Sticks / Uriflet S (9UB)* / AUTION SCREEN * Except devices with 10V specifications	

Instrument Specifications

Measurement items	GLU (glucose), PRO (protein), BIL (bilirubin), URO (urobilinogen), S.G. (specific gravity), BLD (blood), PH (pH), KET (ketones), NIT (nitrite), LEU (leukocytes), CRE (creatinine) and ALB (albumin).
Measurement principle	Test strip: Dual wavelength reflectance method. (one wavelength for BLD measurement)
Measurement wavelengths	3 wavelengths LED (565, 635, 760 nm)
Sample supply method	Manual dipping
Measurement capacity	50 tests per hour
Test strip reaction time	About 60 seconds per test
Measurement types	Normal measurement and check measurement
Display	Custom LCD that displays information including type of test strip, measurement number (up to 4 digits), patient ID (up to 13 digits) and test results.
Operator panel	Panel sheet that provides 14 buttons including numeric buttons and start button.
Memory capacity	Test results for 100 samples
Temperature correction	Automatically corrected between 10°C to 30°C by internal temperature sensor
Specific gravity correction	Automatically corrected based on pH readings
Chromaturia correction	Automatically corrected by color correction test pad
External output	Compliant with RS-232C
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
Dimensions	124 (W) × 81 (D) × 36 (H) mm
Weight	180 g (without batteries)

Power supply	Instrument only: Two AA alkaline batteries or AC adapter Instrument with printer: AC adapter 7.5 V 3 A
Power consumption	3 W
Site location	Indoor use only
Altitude	Up to 2000 m/ 6560 feet
Pollution degree	2
Overvoltage category	П
Test strip direction	Selectable between feeding from "right" or "left" by button operation
Expected life	5 years from first use (installation) of 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

Printer Specifications

Printer	Thermal recording printer
Printer paper	High color development thermal paper (W58 mm × Ø26 mm)
Dimensions	125 (W) × 133 (D) × 36 (H) mm
Weight	180 g (without printer paper)
Power supply	AC adapter 7.5 V 3 A
Power consumption	20 W
Attachment	One-touch attachment
Connection	Contact
Expected life	5 years from first use (installation) of instrument (according to company data)

1-1-3 Measurement Principle

Measurements using double or single wavelength reflection are made, using test strips designed for the PocketChem UA.

Measuring with Test Strips

Dip a test strip in the sample for 2 seconds and place it on the test strip tray. Reagents in the test strip react and change color within 70 seconds after dipping and the reflectance is measured in the photometric section.

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 \cdot Cs / Ts \cdot 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.

 $\mathsf{Rt} = \mathsf{R} + \mathsf{A} \cdot (\mathsf{T}\text{-}26) \cdot \mathsf{R}^2 \cdot (\mathsf{1}\text{-}\mathsf{R})^2$

- 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	Measurement	Reference
Item	wavelength (nm)	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

1-1-4 Rank Table

Please see the table below for the unit and qualitative sign of each measurement item. Default settings are highlighted with **settings** of units and qualitative sign.

• GLU (Glucose)

Qualitative	-	±	1+	2+	3+	4+
	-	±	+	++	+++	++++
Semiquantitative (mg/dL)		50	100	200	500	1000
Semiquantitative (mmol/L)		2.8	5.6	11	28	56

• PRO (Protein)

Qualitative	-	±	1+	2+	3+	4+
Qualitative	-	±	+	++	+++	++++
Semiquantitative (mg/dL)		15	30	100	300	1000
Semiquantitative (g/L)		0.15	0.3	1	3	10

• BIL (Bilirubin)

Qualitative	-	1+	2+	3+	4+
	-	+	++	+++	++++
Semiquantitative (mg/dL)		0.5	2	6	OVER
Semiquantitative (µmol/L)		8.5	34	100	OVER

• URO (Urobilinogen)

Qualitative	NORMAL	1+	2+	3+	4+
Qualitative	NORMAL	+	++	+++	++++
Semiquantitative (mg/dL)		2	4	8	OVER
Semiquantitative (µmol/L)		34	70	140	OVER

• PH (pH)

Semiquantitative	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0

• S.G. (Specific Gravity)

0	<1 005	1 010	1.015	1 000	1 005	. 1 000
Semiquantitative	<1.005	1.010	1.015	1.020	1.025	>1.030

• BLD (Blood)

Qualitative -	-	±	1+	2+	3+
	-	±	+	++	+++
Semiquantitative (mg/dL)		0.03	0.06	0.2	1
Semiquantitative (mg/L)		0.3	0.6	2	10

• KET (Ketones)

Qualitative	-	±	1+	2+	3+	4+
	-	±	+	++	+++	++++
Semiquantitative (mg/dL)		5	15	40	80	150
Semiquantitative (mmol/L)		0.5	1.5	4	8	15

• NIT (Nitrite)

Qualitative	-	1+	2+
Qualitative	-	+	++

• LEU (Leukocyte)

Qualitative	-				
Semiquantitative (Leu/µL)		25	75	250	500

• ALB (Albumin)

Semiquantitative (mg/L)	10	30	80	150	OVER

• CRE (Creatinine)

Semiquantitative (mg/dL)	10	50	100	200	300	OVER
Semiquantitative (g/L)	0.1	0.5	1.0	2.0	3.0	OVER

• A/C (Ratio of Albumin to Creatinine)

Qualitative	NORMAL	1+		2+	
Quantative	NORMAL	+		++	
Semiquantitative (mg/gCr)	<30	100	200	>300	OVER

• P/C (Ratio of Protein to Creatinine)

Qualitative	DILUTE	NORMAL	1+		2+	
Qualitative	DILUTE	NORMAL	+		++	
Semiquantitative (mg/gCr)		<80*	200	400	>500	OVER

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

1-2 Unpacking

The package should contain the components listed below. Check to see if everything is included. If anything is missing or damaged, contact your distributor.

NOTE: Test strips, AA batteries (x2), and urine containers are not included with the instrument. These items are underlined in the "Prepare:" sections on the later pages.



*Rating: 125V 7A (A type plug) and 250V 2.5A (C type plug) Please use the appropriate power cord for your region's power voltage.

1-3-1 Instrument and Printer



Instrument with the printer attached



Reading unit cover opened



	Components	Descriptions	
1	Paper slot	Printouts of results are ejected from here.	
2	Display	Results and error codes are viewed here. See "1-5-1. Display" on page 1-18.	
3	Reading unit cover	Open this cover to perform testing. Perform test with cover closed if an error occurs due to strong room light.	
4	Printer cover	Covers paper roll. Open cover to load printer paper.	
5	FEED button	Feeds printer paper forward.	
6	Operator panel	Fourteen operating buttons are provided here. See "1-5-2. Operator Panel" on page 1-19 for a description of each button.	
7	DATA output terminal	Remove the rubber cap and attach the optional RS-232C cable here for connection to an external device.	
8	Test strip holder	Holds test strip in place during testing.	
9	Battery cover	Open this cover to load two AA batteries.	
10	Printer terminal	The instrument is electrically connected to the printer via this terminal.	
11	Power input terminal (instrument)	For AC operation without the printer, connect the plug of the AC adapter here.	
12	Power input terminal (printer)	For AC operation with the printer attached, connect the plug of the AC adapter here.	
13	Stylus pen	Use this pen to press the buttons on the operator panel if it is difficult for you to do with your fingers.	
14	Serial number	Serial number of the instrument.	

First, set up the instrument. Start with any of the following sections according to your needs.

- For battery operation, see this page.
- For use with the printer, go to page 1-12.
- For AC-power operation without the printer, go to page 1-13.

1-4-1 For Battery Operation

Place two AA alkaline batteries in the instrument. Battery operation is useful when carrying the instrument with you. Batteries have a use life of about 500 sample tests.

NOTE: Use alkaline batteries only, not manganese batteries. The printer cannot run on batteries.

● While lightly pressing the battery cover on the bottom, slide the cover in the direction of the triangle mark (▽) to remove.

Place two AA alkaline batteries in the correct direction in the battery compartment (see the figure).



NOTE: Remove the old batteries before placing new ones.

Slide the battery cover back in position until it snaps into place.

■ This completes the setup. Go to "2-1. Operation Flow Chart" on page 2-1.

NOTE: Dispose of old batteries according to your local environmental regulations.

EU

About the Battery Icon

Battery power is sufficient or AC power in use.
The battery level has lowered, but testing is still possible.
Immediately replace the batteries with new ones. Measurement may stop in progress because of insufficient battery power.
A blinking icon indicates the instrument cannot perform testing anymore because of insufficient battery power. Replace the batteries immediately.

1-4-2 For Use with the Printer

Use the following procedure to attach (or detach) the printer to (or from) the instrument.



The printer must be directly attached to the instrument in order to use it. Therefore, the printer can also be contaminated by pathogenic microbes. Take care when attaching, detaching and storing the printer to prevent exposure to pathogenic microbes.

NOTE: Turn off the power and disconnect the AC adapter from the AC receptacle before attaching or detaching the printer. Failure to do so may cause damage to the instrument and printer. The printer may print nonsense if it is accidentally attached or detached while connected to the AC receptacle. However, this does not mean that there is something wrong with the printer.

How to Attach

NOTE: The printer runs on AC power only, not on batteries. Once the printer is attached to the instrument, connect the instrument through the printer to an AC receptacle.

- Place instrument onto the printer at an angle as shown in the figure.
- **2** Press the top of the instrument to snap it into place.
- Make sure the top of the instrument and printer are horizontally level with one another and that both units are firmly locked to each other.



■ Go to "1-4-3. For AC-Power Operation" on the next page.

How to Detach

• Place the instrument on a level surface (such as a desk).

2 While pressing on the casing above the display at a point aligned with the center of the display (a), lift up the reading unit cover from the bottom to detach the instrument from the printer (b).



1-4-3 For AC-Power Operation

The instrument can run on AC power, instead of batteries. Be sure to use the AC adapter that came with the instrument for AC-power operation.

NOTE: The printer runs on AC power only, not batteries. The printer must be correctly attached to the instrument before connecting the AC adapter to the printer.

1 Insert the flat connector of the power cord into the AC adapter.

• Use the power cord and AC adapter that came with the instrument.

2 Insert the plug of the AC adapter into the power input terminal as shown below.

For use with the instrument only



Plug the AC adapter to terminal on the rear of the instrument.

For use with the printer and instrument



Plug the AC adapter to terminal on the rear of the printer.

③ Connect the plug of the power cord to an AC receptacle.

- And then, ...
- For use with the printer, go to "1-4-4. Loading Printer Paper" on the next page.
- For use without the printer, this completes the setup of the instrument. Go to "2-1. Operation Flow Chart" on page 2-1.

1-4-4 Loading Printer Paper

Set a roll of printer paper in the printer as described below. Also, use this procedure when two red lines appear on both sides of the paper, informing you that paper is running out. <u>Make</u> sure the printer is connected to an AC receptacle (the power can be either turned on or off).

• Cut the end of new printer paper to a straight edge using scissors.

② Open the printer cover.

• Rest your finger on the shaded area () and open the cover.



3 Insert the end of the paper below the roller.

• The direction of the paper roll must be as shown in the figure. Once the paper has been correctly inserted, the printer will feed it automatically.





S Close the printer cover so that the end of the paper extends from the printer.

③ Press the FEED button.

NOTE: The printer does not work until you press the **FEED** button to tell the printer that the paper has been correctly set.



■ This completes the setup of the instrument. Go to "2-1. Operation Flow Chart" on page 2-1.

NOTE: Printer paper is sensitive to light and subject to fade with prolonged exposure to bright light. For storage it is recommended to photocopy the reports.

If Paper Jams in the Printer...

If a paper jam occurs, straighten the paper. Open the printer cover. If the paper is also jammed in the roller or other components, remove the paper. Press the **FEED** button to feed the paper forward.



1-4-5 Changing the Direction of the Test Strip Feeding

This instrument has been factory-set so that you can place the test strip on the test strip holder from the right side of the instrument. You can change the direction to the opposite. This section describes how to change the direction from "the right" to "the left" as an example.

• Turn on the power and open the reading unit cover.

• The test strip holder will extend from the right of the instrument.

2 Press and hold the $[6(\mathbf{b})]$ button.

- The test strip holder will slightly move to the right until a metallic protrusion appears.
- Slide the test strip holder base to the <u>right</u> and remove it.
- Remove the black holder from the holder base. Reattach the holder to the holder base so that the white plate comes to the <u>right</u> side. Be sure to lock the block holder to the gray base.

• Insert the holder base from the <u>right</u> side of the instrument until it stops.

6 Change the setting for the direction of the test strip feeding.

- See "3-10. Customizing the Instrument" on page 3-11.
- The holder base will move to the left.





1-5-1 Display



Components	Descriptions
No.	Steady light: When current measurement number is displayed. Blinking: When you are setting the measurement number.
أ #	Steady light: When current patient ID is displayed. Blinking: When you are setting a patient ID.
	Appears when the instrument is on. In battery operation, this icon indicates battery level. See "About the Battery Icon [
	Steady light: When current date or time is displayed. Blinking: When you are adjusting the date or time.
← MEM	Appears when an existing result has been retrieved from memory and appears on the display.
DEL	When blinking, pressing the <i>L</i> button deletes the currently displayed result (or all results) from memory.
TYPE ?	Steady light: When test strip type currently selected is displayed. Blinking: When you are selecting test strip type.
*	Appears when result(s) are being transferred to an external device.
	Appears when test result(s) are being printed from printer.
SEC	After the $0/0$ button is pressed, the second-based countdown timer appears to indicate the timing of test strip dipping and placing.
Information area	Displays general information including measurement numbers (up to 4 digits), patient IDs (up to 13 digits), date, time and test strip type.
Status indicator	After the O / O button is pressed, these bars disappear one by one to indicate the timing of test strip dipping and placing.
Result area	Abbreviations and test results appear here after a test is performed or when a result has been retrieved from memory for viewing. See "2-7. Examples of Results" on page 2-15.

1-5-2 Operator Panel



REFERENCE:

- A short beep sounds each time a button is pressed.
- If it is difficult for you to press the buttons with your fingers, use the stylus pen that came with the instrument.

Buttons	Descriptions		
0 - 9	Use the numeric buttons to enter numbers from 0 to 9.		
	On the standby screen: Press the $[6(\blacktriangleright)]$ button to change the functions in the order shown below and the $[4(\triangleleft)]$ button, to change them in reverse order.		
	No. → †# → DATE Measurement No. Patient ID Date & time Review Test strip selection		
4(◀) 6(►)	During result review: Press the $[6(\triangleright)]$ button to change the functions in the order shown at right and the $[4(\bullet)]$ button, to change them in reverse order.		
	To move the test strip holder: Press and hold the $[6(\blacktriangleright)]$ button to move the test strip holder to the right and the $[4(4)]$ button, to move it to the left.		
8(▲) 2(▼)	During result review: Use these buttons to view the previous or next result. During test strip selection: Use these buttons to select the previous or next test strip.		
	On the standby screen: Press this button to access the test strip type setting screen.		
— (Hyphen)	During patient ID setting: Press this button to enter a hyphen (-). During result review: Press this button to change the content of the information area in the order of measurement number, patient ID, date, time and "ALL".		
	During date setting: Press this button to move the cursor to the next digit.		
ł	Press this button to confirm your entry.		
	When the power is off: Press this button to turn on the power.		
ტ\�	When the power is on: Press this button to start testing. Holding down this button for 3 seconds or more turns off the power.		
\bigcirc	Cancel button: Press this button to stop testing when in progress. When entering numbers, press this button to cancel your entry.		

2-1 Operation Flow Chart

Before testing samples, review the following flowchart for an overview of the test procedure.



After the final measurement of the day		
 Daily cleaning:	Page 4-1	
Test strip holder, holder base and guide rails Turning off the power	Page 2-4	

2-2 Cautions in Measurement

2-2-1 Handling Samples

BE CAREFUL WHEN HANDLING URINE.

This instrument uses urine as sample. 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.

IMPORTANT:

• Urine samples must be collected within one hour of use.

If samples cannot be tested within an hour, seal and keep them refrigerated. Leaving samples at room temperature for 2 hours or more may alter the chemical composition of the samples.

• Allow samples to adjust to the environment temperature.

Refrigerated samples must be brought to the environment temperature before testing. Testing low temperature samples may result in low values. The temperature of samples immediately after collection must adjust to the environment temperature. Testing high temperature samples tends to produce higher test values.

• Mix each sample well before testing. Do not centrifuge samples.

Centrifuging may cause blood cells to precipitate, whereby producing incorrect results for some testing items.

• Make sure sample is large enough to soak the entire pad area on the test strip in the sample.

The instrument cannot perform testing with an insufficient amount of sample.

- Use samples as collected. Do not add preservatives, disinfectants, or detergents.
- Do not expose samples to direct sunlight. Direct sunlight can alter the quality of samples, whereby producing incorrect results.
- Samples containing ascorbic acid can affect testing results. Testing samples with ascorbic acid can produce lower glucose and occult blood values than actual levels.
- Ingested drugs and highly colored urine can affect measurement results. Measurements of urine containing ingested drugs and highly colored urine can produce incorrect results.

2-2-2 Handling Test Strips

IMPORTANT:

• Use only test strips specified for the instrument.

The test strips, "AUTION Sticks", "Uriflet S (9UB)" and "AUTION SCREEN", are available for use with the instrument. Carefully read the package inserts of the test strips and observe the expiration date.

Check test strip dating before use.

Do not use the test strips beyond the expiration date or test strips with discolored pad areas even if they are within the expiration date. Using old or degraded strips may produce incorrect results.

• Prepare test strips just before use.

Take as many test strips as you need out of the bottle just before measuring samples and immediately cap the bottle. If the test strips exposed to the air are left for a long time without being used, they can absorb moisture in the air or dust can stick to them, whereby producing incorrect results.

• Do not touch the pad area on the test strips.

Touching the test strips can cause sebum to adhere to the surface, whereby producing incorrect results.

Correctly select the test strip type.

Before carrying out measurement, set the type of the test strip you are to use by button operation. An incorrect test strip setting can produce incorrect results. However, you do not have to make the setting for auto-identifiable test strips, whose type can be automatically detected by the instrument during measurement.

• Do not dispose of the desiccant.

Do not dispose of the desiccant in the test strip bottle before using all the test strips. Without the desiccant, the test strips will absorb moisture in the air and lose their effectiveness.

2-3 Start Up

2-3-1 Turning On the Power

() Press and hold the \bigcirc / \diamondsuit button until the power turns on.

• A short beep will sound and the display will change as shown below.



• The test strip holder will extend from the right of the instrument

REFERENCE: For left-handed users, the instrument can be set so that the test strip holder extends from the <u>left</u>. See "1-4-5. Changing the Direction of the Test Strip Feeding" on page 1-15.



- **2** Make sure the standby screen appears at the end of warm-up.
- Go to "2-4. Test Conditions Setup" on the next page.

	TYPE ?
No.	IDER
GLU	URO
PRO	KET
BLD	BIL
NIT	LEU
PH	S.G.
	Standby aaroon

Standby screen

2-3-2 Turning Off the Power

- **Press and hold the** \bigcirc / \bigcirc button for three seconds or more.
- The test strip holder will retract inside the instrument and the display will turn off.

REFERENCE: If the instrument is inactive for three consecutive minutes, it will automatically turn itself off.

2-4 **Test Conditions Setup**

Set the test strip type, measurement number and patient ID (if needed) before testing. If they have already been set correctly, skip this step and go to "2-5. Normal Measurement" on page 2-8.

2-4-1 Selecting Test Strip Type

Select the type of test strip you will be testing. However, you can skip this procedure if you have auto-identifiable test strips, whose type can be automatically detected by the instrument during measurement.

• On the standby screen, press the hyphen button.

· The currently selected type of test strip will appear.

> NOTE: For devices with 10V specifications, the default display is "10V", as shown below. 1011

		10ER
GLU	URO	
PRO	KET	
BLD	BIL	
NIT	LEU	
PH	S.G.	

REFERENCE: Alternately, you can use the following procedure to access this screen:

- On the standby screen, press the [6(►)] button five times.
 Making sure the TYPE ? icon is blinking, press the ↓ button.

2 Press the [8(A)] or [2(V)] button to select the type of test strip.

REFERENCE: "C" is for check strip. Do not select it here.

OPress the button.

· This will confirm your entry and the standby screen will appear again.

		TYPE ?
No. 12	3	IOER
GLU	URO	
PRO	KET	
BLD	BIL	
NIT	LEU	
PH	S.G .	

■ Go to "2-4-2. Setting Measurement Number" on the next page.

2-4-2 Setting Measurement Number

Set the measurement number (up to 4 digits) for the sample to be tested. The numbers of the second and subsequent samples will automatically increment by one. The measurement number is retained even if the power is turned off, unless you set a new measurement number.

● On the standby screen, press the [6(►)] button once.

۲ ZZ ł		
No.	 	

• The current measurement number will appear and the **No.** icon will blink.

Press the button.

• The cursor (_) and **No.** icon will blink.

[≥] No. [≁]	

• Enter the measurement number using the numeric buttons.

No.	123

• A measurement number can contain up to 4 digits.

REFERENCE: To delete the number one digit at a time, press and release the button. To clear the entire entry, press and hold the button for one second.

O Press the button.

• This will confirm your entry and the standby screen will appear again.

REFERENCE: On the standby screen, the measurement number will suppress any zeros. For example, if your entry is "0123", you will see "123" on the display.

		TYPE ?
No. 12	}	1068
GLU	URO	
PRO	KET	
BLD	BIL	
NIT	LEU	
PH	S.G.	

■ Go to "2-4-3. Setting Patient ID" on the next page.

PU-4010 2-7

2-4-3 Setting Patient ID

If your laboratory or office is managing samples based on patient IDs, you can set the patient ID for each sample. A patient ID may contain up to 13 digits including numbers (0 to 9) and hyphens (-).

REFERENCE: The programmed patient ID will be cleared after the completion of a singlesample measurement. Enter a patient ID each time you measure a new sample.

● On the standby screen, press the [6(►)] button twice.

• The last patient ID will appear and the **##** icon will blink. If no patient ID has been set, hyphens (-) will appear instead as shown in the figure.

2 Press the **4** button.

- The cursor (_) will blink.
- The last patient ID will be cleared, if one was set.

0	Enter the patient ID using the numeric	
	buttons or hyphen button.	

• A patient ID may contain up to 13 digits, including hyphens (-).

REFERENCE: To delete the number one digit at a time, press and release the button. To clear the entire entry, press and hold the button for one second.

Our Press the Use Interview Button.

- This will confirm your entry and the standby screen will appear again.
- Once the patient ID has been set, the measurement number and patient ID will alternately appear on the standby screen.

₩	- 1234567890
GLU	URO
PRO	KET
BLD	BIL
NIT	
PH	S.G.

Standby screen showing the patient ID

■ Go to "2-5. Normal Measurement" on the next page.







2-5 Normal Measurement

After completing the test conditions settings, read the following precautions before preparing samples and carrying out testing.

- During sample preparation and testing, wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used samples, test strips and protective gloves in accordance with local regulations for biohazardous waste.

Do not touch the portion where the test strip holder moves. Δ Touching there can cause injury.

IMPORTANT:

- Do not try to move or impact on the instrument. Doing so may cause the instrument to malfunction, producing incorrect results, or may cause test strips to jam.
- If an error code, e.g. "E001", appears and measurement automatically stops in progress, see "5-1. When an Error Occurs" on page 5-1 to clear the error. Then, use a <u>new</u> test strip to retry measurement.

2-5-1 Preparing Samples

Prepare a sample using the following procedure.



IMPORTANT: Do not centrifuge samples. Centrifuging may precipitate blood cells, causing incorrect results for some measurement items.



2-5-2 Preparing Test Strips

For information on how to handle test strips see the package insert.

O Remove only enough strips for immediate use.



2 Immediately cap the bottle.

2-5-3 Testing Samples

Once the sample and test strip have been prepared, dip the test strip into the sample and test it. Quick, precise handwork is required especially for dipping. Therefore, read this section thoroughly before testing.



REFERENCE: You can manually stop measurement in progress anytime after pressing the 0/ button in step 4. To do that, press and hold the \odot button for one second or more.

Open the reading unit cover.



2 Keep one or two pieces of tissue paper (or absorbent paper) at hand.

• This paper is used to remove excess sample from the test strip in later steps.

③ Hold the test strip. Do not dip it into the sample at this point.

- **4** Press the \bigcirc / \bigcirc button.
- The 3-second countdown timer will start and three short beeps will sound.





• When a long beep is heard, immediately dip the test strip into the sample. When the beep stops, take the strip out of the container.

IMPORTANT:

- The test strip must be dipped into the sample for 2 seconds exactly. Shorter dipping may generate insufficient color development, while longer dipping may cause the reagents on the test strip to leak into the sample, whereby producing incorrect results.
- Keep the black marker on the test strip dry.
- **(b)** Blot one side of entire test strip to the tissue paper (or absorbent paper) to remove excess urine. Do not blot front or back of test strip.



IMPORTANT: The error code "E008" may appear during countdown in step 4 and later if room light is too strong for the instrument to read the test strip. In this case, close the reading unit cover and make sure that the error code disappears. The timer will continue to count down, so you can continue testing.
Before the timer reaches "18sec", place the test strip on the test strip holder.

• Slide the strip to the left along the grooves of the test strip holder <u>as far as it will go</u> (see the figure at below right).

IMPORTANT:

- Be sure to place the test strip before "18sec". At "17sec", the test strip holder will start moving and you can no longer place the test strip on the holder.
- An incorrectly positioned test strip may cause incorrect results.
- When the timer reaches "17sEc", the holder will move to the left and back again, thus the instrument will read the test strip.



<u>A short beep will sound when the test is</u> <u>complete.</u> Check the result.

- See "2-7. Examples of Results" on page 2-15.
- The result will print from the printer, if attached. Pull the paper toward you and cut it accordingly.
- The result will also be transmitted to an external device, if connected.

③ Remove test strip from holder and dispose.

Discard used test strips in accordance with local regulations for biohazardous waste.

IMPORTANT: Wipe adhered sample off the test strip holder.

■ This completes testing.

- To test another sample, return to step 2 on page 2-10.
- If all urine tests has been completed, wash the test strip holder (See "4-1. Daily Cleaning" on page 4-1).

2-6 Check Measurement

If you suspect the obtained results are inaccurate, use the check strip that came with the instrument to see if the instrument is working properly. The check strip container contains two gray strips. Use either one for the test.

• Wash the test strip holder.

• See "4-1. Daily Cleaning" on page 4-1.

NOTE: Unless the holder is washed before check measurement, the check strip may be contaminated and lose its effectiveness.



- **2** Select the type of the test strip, "C", for check measurement.
- See "2-4-1. Selecting Test Strip Type" on page 2-5.

No. 150]	
GLU	URO	
PRO	KET	
BLD	BIL	
NIT	LEU	
PH	S.G.	

3 Take a check strip out of the container.

IMPORTANT: Do not touch the surface of the check strip. A check strip contaminated by sebum may cause incorrect results.



4 Open the reading unit cover.

Θ Press the \bigcirc / \bigcirc button.

• Three short beeps will sound, followed by a long beep.



Before the timer reaches "18sec", place the test strip on the test strip holder.

• Slide the strip to the left along the grooves of the holder <u>as far as it will go</u>.

IMPORTANT: An incorrectly positioned test strip may cause incorrect results.

• When the timer reaches "17sEc", the holder will move to the left and back again, thus the instrument will read the test strip.



• A short beep will sound and results will print when testing is complete.

③ Compare results to ranges shown on the check strip bottle label to see if they fall within range.



Qualitative value label

Within range:

Indicates instrument is working properly. This completes check measurement.

Outside of range:

Indicates either the instrument or the check strip may not be working properly. Repeat test with another check strip and go to step 9.



No. 15		
GLU -	URO -	
PRO -	KET -	
BLD ¦÷	BIL -	
NIT -	LEU - Leu/µL	
PH 5.0	S.G. Ⅰ,[] ∃[] <	

* The BLD value will read "0.06 mg/dL" on the printout.

9 Check the results of the second measurement.

Within range:

Indicates check strip used for the first check measurement may not be working properly. Do not use it further.

Outside of range:

Indicates instrument may be malfunctioning. Contact your distributor.

2-7-1 On the Display

The following figure is an example of how results will be displayed after testing.



	Items	Descriptions	
1	Measurement number or patient ID	The measurement number (up to 4 digits) assigned to the sample. If the patient ID has been set, the measurement number and patient ID will alternately appear.	
2	Test strip type	The type of test strip used for testing.	
3	Measurement result	Values of the tested measurement items are listed here.	
		GLU (glucose), URO (urobilinogen), ALB (albumin), PRO (protein), KET (ketones), CRE (creatinine), BLD (blood), BIL (bilirubin), CRE (creatinine), NIT (nitrite), LEU (leukocytes), PH (pH), S.G. (specific gravity), P/C (ratio of protein to creatinine) and A/C (ratio of albumin to creatinine)	
		The (Dil.) icon appears if an incorrect value has been obtained for the ratio of protein to creatinine (P/C) because of diluted sample. Retry measurement using a newly collected sample. Three hyphens () indicate that the semiquantitative value is "OVER" the limit.	

2-7-2 On Printouts

The following figures are examples of how results will print.



Abnormal Result

*MEAS No. 0 0 0 1
ID# 10-1234567890
2005-03-08 12:34 10EA 25°C

*GLU 2 + 200 mg/dL
PR0 + - 1 5 mg/dL
*BIL 1 + 0.5 mg/dL
*UR0 2 + 4 mg/dL
PH 7.0
S.G. 1.010
*BLD 1 + 0. 0 6 mg/dL
KET +- 5 mg/dL
*NIT 1+
LEU 2.5 Leu/uL
6 7
5 1

	Items	Descriptions	
1	Measurement number	The 4-digit measurement number for the sample. The measurement number of an abnormal sample is preceded by an abnormal marker (*).	
2	Patient ID	The 13-digit patient ID preset before testing. If no patient ID has been set, hyphens () appear instead.	
3	Date and time	The date and time when the test was performed. The date format can be any of "year/month/day (default)", "year/day/month" and "day/month/year" according to your setting (See "3-10. Customizing the Instrument" on page 3-11).	
4	Test Strip Type	The type of test strip used for testing.	
5	Environment temperature	The environment temperature (centigrade) inside the instrument during testing.	
6	Abbreviations of measurement items	 The abbreviations of the measured items. Only the measurement items supported by the test strip appear on the printout. * : Indicates that the measurement item is abnormal. ! : Indicates that an incorrect value has been obtained for the ratio of protein to creatinine (P/C) because of diluted sample. 	
7	Test result	The result is shown as qualitative and semiquantitative values. DILUTE: Indicates that an incorrect value has been obtained for the ratio of protein to creatinine (P/C) because of diluted sample. Retry measurement using a newly collected sample.	

Chapter 3 Auxiliary Operations

This instrument provides the following auxiliary functions for managing results or customizing the instrument as you need.

Functions	Reference pages
Selecting test strip type	Page 2-5
Setting measurement number	Page 2-6
Setting patient ID	Page 2-7
Setting the date	Page 3-2
Setting the time	Page 3-3
Reviewing results	Page 3-4
Deleting a specific result from memory	Page 3-5
Clearing all results from memory	Page 3-6
Transferring a specific result to an external device	Page 3-7
Transferring all results to an external device	Page 3-8
Reprinting a specific result	Page 3-9
Reprinting all results	Page 3-10
Customizing the instrument Direction of test strip feeding Date format Unit and qualitative sign Print format Display format Strip type	Page 3-11

3-1 Setting the Date

Use the following procedure to view or adjust the date. The date appears in the "year-monthday" format by default and can be changed to another format such as "month-day-year" or "day-month-year" (see "3-10. Customizing the Instrument" on page 3-11).

0	On the	standby	screen,	press	the [6(▶)]
	button	three tin	nes.		

• The DATE icon will blink.

C C C C C C C C C C C C C C C C C C C	

2 Press the **J** button.

• The current date will appear.

-P005	12-	IS 👘

🕄 Press the 📣 button again.

• The second lowest digit of the year will blink.

- 12- 15

2005-0 1-28

• Enter a new date using the numeric buttons.

- For the year, only the lowest 2 digits can be changed.
- To move among the entry fields, press the **hyphen** button.

REFERENCE: To cancel your entry, press the \bigcirc button.

6 Press the 🖊 button.

• This will confirm your entry and you will be prompted to enter a new time.

Ŭ	ΪϽ・ϹϹ

And then, ...

- To adjust the time go to step 5 in the "3-2. Setting the Time" on the next page.
- To return to the standby screen, press the \bigcirc button.

3-2 Setting the Time

Use the following procedure to view or adjust the time.

● On the standby screen, press the [6(►)] button three times.

• The \bigcirc^{DATE} icon will blink.

2 Press the **4** button.

• The current date will appear.



③ Press the $[8(\blacktriangle)]$ or $[2(\triangledown)]$ button.

• The current time will appear.

	þ
12:55	
	-

④ Press the **↓** button.

• The Date icon and the left-most digit of the time will blink.

<i>`</i> г.гг
 <u>ic·bb</u>

6 Enter a new time using the numeric buttons.



• To move between the entry fields, press the **hyphen** button.

REFERENCE: To cancel your entry, press the \bigcirc button.

6 Press the 🖊 button.

• This will confirm your entry and the standby screen will appear again.

3-3 Reviewing Results

Up to 100 test results are automatically stored in memory and can be retrieved as needed. When more than 100 tests have been performed, the newest result will replace the oldest result, making it no longer possible to view.

● On the standby screen, press the [6(►)] button four times.

₩ MEM

• The ←MEM icon will blink.

2 Press the **J** button.

- The most recent test result will appear.
- If there is no result in memory nothing will appear on the display.
- On the review screen, you can do the following.

				TYPE ?	
No.	<u>123</u>	}		<u>1068</u>	
GLU	+ -	URO	-		
PRO	¦ +	KET	-	-	
BLD	-	BIL	2+	-	
NIT	-	LEU	25.	- eu∕μL	
PH (5.0	S.G .	1.0 1		

Functions	Button operations
View the next result	Press the [8(▲)] button.
View the previous result	Press the [2(v)] button.
View results continuously	Press and hold the [8(▲)] or [2(▼)] button.
Check the measurement number, patient ID and test date and time	Press the hyphen button one or more times until the desired information appears.
Delete the results from memory	(See pages 3-5 and 3-6.)
Transfer the results to an external device	(See pages 3-7 and 3-8.)
Print the results	(See pages 3-9 and 3-10.)

3 To return to the standby screen, press the \bigcirc button.

3-4 Deleting a Specific Result from Memory

Unnecessary results can be manually deleted from the memory. Use the following procedure to delete one result at a time. Please note that deleted data cannot be recovered.

1 Display the result you want to delete.

• See steps 1 and 2 in "3-3. Reviewing Results" on page 3-4.

		TYPE ?
<u>No. 12</u>	3	<u> </u>
GLU + -	URO	-
PRO ¦÷	KET	-
BLD -	BIL	2+
NIT -	LEU	25 Leu/µL
PH 8.0	S.G.)	1.0-10

② Press the [6(▶)] button once.

- If the printer is attached, press the [6(►)] button twice.
- The DEL icon will blink.

	←MEM DEL	TYPE ?
No.	<u>123</u>	<u> 1068 - </u>

3 Press the 🖊 button.

• The result will be deleted from memory and the next result will appear. If there are no more results, the standby screen will appear again.

NOTE: The delete operation cannot be cancelled in progress.

3-5 Clearing All Results from Memory

All stored results can be cleared in a single operation. Please note that deleted data cannot be recovered.

1 Display any of the existing results.

• See steps 1 and 2 in "3-3. Reviewing Results" on page 3-4.

				TYPE ?	
No.	<u>123</u>			<u> 108</u>	8
GLU	+ -	URO	-		
PRO	¦ +	(KET)	-		
BLD	-	BIL	5 ÷		
NIT	-	LEU	25	u∕µL	
PH {	5.0	S.G.	1.0 1		

	←MEM DEL	
No.	<u>123</u>	<u> 1068 - </u>

• The DEL icon will blink.

button twice.

2 Press the $[6(\blacktriangleright)]$ button once.

3 Press the hyphen button four times.

• If the printer is attached, press the [6(►)]

• "ALL" will appear to indicate all results will be cleared.

NEM DEL
ALL

🕑 Press the 📣 button.

- This will clear all the existing results from memory.
- After completion, a short beep will sound and the standby screen will appear.

NOTE: The clear operation cannot be cancelled in progress.

Use the following procedure to transfer an existing result in memory to an external device connected to the instrument.

• Display the result to be sent to the external device.

• See steps 1 and 2 in "3-3. Reviewing Results" on page 3-4.

		TYPE ?
No. 12	3	<u> 1068 - </u>
GLU + -	URO	-
PRO ¦÷	KET	-
BLD -	BIL	2+
NIT -	LEU	25 Leu / µL
PH 5.0	S.G.)	1.0 10

② Press the [6(►)] button twice.

- If the printer is attached, press the [6(►)] button three times.

• The 🗲 icon will blink.

3 Press the 📕 button.

- The 🗲 icon will light steadily to indicate that the result is being transferred to an external device.
- After completion of transfer, the \checkmark icon will disappear.

NOTE: The transfer operation cannot be cancelled in progress.

All results in memory can be transferred to an external device connected to the instrument all at once.

1 Display any of the results in memory.

• See steps 1 and 2 in "3-3. Reviewing Results" on page 3-4.

		TYPE ?
No.	23	<u> </u>
GLU +	- URO	-
PRO	+ KET	-
BLD -	BIL	2+
NIT -	LEU	25 Leu / µL
PH 6.0	} (S.G.)	1.0 10

	← MEM	
No.	123	<u>1068 </u>

2 Press the [6(▶)] button twice.

- If the printer is attached, press the [6(►)] button three times.
- The 🗲 icon will blink.

③ Press the hyphen button four times.

• "ALL" will appear to indicate all of the results will be transferred.

← MEM>	×
RLI	L

🕑 Press the 📥 button.

- The ≠ icon will light steadily to indicate that the results are being transferred to an external device.
- After completion, a short beep will sound and the standby screen will appear.

REFERENCE: To cancel transmission, press the *⊙* button. The instrument will transfer the current result before completely stopping the operation.

3-8 Reprinting a Specific Result

Use the following procedure to print an existing result in memory when the printer is attached to the instrument. Make sure the printer is properly connected to an AC receptacle.

1 Display the result you want to print.

• See steps 1 and 2 in "3-3. Reviewing Results" on page 3-4.

				TYPE ?	
No.	<u>123</u>			<u> 1088</u>	
GLU	÷ -	URO	-		
PRO	÷	(KET)	-		
BLD	-	BIL	2 +		
NIT	-	LEU	25 Lei	u∕µL	
PH 8	5.0	S.G.	1.0 1	0	

2 Press the [6(►)] button once.

• The **____** icon will blink.

	← MEM	
No.	<u>123</u>	1088

🕄 Press the 🚚 button.

• The **____** icon will light steadily to indicate that the result is being printed out.

NOTE: The print operation cannot be cancelled in progress.

3-9 Reprinting All Results

All results stored in memory can be printed in a single operation when the printer is attached to the instrument. Make sure the printer is connected to an AC receptacle.

1 Display any of the results in memory.

• See steps 1 and 2 in "3-3. Reviewing Results" on page 3-4.

		TYPE ?
No. 1	<u>'3</u>	1028
GLU + -	URO	-
PRO ¦+	KET	-
BLD -	BIL	2+
NIT -	LEU	25 Leu / µL
PH 6.0	S.G .	1.0 10

₩₩₩ No. 123 1058

③ Press the hyphen button four times.

2 Press the $[6(\blacktriangleright)]$ button once.

• The **____** icon will blink.

• "ALL" will appear to indicate all of the results will be printed.

←MEM>	` ه
 RLL	

Press the button.

- The **____** icon will light steadily and the results will print with the most recent result first.
- After the completion, a short beep will sound and the standby screen will appear.

REFERENCE: To cancel printing, press the button. The printer will print the current result before completely stopping.

3-10 Customizing the Instrument

This instrument provides "special parameters" that allow you to customize the instrument at your convenience. Changes to these parameter settings remain effective even after turning off and on the power.

Parameter	Description	Options (Boldface and frame: default)	
Direction of test strip feeding	Switches the direction in which the test strip is placed on the test strip holder. The test strip holder must be removed from the instrument before changing this setting (see steps 1 to 3 in the "1-4-5. Changing the Direction of the Test Strip Feeding" on page 1-16).	From right From left	
Date format	Changes the date format. This setting is effective on both the display and printouts. The default for the date format for external output is "year-month-day".	Year-month-day Month-day-year Day-month-year	
Unit and qualitative sign	Changes the unit of the results (conventional or SI) and qualitative sign (+++, +n, or n+).	mg/dL, +++ mg/dL, +n mg/dL, n+ mmol/L, +++ mmol/L, +n mmol/L, n+	
Print format	Changes the print format of results.	Conventional JCCLS compliant	
Display format	Changes the display format for the glucose (GLU) and protein (PRO) values.	Conventional JCCLS compliant	

2 Press the [9] button twice.

• The special parameters screen (shown in step 3) will appear.

Set new values for the parameters using the numeric buttons.

• See the table below. You need to enter new values for the desired parameters only.



Current settings

	Parameters	Options		
1	Direction of test strip feeding	1: From right 2: From left		
2	Date format	1: Year-month-day 2: Month-day-year 3: Day-month-year		
3	Unit and qualitative sign	1: mg/dL, +++ 2: mg/dL, +n 3: mg/dL, n+ 4: mmol/L, +++ 5: mmol/L, +n 6: mmol/L, n+		
4	Print format	1: Conventional 2: JCCLS compliant		
5	Display format	1: Conventional 2: JCCLS compliant		

REFERENCE:

- For example, if you enter "23211", the instrument will be set to "feed test strip from the left, day-month-year, mg/dL, +n, conventional and conventional".

④ Press the **↓** button.

• This will confirm your entries and the standby screen will appear again.

Chapter 4 Maintenance

This section describes how to clean the components of the instrument.

- During maintenance, wear protective gloves to prevent exposure to pathogenic microbes.
- Discard used test strips, cloth and protective gloves in accordance with local regulations for biohazardous waste.

4-1 Daily Cleaning: Test Strip Holder, Holder Base and Guide Rails

Samples may adhere to the test strip holder during testing and contaminant may build up on the holder as more samples are measured. Wash the holder, holder base, guide rails and sliding areas after completing all testing for the day. Also, use this procedure if the error code "E001" appears on the screen. This section assumes that the direction of test strip is set to feed "from the right (default)" (see page 1-15).

1 Turn on the power.

• The test strip holder will extend from the right of the instrument.



❸ Press and hold <u>the [6(►)] button</u>.

- The test strip holder will slightly move to the right until a metallic protrusion appears.
- Slide the test strip holder base to the <u>right</u> and remove it.



6 Turn off the power.

• In the case of AC-power operation, detach the cord of the AC adapter from the instrument.

NOTE: Be sure to turn off the power. Cleaning the guide rails with the power on may damage the instrument.

③ Remove the test strip holder from the test strip holder base.

• Slide the test strip holder approx. 20 mm to the right to unlock. Lift up the holder without hitting the holder base.



Wash the test strip holder and test strip holder base.

• Clean the holder and holder base with a neutral detergent and carefully wash adhered urine off with running water. Use a soft piece of cloth to wipe water off the holder and holder base and dry completely.



③ Wipe dirt off the grooves of the guide rails.

• Use a soft piece of cloth or cotton swab dampened with neutral detergent diluted with water to wipe dirt off the guide rails. Use a soft piece of cloth to wipe water off and dry the guide rails completely.



9 Wipe dirt off the sliding areas.

- Wipe off dirt on the sliding areas (black areas in the enlarged view below) of the reading unit using a swab moistened with diluted nuetral detergent. Move the swab in the direction of arrows as shown below.
- Blot the areas with a dry swab



• Attach the test strip holder to the test strip holder base.

• As shown at the right, place the holder on the holder base. Slide the holder to the left to lock it into place.

1 Insert the test strip holder base from the <u>left</u> side of the instrument until it stops.

• Make sure the grooves on the rear of the holder base are aligned with the guide rails.

• While lightly pressing the <u>left end</u> of the test strip holder base to the right with a finger, turn on the power.

• Make sure the power turns on and the holder base is automatically drawn to the position to the right as shown in the figure and release the holder base.



REFERENCE: If the holder base is not drawn and the error code "E001" appears, press the \bigcirc button to clear the error. While pressing and holding the [$6(\mathbf{F})$] button, lightly press the left end of the holder base to the right. The holder base will then be drawn into the instrument. Release the [$6(\mathbf{F})$] button when the metallic protrusion is completely hidden inside the instrument. The holder will be automatically positioned in place when the next measurement takes place.

4-2 Cleaning the Reading Unit

If the error code "E002" or "E003" appears, clean the reading unit.

1 Remove the test strip holder base from the instrument.

• See steps 1 to 4 in "4-1. Daily Cleaning" on page 4-1.

2 Turn off the power.

• In the case of AC-power operation, detach the cord of the AC adapter from the instrument.

NOTE: Be sure to turn off the power. Cleaning the reading unit with the power on may damage the instrument.

3 Locate the cleaning slot on the bottom of the instrument.



Bottom of the instrument

Insert a cotton swab into the cleaning slot and wipe dirt off the sensor.

• Make sure the tip of the swab touches the sensor while cleaning it.



6 Attach the test strip holder base to the instrument.

• See steps 10 and 11 in "4-1. Daily Cleaning" on page 4-3.

С

4-3 Exterior Cleaning

- The exterior of the analyzer can be cleaned using a soft cloth moistened with distilled water.
- To avoid damage, do not use chemical solvents, lubricants, oils, greases, or silicone sprays to clean the instrument.
- The display screen may be cleaned as needed by wiping with a soft non-abrasive cloth dampened with water.

5-1 When an Error Occurs

You will see an error code on the display (and also on the printout, if using the printer) when there is something wrong with the instrument. See the following table to recover the instrument from the error. If the error persists, contact your distributor.

IMPORTANT: If an error code appears, clear the error and retry testing using a new test strip. You may obtain incorrect results if a certain amount of time has passed since the test strip was dipped into the sample.

Code	Cause	Remedy	
E001	The test strip holder does not move correctly.	Check to see if the test strip holder is correctly attached to the instrument and turn on and off the power. Clean the holder base and guide rails (see page 4-1).	
E002	The LED emits too much light for the instrument to perform testing.	Turn off the power. Wipe dirt off the white plate (white circle portion) on the test strip holder using a soft cloth dampened with water or alcohol. Then, clean the reading unit (see page	
E003	The LED emits insufficient light for the instrument to perform testing.	4-4).	
E004	The printer ran out of the printer paper.	Press the \bigotimes button to return to the standby screen. Load a printer paper and press the FEED button.	
E005	The printer is not working correctly.	Press the button to return to the standby screen. Check to see if the printer is correctly attached to the instrument (see page 1-12). Detach the printer and wipe dirt off the gold metallic printer terminal on the instrument and the gold four- wire terminal on the printer using a dry, soft piece of cloth or cotton swab.	
E006	The test strip is not correctly positioned on the test strip holder.	Press the \bigcirc button to return to the standby screen. Check to see if the tip of test strip contacts the end of the grooves on the test strip holder. If samples or contamination are coagulated on the grooves, remove them.	
E007	The test strip on the test strip holder does not match the test strip type selected.	Check to see if: • You have selected the correct test strip type (see page 2-5). • The test strip is applicable with the instrument.	
E008	The reading unit is subjected to strong light.	If "E008" appears half way through measurement, close the reading unit cover. Make sure "E008" disappears and continue the measurement.	

6-1 Addendum

Differences Between the Human Eye and Instrument Optics

There are inherent differences between the colors that are perceived by the human eye and those that are detected by any instrument optical system. The human eye is capable of detecting minute differences in shade and very small areas of color; artificial optical systems are less sensitive to such small changes. Conversely, instrumental optics are capable of detecting certain colors that are masked by, or blended with, other colors to the human eye.

For this reason, exact agreement between visual results and instrument results might not be found. However, agreement is generally within one visual block or reported level and is equal to, or better than, the agreement between two visual readers.

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 3%		

6-2-2 Clinical Performance

In the PocketChem UA PU-4010 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	98	100	100
Protein	95	99	99
Bilirubin	100	100	100
Urobilinogen	100	100	100
Blood	100	99	99
Ketones	100	100	100
Nitrite	95	100	100
Leukocytes	94	99	99
P/C ratio	88	78	82
A/C ratio	84	91	89

[A/C ratio] vs. Quantitative measurement system H7070 [Other than A/C ratio] vs. AUTION MAX AX-4280



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