

URI-TEX 300

User Manual

Urine Chemistry Analyzer



DU(V6). 2015.05



WARNING

Please read the User's Manual before you operate this instrument.

- 1) Never use ***bent Strip*** and make sure ***remove exceed urine*** on the strip by using soft tissue paper.
- 2) Clean instrument daily to prevent malfunction (If the machine is carefully kept free of excess urine then daily cleaning may not be necessary)
(Refer to 7. How to Clean the Strip Loader(Plate) after Use)
- 3) The instrument **calibrates manually.** (Refer to 5.1 Calibration)
- 4) If battery needs replacing, ensure the correct type is used to prevent the possibility of an explosion. Dispose of used batteries correctly.
- 5) Software version (1st version) on LCD screen in this operation manual can be different from the version(updated) of actual instrument's LCD screen. But, it is no problem in referring use of the instrument to this operation manual.



BIOHAZARD: Wear personal protective equipment. Use universal precautions. Refer to Appendix A for recommended precautions when working with biohazardous materials.

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1. Introduction

Urine test strips simplify laboratory diagnosis through ease of use, high sensitivity and specificity. These benefits allow you to identify pathological changes in the urine quick and reliably. The addition of the Urine Analyzer to the urinalysis process allows for standardization and efficiency of urine test by eliminating potential sources of error associate with the visual reading of test strips, such as improper lighting at the workplace, or different color discrimination by the user or different timing when the values are read. The urine test strips that shall be used with the instrument are multi parameter strips for the determination of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood in urine.

2. System Description

2.1 Principles of Measurement

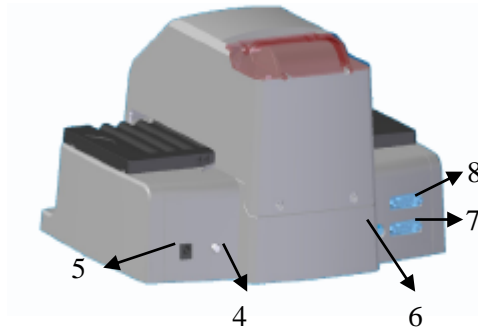
The Urine Analyzer is a urine strip reader and analyzer device for laboratories. The reader is semiautomatic; the forwarding, reading and evaluating are automated. The only thing the operator has to do is to dip the strip into the sample and place it on the strip loading plate.

The Urine Analyzer is a reflectance photometer. The strip is illuminated by white light, and the reflected light from the strip is detected by the Sensor. The RGB signals are digitized, and this digitized image is interpreted by the processor. The intelligent image analyzer SW locates the strip and the pads, and based on these color data the parameter values are determined. The results including the date and time of the measurement, sequence number and the ID are stored and printed out by the internal printer.

2.2 Components and Functions



View from above



View of rear

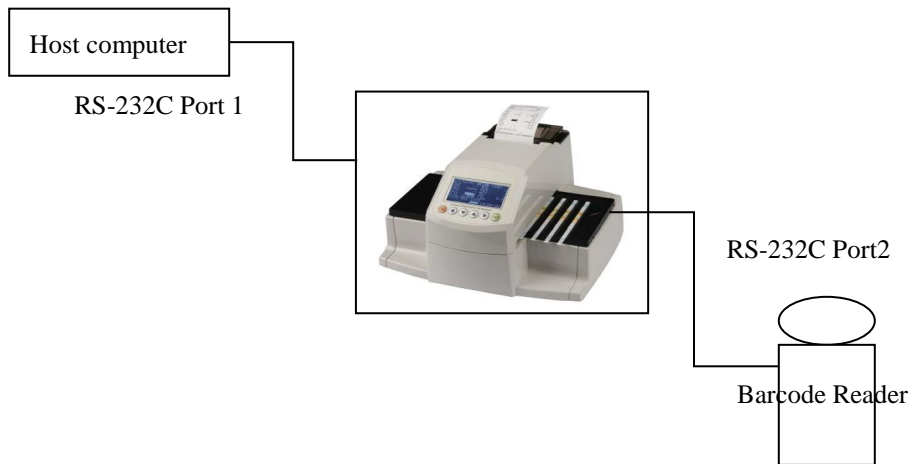
Component	Function
1. Printer Cover:	Can be lifted to insert paper.
2. Strip Loading Plate:	Moves the test strip to the measuring position.
3. LCD Display / Key:	with 6 function keys LCD screen demonstrates working process
4. Power Switch:	Can be ON or OFF with electronic power.
5. Power Connector:	Socket used to connect the analyzer to the external power supply.
6. PS/2 Port:	Keyboard Socket
7. RS 232C Port (COM1):	Serial interface port used for connection to a PC or central laboratory (host) computer.
8. RS 232C Port (COM2):	Connect Barcode Reader(scanner)

2.3 Technical Information

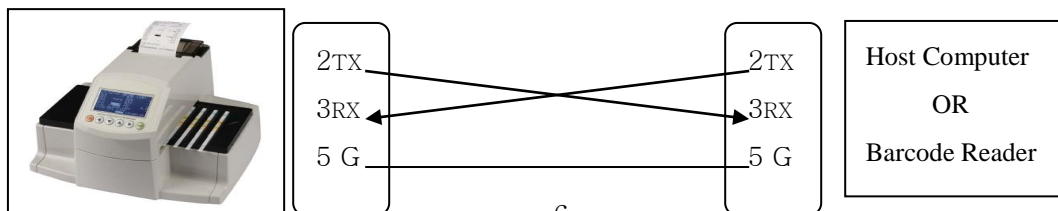
Measurement Method	Reflectance Photometer
Wave Length	460, 550, 650 nm
Dimensions	275*250*170mm
Weight	1300g
Power Supply	Input: 100-250V / Output: DC 12V, 3A
Throughput	300 / Hour (Max 800 tests/hour)
Memory	Up to 2000 samples
Printer	Thermal Printer (Paper size:51(W)*50(D)mm)
Operating Conditions	Temperature(2 °C -30 °C) / Humidity(10%-70%)
Serial Communication	RS232C Interface Port
Available extras	Keyboard / Barcode Reader (Scanner)

2.4 Interfacing System

Users can interface Uri-Tex 300 to Host computer or Barcode Reader through the serial I/O port (RS-232C).



Connection diagram between Uri-Tex 300 and Host Computer



3. Instrument Installation

3.1 The instrument and parts

Urine Analyzer

Strip Loading Plate: Right 2EA

AC adapter 100-240V / 12V DC 3A : 1EA

Power Cable: 1EA

Thermal printer paper: 2 Roll

Calibration Strip: 1 Bottle

Operating Manual

Serial RS-232 cable

Optional accessories

Barcode Reader (Scanner) / External Keyboard

3.2 Environmental & Storage Requirements

1) Environmental Requirements

As with all sensitive electronic instruments, prolonged exposure to excessive humidity and temperature should be avoided. Place the instrument where it will not be subjected to extreme temperature variations. Avoid proximity to open windows, direct sunlight, ovens, hot plates, open burners, radiators, and dry ice baths.

2) Storage and Handling

Locations to be avoided

Avoid using the unit in the following locations since they can cause malfunctioning.

- High humidity, high-temperature, and low-temperature storage places
- Warehouses and other dusty places
- Very hot places near heating appliances, etc

Do not leave the instrument exposed to direct sunlight for long periods of time. This may deform or discolor the body of instrument and may also cause malfunctioning. Do not touch the power-plug with a wet hand. It causes an electric shock. Clean with a dry towel after wiping clean with a towel dampened by a neutral detergent or water.

Do not wipe the body clean with benzene, thinner, gasoline, etc. This may discolor the body of instrument.

3.3 Installation

1) Carefully unpack the Urine Analyzer and place it on a firm and level surface. Do not place the analyzer under direct sunlight or any direct light source.

2) Insert the plate: Grasp the plate end and insert it along the visible sliding rail until it gets between motor gear and bearings sufficiently.

3) Insert the printer paper roll



4) Unpack the adapter and connect it to the socket in the backside of Urine Analyzer. Plug the adapter into the wall socket. Use only the provided adapter. Use of other type adapter can cause defective measurement and general failure.

5) In case of viewing the test results in your computer connect the serial cable to a serial port COM1 of Urine Analyzer and a port for COM1 in the back of computer. Open the PC management program in the connected computer. Then you can see the test results automatically in your computer after testing

6) To use a Barcode reader/scanner to identify samples etc., plug it into the Serial Port (COM2) on the backside of the Urine Analyzer.

7) To use keyboard to identify samples etc., plug it into the socket on the backside of the Urine Analyzer and input the patient's ID.

The Urine Analyzer is now ready to use.

4. Main Process

Step 1. Put the plate into the middle of the instrument and connect AC adapter to the port on the backside of instrument and power on.

Step 2. Automatically the Instrument executes System Check and then the plate moves to the middle of the reader.

Step 3. Calibration (Refer to 5.1 Calibration)

Step 4. Measurement MODE

On condition the plate is stopped, place each strip dipped in the urine one by one.

At this time, there are three selective modes for detecting the test strips.

General Mode: Calculate placing time of 'whole strips'. [press start(▶) key 'after' putting 1st test strip on the groove located in the nearest to center of instrument, place next test strip (max. 10 test strips) and then press **End (ENT)** key after placing the last test strip] (**Refer to 5.2 General Mode**)

One by One Mode: Recognize placing time of 'each strip'. [press start(▶) key 'after' putting 1st test strip on plate like general mode and press another next(▶) key whenever you place each additional strip(max. 10 test strips) and then press End (ENT) key after placing the last test strip] (**Refer to 5.3 One by One Mode**)

Quick Mode: Place all test strips and then press End (ENT) key. (**Refer to 5.4 Quick Mode**)

Step 5. Waiting

Standby Urine Analyzer until the color incubation of 1st strip is completed.

Step 6. Reading

After the 1st strip finish color incubation, the instrument starts to measure.

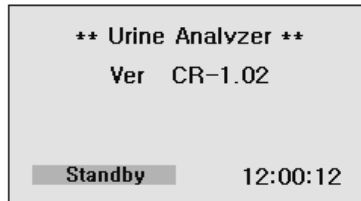
Step 7. Remove Strips

As soon as Urine Analyzer finishes the measurement, it will be changed to waiting mode. At this time, operator can check the result by watching display or prints out with the naked eye before he/she throw away these already checked out strips.



5. How to operate instrument

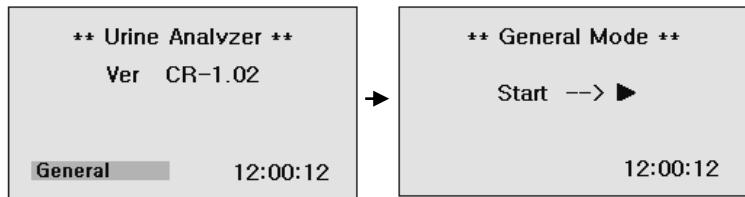
Turn ON the Power switch in the rear of instrument. Then the start page will be shown as [Fig.5] and the instrument checks the system automatically.



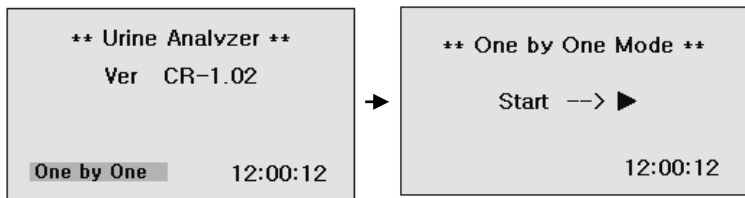
[Fig. 5] Standby mode

Depending on the method of measurement, 3 different measurement modes can be selected by Function Key (◀) and press ENT key to set.

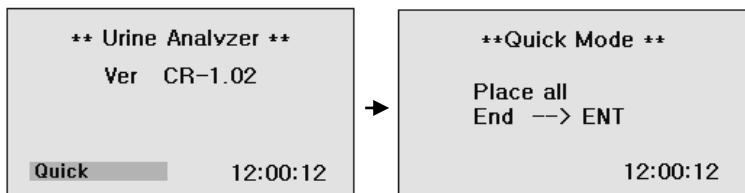
General Mode



One by One Mode



Quick Mode



For more detailed working procedures under each mode, please refer to 5.2, 5.3 and 5.4.

5.1 Calibration

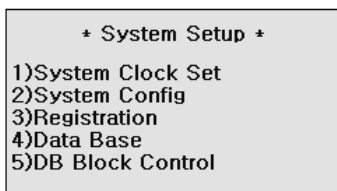
The Urine Analyzer is calibrated before shipment by the manufacturer. The Calibration of instrument should be done prior to first use and then the same process from the 2nd time can be recommended to do in **every 4 weeks** with Calibration Strip in the package. Calibration Strip is used for checking aging processes of the optical system and variation of other internal conditions of instrument. When strong variation is detected which may be caused, for instance, by contamination of the reference pad or low light intensity of a defective light source, an error message will be printed.

The Calibration Strips are plastic white standard strips with defined and constant reflectance characteristics. The Calibration Strip should remain in the vial until use and should be used only once. Do not touch in the middle areas of the strip. The plate strip tray should be clean and dry before a calibration is performed.

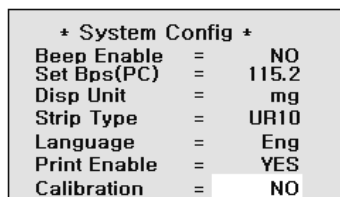
For calibration, proceed as follows:

Step1. In the 'Standby' mode, Press < Esc > **key twice** to display "System Setup" [Fig.6].

In System Setup, press number **2** key and the display [Fig.6.2] will be shown as below.



[Fig.6] System Setup Mode



[Fig.6.2] System Configuration Mode

Step2. Move to **Calibration** by using ▲▼ (up, down) keys and select **YES** by using ◀▶ (left, right) keys.

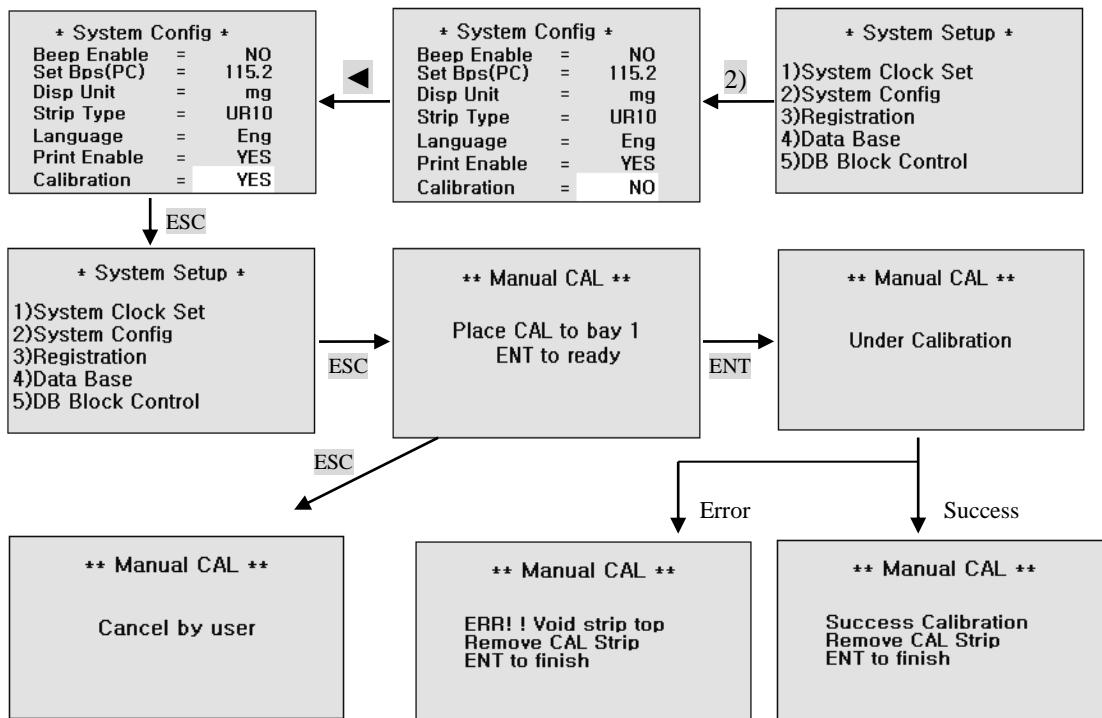
Step3. Press **ESC** key twice

Step4. Put the 'Calibration Strip(CAL)' into **the 1st position of Strip Loading Plate** and then press < **ENT** >.

The calibration checking procedure can be stopped by pressing <**ESC**>.

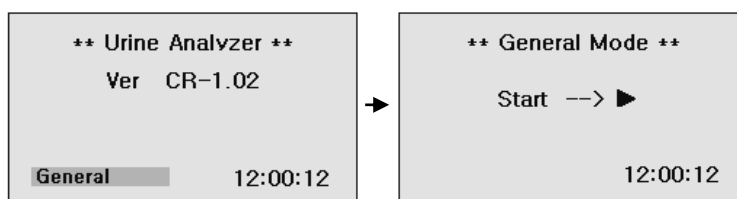
Step5. After calibration finished, the result of calibration print out.

If the calibrations values are between 333+/-10(323 ~ 343), it is OK.



5.2 General Mode (Press ◀ key at 'Standby' mode)

1) In the state of **Standby**, following will be displayed after pressing the ENT key.

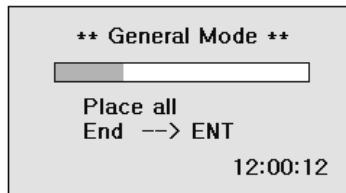


Press **ESC** key and you will return to **Standby** mode.

2) After the 1st strip dipped in the urine is placed on the plate, press **Start** key (▶).

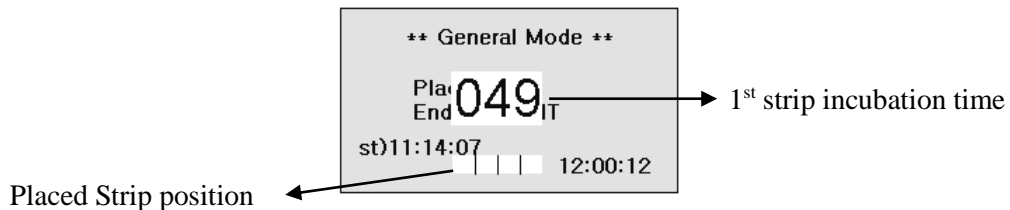
Put the 2nd ~ 10th (max.) strips one by one from the center of instrument after dipping in each collected urine. (The Progress Bar display for 100 sec incubating time)

After the last reagent strip of a batch is placed, press **End (ENT)** button. On pressing End key, recognition of measurement time from Start to End can be calculated by the instrument.



Press **ESC** key to cancel placing strip and evaluation.

3) Waiting for incubation of 1st strip



4) After incubation time of the 1st test strip, it start to read test result of the strips on the plate one by one.

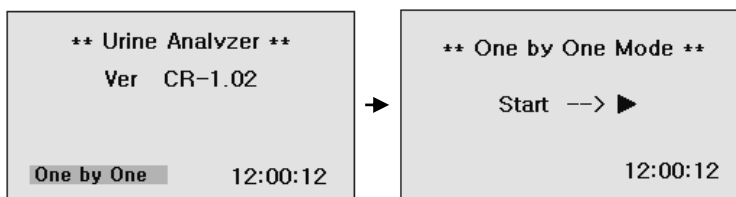
5) Test result will be printed out, shown on the LCD and automatically saved in the memory.

6) Press **ESC** key and you will return to **General** mode.

5.3 One by One Mode

1) In the state of Stand by, following will be displayed after pressing the **ENT** key.

Press **ESC** key and you will return to **Standby** mode.

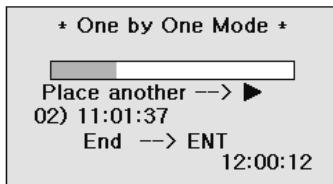


2) After the 1st strip dipped in the urine is placed on the plate, press **Start** key (►).

Button **Place another** key(►) whenever each of next strip is placed on the plate one by one from the center of instrument after dipping in the collected urine and placing on the plate.

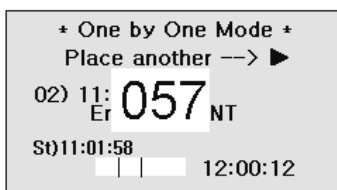
(The Progress Bar display for 100 sec incubating time) By pressing **Place another** key(►) per

measurement of each strip, the exact measuring/starting time is recognized.
After the last reagent strip of a batch is placed, press **End (ENT)** button.



Press **ESC** key to cancel placing strip and evaluation.

3) Waiting for incubation of 1st strip



4) After incubation time of the 1st test strip, it start to read test result of the strips on the plate one by one.

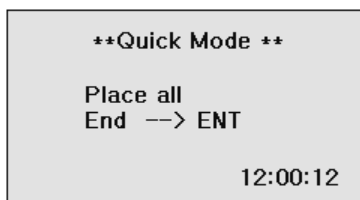
5) Test result will be printed out, shown on the LCD and automatically saved in the memory.

6) Press **ESC** key and you will return to One by One mode.

5.4 Quick Mode

1) In the state of **Standby**, following will be displayed after pressing the **ENT** key.

Press **ESC** key and you will return to **Standby** mode.



2) Test strips are temporarily incubated outside the instrument and inserted at the correct time.

After the last reagent strip of a batch is placed, press **End (ENT)** button.

3) Test result will be printed out, shown on the LCD and automatically saved in the memory.

4) Press **ESC** key and you will return to **Quick** mode.

5.5 How to input ID

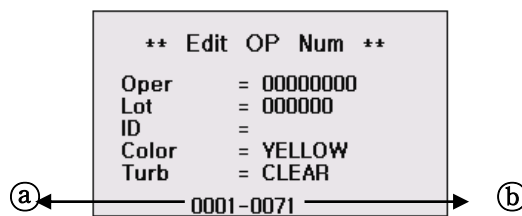
There are 2 ways to input ID into Urine Analyzer.

1st Method

The user can input patient/sample's ID using barcode Reader (scanner) while measurement.

2nd Method (Multi ID input)

In **System Control** mode press ③ key and the display [Fig.6.3] will be shown as below. Use ▲ ▼ key to move to each item. Press ESC key and you will return to System Setup mode.



[Fig.6.3] Registration Mode

● ID

- 1) Enter patient/sample's ID using Keyboard or Barcode Reader. Press ENT key or ► (Right direction) key. Then enter next patient/sample's ID. If you want to change the ID number, you can go to the ID using ◀► (Right direction, Left direction) key and enter ID number again.
- 2) Part ① is serial number of urine samples to be tested. As you register patient/sample's ID numbers, the number in entry ① increases in order.
- 3) Part ② is data location number; this will be stored in data base memory after measurement.
- 4) If patient/sample's IDs are as same as serial numbers, you may register only the first patient/sample's ID. Then the others will be numbered in order automatically. In that case, next ID number will be increased one by one from the first number. This number will increase even when restarting the system after turning off the power.
- 5) If patient/sample's ID is not registered before a test, ID columns will be blank.
- 6) To stop printing patient/sample's ID before the test, make it blank in ID (just input only"0" key, this will erase ID area)

6. System Setup

In **Standby Mode** of [Fig.5] press **ESC** key twice to display **System Setup** [Fig.6].

* System Setup *	
1)System Clock Set	
2)System Config	
3)Registration	
4)Data Base	
5)DB Block Control	

[Fig.6] System Setup Mode

6.1 System Clock Set: Set Date and Time.

* System Clock Set *		
YEAR	=	2006
MONTH	=	12
DATE	=	21
HOUR	=	13
MINUTE	=	31
SECOND	=	8

[Fig.6.1] System Clock Set Mode

- 1) Move to each item by using ▲▼ (up, down) keys and adjust time by using ◀▶ (left, right) keys or NUM keys.
- 2) After adjusting local time, press ENT key to set.
- 3) To escape System Clock Set mode, press ESC key and you will return to **System Setup** mode.

⚠ **Do not forget to press ENT key after finishing time adjustment.**

6.2 System Configuration

In case of changing the **System Configuration** saved in the analyzer, in **System Setup** press 2) key and the display [Fig.6.2] will be shown as below.

Move to each item the System Configuration by using ▲▼ (up, down) keys and adjust the details of each System Configuration item by using ◀▶ (left, right) keys.

If you press the **ESC** button in the selecting screen of the details, you can return to the previous screen.

* System Config *		
Beep Enable	=	NO
Set Bps(PC)	=	115.2
Disp Unit	=	mg
Strip Type	=	UR10
Language	=	Eng
Print Enable	=	YES
Calibration	=	NO

[Fig.6.2] System Configuration Mode

- **Beep Enable**

If you select **YES**, beep will sound while operating instrument.

Use ◀▶ keys to select **YES** or **NO**.

- **Set Bps(PC)**

This is to select speed rate while transferring data with each other between the instrument and PC. Under general conditions **115.2** should be selected.

- **Disp Unit**

Select the unit of test results: **mg** or **mol**.

- **Strip Type**

This is to select the Strip type for test.

The Strip type should be matched with the Strip type being used.

Name	1	2	3	4	5	6	7	8	9	10	11	12
DS 4SG	P	G	S	H								
DS 5	B	K	G	P	H							
DS 6	P	H	O	K	B	G						
DS 7	U	P	H	O	K	B	G					
DS 8	N	U	P	H	O	K	B	G				
DS 9	N	U	P	H	O	S	K	B	G			
DS10	L	N	U	P	H	O	S	K	B	G		
DS11	L	N	U	P	H	O	S	K	B	G	A	
DS 2AC	M	C										
DS10AC	L	N	O	H	S	K	G	P	M	C		
DS12AC	L	N	U	P	H	O	S	K	B	G	M	C

U=Urobilinogen, G=Glucose, B=Bilirubin, K=Ketones, S=S.G, O=Blood, H=pH,

P=Protein, N=Nitrite, L=Leukocytes, A=Ascorbic Acid, M=Microalbumin, C=Creatinine

- **Language**

English, French, German, Spanish, Italian, Portugal and Chinese

- **Print Enable**

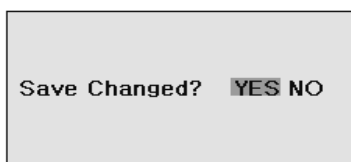
Select printer on or off by selecting **1YES / 2YES** or **NO**.

If you select **1YES**, test results will be shown both on LCD and printing paper.

If you select **2YES**, test results will be print out **TWO** times.

When you finish selecting all conditions, press **ESC** key.

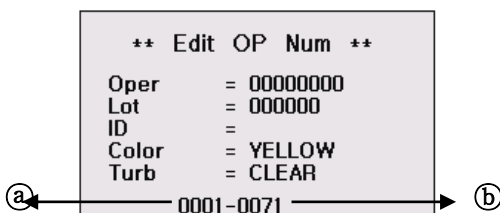
If change from present conditions is not required, just return to System Setup mode. But if any change is needful, the display will ask you to confirm saving the change.



If you decide to change anything (YES or NO) and press **ENT** key, you will go back to **System Setup** mode.

6.3 Registration

In **System Setup** mode press 3) key and the display **[Fig.6.3]** will be shown as below. Input data on each item and use **▲▼** key to move to next item. Press **ESC** key and you will return to **System Setup** mode.



[Fig.6.3] Registration Mode

- **Oper , Lot**

Enter operator's ID and strip lot number by using numeric keys. If you don't need to record the test operator's ID you may skip and leave it blank.

- **ID**

Enter patient/sample's ID using numeric keys, external keyboard or barcode reader (scanner). Press **ENT** key or **▶** (Right direction) key. Then enter next patient/sample's ID. If you want change ID number, you can go to the ID using **◀▶** key and enter ID number again.

(Refer to 5.5 How to input ID)

- **Color**

Color changes in order of YELLOW, DK YELLOW, STRAW, AMBER, RED, ORANGE, GREEN and OTHER, by pressing ◀▶ keys.

- **Turb**

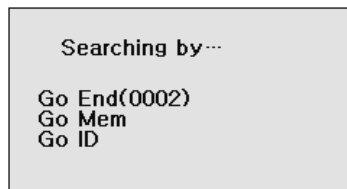
Turbidity changes in order of CLEAR, SL CLOUDY, CLOUDY, TURBID and OTHERS, by pressing ◀▶ keys.

- 1) Select patient/sample's Color/Turb using ◀▶ keys. Press ENT key. And then enter next patient/sample's Color/Turb.
- 2) Part ① is serial number of urine samples to be tested. As you register patient/sample's Color/Turb one by one, the number in entry ① increases in order.
- 3) Part ② is data location number; this will be stored in data base memory after measurement.
- 4) If patient/sample's Color/Turb is not registered before a test, Color/turb columns will be blank.
- 5) To stop printing patient/sample's Color/Turb before the test, make it blank in Color/Turb.

6.4 Data Base

In **System Setup** mode press 4) key and the **Searching by** will be shown as [Fig.6.4].

The data saved in the memory of instrument can be searched by using ▲▼ keys.



[Fig.6.4] Data Base Mode

- **Go End:** Press ENT key and then latest result will be shown as [Fig.6.4.1].
- **Go Mem :** Input SEQ Number by Keyboard and then the result will be shown as [Fig.6.4.1].
- **Go ID:** Input patient/sample's ID by Keyboard and then the result will be shown as [Fig.6.4.1].

- ① shows the time of measurement.

- ② shows strip type.

① ←	17:47:10	URINE(10)	→ ②
	URO norm	GLU -	
	BIL	KET -	
	S.G 1.020	BLD -	
	pH 6.0	PRO -	
	NIT -	LEU -	
←	0125		

- © is data's number saved in data base. ©

[Fig.6.4.1] Data Base

- 1) You can also go to the data by using ◀▶ keys.
- 2) You can print out the result on the display by pressing ENT key.

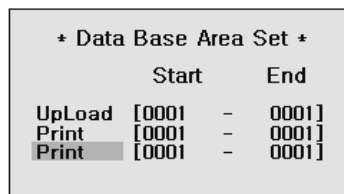
Data base can save up to 2000 test results in its memory. When memory is full, the data can be transferred to PC by **RS232c interface cable** and sorted by its tested Date in PC. Otherwise the oldest data of the instrument will be erased on the 'first in first out' basis.

3) To erase all data in Data Base Type in "9999" and press "ENT" key at area © by using keyboard . After clearing this number restarts at 0001.

⚠ **Do this with care as stored data cannot be recovered.**

6.5 DB Block Control

In **System Setup** mode press 5)key and the display will be shown as [Fig.6.5].



* Data Base Area Set *			
	Start		End
UpLoad	[0001	-	0001]
Print	[0001	-	0001]
Print	[0001	-	0001]

[Fig.6.5] Data Base Block control

- **UpLoad**

To transfer test results data to PC by RS 232C.

You can input data using Keyboard. Press ENT key to operate a system.

- **Print**

To print out the results data.

Note: Printing Area is limited to max. 50 test results at one time.

- **Print** (=Abnormal result Print)

To print out **the abnormal results**.

- 1) Select Upload or Print mode, **Print** mode by using ▲▼key and select the **Start Num** and **End Num** by using Keyboard.
- 2) If DB is empty, an error message of "**No Data in Data Base**" will appear at the center of display and go back to its previous mode.

3) After all data completely finished, “**OK Finish**” message will appear.

7. How to Clean the Strip Loader Plate after Use

⚠ Caution: It is better for the strip loader plate to be cleaned everyday because it can be stained by the tested strip and remaining urine smeared into the loader.

Step1. Turn the instrument **power OFF in advance and then separate the plate** from the body of the instrument.

Step2. Completely clean all the grooves of the detached strip loader plate and clean the contaminated area using a neutral detergent or a water-wet towel. Do not use volatile material like thinner, gasoline, and benzene for cleaning the body.

Step 3. Polish the plate with a soft cloth and make sure to dry it completely



8. Quality Control

Performance of reader result should be confirmed by testing known negative and positive specimen or controls whenever a new bottle is first opened or calibration.

Water should NOT be used as a negative control.

Controls should be tested after performing maintenance or service on the Uri-Tex 300. Quality Control materials should be used in accordance with local, state, and/or federal guidelines.

- 1) Quantimetrix the dipper urine dipstick control (Homepage: www.4qc.com)
- 2) MAS UA Control (Homepage: www.mas-inc.com)
- 3) Liquicheck Urinalysis Control (Homepage: www.bio-rad.com)

9. Table Result

Item	Abbreviation	Unit		Result of Reading								
				Neg.	±	+1	+2	+3	+4			
Leukocytes	LEU	Con.	WBC/ μ l	neg	15	70	125	500				
		SI										
		Arb										neg
Nitrite	NIT	Con.		neg	Pos							
		SI										
		Arb										+
Uribilinogen	URO	Con.	mg/dl	0.1		1	2	4	8			
		SI	μ mol/l	1.6		16	33	66	131			
		Arb		norm		+	++	+++	++++			
Protein	PRO	Con.	mg/dl	neg	15	30	100	300	1000			
		SI	g/l	neg	0.15	0.3	1	3	10			
		Arb		neg	±	+	++	+++	++++			
pH	pH	Con.		5	6	6.5	7	7.5	8	8.5	9	
		SI										
		Arb										
Blood	BLD	Con.	RBC/ μ l	neg	10	25	80	200				
		SI										
		Arb										neg
Specific Gravity	S.G	Con.		1.000	1.005	1.010	1.015	1.020	1.025	1.030		
		SI										
		Arb										
Ketones	KET	Con.	mg/dl	neg	5	15	40	80	160			
		SI	mmol/l	neg	0.5	1.5	3.9	8	16			
		Arb		neg	±	+	++	+++	++++			
Bilirubin	BIL	Con.		neg		Small	Moderate	Large				
		SI										
		Arb										neg
Glucose	GLU	Con.	mg/dl	neg	100	250	500	1000	2000			
		SI	mmol/l	neg	5.5	14	28	55	111			
		Arb		neg	±	+	++	+++	++++			
Ascorbic Acid (Vitamin C)	VTC	Con.	mg/dl	neg		20	40					
		SI	mmol/l	neg		1.2	2.4					
		Arb		neg		+	++					
Microalbumin	ALB	Con.	mg/l	10	30	80	150					
		SI										
		Arb										
Creatinine	CRE	Con.	mg/dl	10	50	100	200	300				
		SI	mmol/l	0.9	4.4	8.8	17.7	26.5				
Albumin to Creatinine ratio	A:C	Con.	mg/g	<30		30-300		>300				
		SI	mg/mmol	<3.4		3.4-33.9		>33.9				
				Normal		Abnormal		High Abnormal				
Protein to Creatinine ratio	P:C	Con.	mg/g	<150		≥150						
				Normal		Abnormal						

10. Troubleshooting & Maintenance

<u>Symptoms of Error</u>	<u>Possible Cause or Related Symptoms</u>	<u>Cause/Symptom No.& Remedy</u>
<p>A-1 The instrument will not work even though power is on</p>	<ol style="list-style-type: none"> 1. The connection part for power source may be loose. 2. Defective system electronics 	<ol style="list-style-type: none"> 1. Turn the instrument power OFF. Check that the power cord is firmly plugged into the instrument and into a live AC electrical outlet then turn the power ON (AC adapter : 100-240V/12VDC 3A) 2. Contact your Customer Service Office
<p>B-1 Always shows 'false positive (+) test result' - Result by visual test with color chart shows negative results - Other reference tests show Negative results</p>	<ol style="list-style-type: none"> 1. Examine state of used strip and check out if any belong to a case described below; <ol style="list-style-type: none"> a) Order(sequence) of test parameter on printed results is differ from it of the label on strip's bottle. (Tested strip model is not fit for this mode analyzer) b) Reacted color(s) of reagent pad on the strip is(are) much different from those of the color chart label on the strip bottle. c) Shape of used strip was bent(curved) strip d) Detection was done with dry strip(before dipping in the urine) or any other test strip instead of the reagent strip for this model analyzer e) Tested without placing the dipped strip on the plate f)Strip position was turned upside-down or wrongly positioned g) Reagent pad(s) were not fully wetted by the urine h) Reagent strip was not placed on the tray 'immediately' after dipping in the urine and removal of excessive urine 2. Strip type is wrongly set up (Location for strip set-up: System Setup/ 2.System Config / strip type) 3. There is a lot of dirty urine(contamination) on the Strip Loader Plate 4. The Calibration Value not included 333(+/-10) 	<ol style="list-style-type: none"> 1. <ol style="list-style-type: none"> a) Misuse by user b) c) Retry to test with a new unopened bottle Strips d)e)f)g)h) Careful handling of the strips by referring to instruction of use for strip 2. Careful handling of the analyzer by referring to user manual for the analyzer 3.Cleaned Strip loader Plate (referring to User manual/7.How to clean the Strip Loader Plate after use) 4.Retry to calibrated with a new calibration stik

<u>Symptoms of Error</u>	<u>Possible Cause or Related Symptoms</u>	<u>Cause/Symptom No. & Remedy</u>
<p>C-1 Calibration values are out of normal values</p>	<p>1. There is a lot of dirty urine (contamination) on the calibration strip</p> <p>2. The shape of calibration stick is bent (curved) strip</p> <p>3. CIS Module contamination Problem</p>	<p>1,2: Retry to calibrated with a new calibration stick</p> <p>3. Clean the CIS Module</p> <p>If you have the same error even after re-install of the paper correctly, Contact your Customer Service Office</p>
<p>D-1 Does not print</p>	<p>1. Printer mode is set as "NO" (Location for changing printer mode: System Setup /2. System Config /Print enable)</p> <p>2. Test results can be displayed through LCD monitor and other functions (drive, measurement etc.) works correctly</p> <p>3. Test results can't be displayed through LCD monitor and other functions (strip detection, printing etc.) works incorrectly</p>	<p>1. Print enable "Yes" setting</p> <p>2. Check the Printer Paper width (Normal Standard: 51mm(W) * 50mm(D))</p> <p>3. Replace the adapter and power cable and then direct connection into a fixed socket-outlet</p>
<p>E-1 Display a message "Misplaced strip"</p>	<p>1. The strip for test is wrongly positioned on the strip plate</p> <p>2. Calibration Problem</p> <p>3. CIS Module contamination Problem</p>	<p>1. Misuse by the user</p> <p>2. Calibrated by calibration stick (refer to Operating Manual/ 5.1 Calibration)</p> <p>3. Clean the CIS Module</p>
<p>F-1 'Error void strip top'</p>	<p>Calibration stick position problem</p>	<p>Put the calibration strip on right position of tray up to the top edge and retry to calibration</p>

<u>Symptoms of Error</u>	<u>Possible Cause or Related Symptoms</u>	<u>Cause/Symptom No. & Remedy</u>
<p>G-1 Strip Plate does not move into(out from) the machine</p> <p>G-2 Strip Plate always pull out</p> <p>G-3 A Strip Plate stops unexpectedly during operation</p>	<ol style="list-style-type: none"> 1. Not used power supply of adapter (12V, 3A) 2. Plate malfunction problem 3. Plate Sensor Problem 4. Motor Problem 	<ol style="list-style-type: none"> 1. Misuse by the user 2. Replace 'Plate' with a new one. 3,4 Contact your Customer Service Office
<p>H-1 Key does not work</p>	<ol style="list-style-type: none"> 1. Key PCB Problem 2. LCD PCB Problem 	<ol style="list-style-type: none"> 1,2 Contact your Customer Service Office
<p>I-1 LCD is black (shows nothing) or wrong</p>	<ol style="list-style-type: none"> 1.LCD PCB Problem 2.Main PCB Problem 	<ol style="list-style-type: none"> 1,2. Contact your Customer Service Office
<p>M-2 Can't connect to LIS</p> <p>M-3 LIS results include strange letters</p> <p>M-4 When connect to PC, the items can't be shown correctly on the results</p>	<ol style="list-style-type: none"> 1. Check out settings are as followings; Baud rate : 115200, Com Port: COM1 2. Serial cable between analyzer and PC is incorrectly connected 3. Serial port in the computer is USB Port 	<ol style="list-style-type: none"> 1. If the set up condition is different from the left conditions, make it as same like left side 2. Correctly connected. But if it is not working, replacement RS232C Cable 3. Use 'USB To RS232 Converter Cable' instead of USB
<p>O-1 Barcode does not work</p>	<ol style="list-style-type: none"> 1.Checked as follows; Baud rate : 9600 2.The port set with the machine is COM2 3. The barcode is serial port (not PS2) 	<ol style="list-style-type: none"> 1,2 It the set up condition is different from the left conditions, make it as same like left side 3. Check the Interface RS232C 9pin configuration

Appendix A: Safety Information

Protecting Yourself from Biohazards

This information summarizes the established guidelines for handling laboratory biohazards. This summary is based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- needlesticks
- hand-to-mouth contact
- hand-to-eye contact
- direct contact with superficial cuts, open wounds, and other skin conditions that may permit adsorption into subcutaneous skin layers
- splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the system that have contact with body fluids such as serum, plasma, urine, or whole blood
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves
- Perform procedures carefully to minimize aerosol formation

- Wear facial protection when splatter or aerosol formation are possible
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants
- Keep your hands away from your face
- Cover all superficial cuts and wounds before starting any work
- Dispose of contaminated materials according to your laboratory's biohazard control procedures
- Keep your work area disinfected
- Disinfect tools and other items that have been near any part of the system sample path or waste area with 10% v/v bleach
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory
- Do not mouth pipet any liquid, including water
- Do not place tools or any other items in your mouth
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands

Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand. Needlestick injuries may result.

Registration sheet

Please complete the following Registration Sheet, and fax back within two weeks to your local distributor.

These data are recorded in the Service Registration File, providing assistance for our Support Service.

Serial Number of the Instrument: _____

Date of delivery:

Date of Installation:

The Institution / Laboratory

address:

telephone:

The person, who is responsible for the operation:

Number of the samples in daily routine:

The previously used method for urine analysis:

Your distributor:

Manufacturer:

PZ Cormay S.A.

Wiosenna 22, 05-092 Lomianki, Poland



