

# **User Manual**

## Urine Chemistry Analyzer





DU(V2). 2015.01

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**Appendix A. Safety Information** 

## WARNING A

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

1) Never use *the bent strip* and make sure *to remove excess urine* in the strip by using a clean absorbent soft tissue paper.

2) Clean instrument daily to prevent malfunction.

To Clean the instrument, Refer to 7. How to Clean the Strip Loading Plate after Use.

3) If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

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

#### 1. Introduction

Urine test strips simplify diagnosis of disease 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, blood, microalbumin , creatinine, calcium and so on in urine.

#### 2. System Description

#### 2.1 Principles of Measurement

The URI-TEX is a urine strip analyzing device. The reader is semiautomatic but the forwarding, reading and evaluating are automated. The only thing that the operator need to do is to dip the strip into the urine sample and place it on the Strip Loading Plate.

The URI-TEX 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 ID are stored.

#### 2.2 Components and Functions



View from above

View of rear

#### Component

Function

**()**Full-color 'touch-screen' TFT LCD: Displays the result and the process of test

②Strip Loading Plate: Moves the test strip to the measuring position

#### **3Battery cover**

(4) USB Port: Serial interface port used for connection to a PC or central laboratory (host) computer

**5**Power Button: Turns on/off the system

**(6)Power Connector**: Socket used to connect the analyzer to the external power supply

#### **2.3 Technical Information**

Measurement Method	Reflectance Photometer
Wave Length	470, 530, 626 nm
Dimensions	Width(188mm), Depth(74mm), Height(77mm)
Weight	460g
Power Supply	Input: 100-240V / Output: DC 12V, 3.33A
Battery	AAA 1.5V * 8
Throughput	45 / Hour (120 tests/hour under 'Quick' mode)
Memory	Up to 2000 samples
Operating Conditions	Temperature( 2°C-30°C) / Humidity(10%-70%)
Serial Communication	USB Port
Options	External Printer

#### 2.4 Interfacing System

Users can interface URI-TEX to Host computer through the USB port. Baud Rate : 38400, Data bit : 8, Parity: none

#### **3. Instrument Installation**

**3.1 The instrument and parts** URI-TEX : 1EA Strip Loading Plate: 1EA AC adapter 100-240V / 12V DC 3.33A : 1EA Power Cable: 1EA Operating Manual USB cable

#### **Optional accessories**

External Printer for exclusive use with URI-TEX analyzer

#### 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

Avoid following locations to prevent malfunctioning of the analyzer

- High humidity, high-temperature, and low-temperature storage places
- 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 instrument body and cause malfunctioning. Do not touch the power-plug with a wet hand. It causes an electric shock. Use a dry towel after cleaning by a neutral detergent or water. Do not use benzene, thinner, gasoline, etc. to clean the instrument body. This may discolor the body of instrument.

## 3.3 Cautions & Warnings AC adaptor

## (AC CORD Type, Input Voltage: AC 100~240V, 50/60Hz, 1.2A Output Voltage: DC 12V/3.33A)

Handle the AC adaptor carefully. Improper handling is dangerous.

- Do not touch it with wet hands.
- Do not place heavy objects on top of it.
  - ▲ Be sure to connect only the AC adaptor provided with the instrument
  - $\triangle$  Disconnect the AC adaptor from the power outlet if the instrument is not going to be used for a long time.

## Instrument

 $\heartsuit$  No altering or remodeling. This can cause malfunction.

 $\heartsuit$  No dropping or strong impacts. This can damage the instrument.

A Do not forcibly pull/push the Strip Loading Plate. It may cause malfunction.

 $\triangle$  Be sure to read carefully user's manual before operating the instrument.

### 4. How to operate instrument

Turn ON the power button in the rear of instrument. Automatically the reader executes System Initialize [Fig 1.1] and then the 'Standby' mode shall be shown as [Fig.1.2].



[Fig.1.1] System Initialize



[Fig.1.2] Standby mode

#### 2014-01-29 10:32:30 Strip Selection 01 URINE-10 02 URINE-2AC 03 04 05 06 07 08 09 ▼ Test

4.1 Strip type Selection

Touch the strip type in order to change the strip to be tested. Use the  $up(\blacktriangle)$  and  $down(\triangledown)$  symbol to scroll through the list until the strip type you want to use is searched.

Touch the strip type to confirm and the selected strip type color change from black to blue. Touch **Test** and return to the Standby mode screen.

 $\triangle$  Do not use any reagent strip product other than what is shown on the display. Using the wrong reagent strip will give you incorrect results.

[Fig. 1.2.1] Strip Selection

#### 9

#### 4.2 Seq (Sequence)



[Fig. 1.2.2] Set Seq

The test sequence numbers run from 1 to 2000 and can be reset.

Use the move left key( $\triangleleft$ ) or C (clear) to erase the existing sequence number.

Touch **Test** to confirm the reset or to leave the screen if you have not selected the option to reset the number. You will return to the Standby mode screen .

#### 4.3 ID No



Input patient/sample's ID number (Max. 10 numbers) by touching number keypad of display.

Use the move left key  $(\blacktriangleleft)$  or C (clear) to erase the existing ID number.

Touch **Test** when you finish inputting the ID to return to the Standby mode screen.

[Fig. 1.2.3] Set ID No

#### 4.4 Color



The urine sample must be visually observed and then the appropriate color must be selected.

Touch the color name to confirm, then the selected color name area change from black to blue color. Touch **Test** to return to the Standby mode screen.

[Fig. 1.2.4] Color Selection

#### 4.5 Turbidity



The urine sample must be visually observed and then the appropriate Turbidity must be selected.

Touch Turbidity name to confirm, then the selected turbidity name color change from black to blue. Touch **Test** to return to the Standby mode screen.

[Fig. 1.2.5] Turbidity Selection

#### 4.6 Menu



[Fig. 1.3] Menu

#### 4.6.1 Date/Time



The date and time are displayed on the Select screen and are recorded with test results. If the date and time values are incorrect, change it by touching number key on the display.

Touch **Test** to return to the Standby mode screen. Touch **Menu** to return to the **Menu** screen.

[Fig. 1.3.1] Date/Time

#### 4.6.2 System Check



[Fig. 1.3.2] System Check

**System Check** is used for checking aging processes of the optical system and

variation of other internal conditions of instrument. If the values are within the normal range values on the result, **"Success"** message will be displayed.

If the values are not within the normal range values on the result, **"Fail"** message is displayed.

 $\triangle$  If Fail message is displayed. Please retry for System Check !!

Touch **Test** to return to the Standby mode screen. Touch **Menu** to return to the **Menu** screen.

#### 4.6.3 Memory



[Fig. 1.3.3] Memory

This allows managing the result data saved in the memory, touch **Memory** on the MENU.

Touch **Test** to return to the Standby mode screen. Touch **Menu** to return to the **Menu** screen.

#### 4.6.3.1 View Data

This allows seeing the saved result selectively



Input SEQ No

**Result Data** 

[Fig. 1.3.4] View Data

After selecting the Seq. number, touch **View** to see the saved result. The data of the selected SEQ number shows on the screen.

#### 4.6.3.2 Send Data



[Fig. 1.3.5] Send Data

This allows sending the saved data to PC.

After selecting the **Star**t-number and **End**-number of the result data's Seq., touch the **Send** icon, then the selected data is sent to PC.

 $\triangle$  Confirm the condition of connecting communication with PC before performing the command.

#### 4.6.3.3 Delete Data



This allows deleting the saved data selectively.

After selecting the **Start**-number and **End**-number of the result data's Seq., touch the **Delete** icon, then part of saved data is deleted.

[Fig. 1.3.6] Delete Data

#### 4.6.4 Instrument Setting



It has a series of screen to control & change the Result format, System Setting and %R value.

Touch **Test** to return to the Standby mode screen. Touch **Menu** to return to the **Menu** screen.

[Fig. 1.3.7] Instrument Setting

#### 4.6.4.1 Result Format



This allows selection and change of the result display format.

Unit: Select the result format (Conv. / SI)

**Mark Plus:** Select **Enable** if you wish to make plus symbol (+) instead of clinical units such as mg/dl or mmol/L) shown in the results.

Mark Positive: Allows you to choose whether the positive results are highlighted in red color. (Yes/No)

[Fig. 1.3.8] Result Format

#### 4.6.4.2 System Setting

This allows selecting the measurement Speed, Sound and Baudrate.



**Speed:** To select the measurement speed

.(General/Quick)

**Sound:** To select the audible tones while operating reader. (**Enable/Disable**)

**Baudrate:** To select the speed rate of transferring data with each other between the reader and PC. (9600/38400/19200)

[Fig. 1.3.9] System Setting





[Fig. 1.3.10] Change %R

This allows changing the %R value of each parameter's concentration value limit. Select the parameter and the value change by using Direction key. ( $\blacktriangleleft$ 

►)

#### 4.6.5 System Info.



[Fig. 1.3.11] System Info.

This screen has information about the analyzer.

It shows the current System information. The information can be changed if you change the setting at Result format and System Setting menu.

## 5. How to Use

## Step1.

Power-'on' and let the initial screen for starting tests displayed through the process of the calibration.

#### Step2.

Dip a strip into fresh urine sample and take it out immediately. Remove excessive urine by touching the edge of strip on a soft absorbent tissue. Place the strip on the plate loader. Touch the **Test Start**.

#### Step 3.

After completing the test and analyzing the result, the result is displayed.



These results can be also transmitted into a PC to be observed. (Refer to the View Data function by clicking Memory button for reconfirming the test result.)

#### Step 4.

Touch the **Power OFF** to finish the test. To completely finish the test, press the main power button in the back of instrument.



## 6. Table of Results

lte m	Abbreviation	Unit		Result of Reading						
			1	Neg.	±	+ 1	+ 2	+ 3	+ 4	
Leukocytes	LEU	Con. Sl	WBC/µl	neg	trace	70	125	500		
	_	Arb		neg	±	+1	+2	+3		
		Con.		- J						
Nitrite	NIT	SI	1	nea	DOS					
		Arb	1	Ũ						
		Con.	m g/dl	norm	1	2	4	8		
Uribilinogen	URO	SI	µm ol/l	norm	16	33	66	131		
		Arb	E.U./dL	norm	+1	+2	+3	+4		
	PRO	Con.	m g/dl	neg	trace	30	100	300	1000	
Protein		SI	g/l	neg	trace	0.3	1	3	10	
		Arb	Ŭ	neg	±	+1	+2	+3	+4	
	рH	Con.								
pН		SI	1	5	6	6.5	7	7.5	8	8.5
		Arb	1							
		Con.			haaa	05	00	200		
Blood	BLD	SI	квс/ш	neg	liace	25	00	200		
		Arb		neg	±	+1	+2	+3		
		Con.			e.					5
Specific Gravity	SG	SI	1	1.000	1.005	1.010	1.015	1.020	1.025	1.030
		Arb	1							
	KET	Con.	m g/dl	neg	5	15	40	80	160	
Ketones		SI	m m ol/l	neg	0.5	1.5	3.9	8	16	
		Arb		neg	±	, +1	+2	+3	+4	
	BIL	Con.		nea		Small	Moderate	Large		
Bilirubin		SI		nog		oman	moderate	Large		
		Arb		neg		+1	+2	+3		
	GLU	Con.	m g/dl	neg	100	250	500	1000	2000	
Glucose		SI	m m ol/l	neg	5.5	14	28	55	111	
		Arb		neg	±	+1	+2	+3	+4	
Ascrobic Acid	AsA	Con.	m g/dl	neg		20	40			
		SI	m m ol/l	neg		1.2	2.4			
		Arb		neg		+1	+2			
Microalbumin	ALB	Con.	mg/l	10	30	80	150			
		SI								
		Arb								
Creatinine	CRE	Con.	m g/dl	10	50	100	200	300		
		SI	m m ol/l	0.9	4.4	8.8	17.7	26.5		
		Arb		10	50	100	200	300		
Albumin to	A:C	Con.	m g/g	<30		30-300		>300		
		SI	m g/m m ol	<3.4		3.4-33.9		>33.9		
Greannine radio				No	Normal Abnormal High Abnorr		bnormal			
Dut i i		Con.	m g/g	<	150	>=150				
Creainine ratio	P:C	SI	m g/m m ol	<17.0		>=17.0				
				Normal		Abnormal				

#### 7. How to Clean the Strip Loading Plate after Use

Clean the dirty 'Strip Loading Plate' by using a neutral detergent or water-wet towel or swab. Do not use volatile matters like thinner, gasoline and benzene for cleaning the body. It is better to clean the Strip Loading Plate everyday because the rest urine from the tested strip can smear on the 'Strip Loading Plate'.

- **Step1.** Touch the Clean icon Clean and separate the Strip Loading Plate from the body of the instrument.
- **Step2.** Completely wipe the groove of the detached Strip Loading Plate with a water-wet swab.



- **Step3.** After the cleaning, put back the Strip Loading Plate on the reader and touch the Clean icon. Then the Strip Loading Plate is moving in its original position. If the loader is not retreated immediately, slightly push the loader.
- **Step4.** The Strip Loading Plate slightly goes in and comes out then it is ready to start the test.

## 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 for calibration. Water should NOT be used as a negative control.

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

 Quantimetrix Dipper Urine Dipstick, Dropper Urine Dipstick, Dip&Spin Urine Dipstick (Homepage: <u>www.4qc.com</u>)
 Thermo SCIENTIFIC MAS UA Control (Homepage:

www.thermoscientific.com)

3) Bio-Rad qUAntify Plus Control (Homepage: <u>www.bio-rad.com</u>)

#### 9. Troubleshooting & Maintenance

#### 9.1 Maintenance

No maintenance is required other than routine cleaning.

• Clean the outside of the Uri-Tex body with a dry towel after wiping clean with a towel dampened by a neutral detergent or water.

• Do not wipe the body of the Uri-Tex clean with benzene, thinner, gasoline, etc.

- **Do not force the Strip Loading Plate**. It works automatically. Refer to How to Clean the Strip Loading Plate after use of the user's manual.
- If you want to know detailed information for environmental factors and cautions, refer to Specifications, Cautions & Warnings under User's manual.

## 9.2 Troubleshooting

SYMPTOM	POSSIBLE CAUSE	REMEDY				
The Instrument does Not operating normally.	No power.	Check the connection of instrument to the power supply using given adaptor. If it is still unable to be operated, contact your local Customer Service Office.				
Strip Loading Plate stops unexpectedly during operation.	Unstable electricity.	Use a rated current. Contact your local Customer Service Office if it doesn't operate correctly				
Test results are not being transmitted into a PC.	<ol> <li>Disconnected a serial cable to your computer.</li> <li>User's program is not opened.</li> <li>Your serial port is not in a proper location.</li> <li>You have no serial port in your computer and only a USB port.</li> <li>It had been selected as <b>OFF</b> option in Data Transfer of Host shortcut button.</li> </ol>	<ol> <li>Check connection of a serial cable between the instrument and the computer.</li> <li>Open the User's program.</li> <li>Connect correctly a serial port for Com1.</li> <li>Purchase a cable to convert USB to Serial.</li> <li>Select <b>On</b> option in Data Transfer of Host.</li> </ol>				

### **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-tomouth contact -handto-eye contact

-direct contact with superficial cuta, 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 non-contaminated 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:

Manufacturer:

PZ Cormay S.A. Wiosenna 22, 05-092 Lomianki, Poland

## CEIVD