

*UroMeter 120*TM

Urine Chemistry Analyzer

User's Manual



SD

STANDARD DIAGNOSTICS, INC.
www.standardia.com



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1. General Information of UroMeter 120

1.1 Intended Use

SD “UroMeter 120” (model number : UM0120) as urine chemistry analyzer give the information on blood, bilirubin, urobilinogen, ketones, protein, nitrite, glucose, pH, specific gravity, leucocytes and ascorbic acid in human urine, in combination with SD Urocolor 11 parameter, urinalysis reagent strips.

1.2 Technical Specification & information

Supply voltage	12V --- 3A
Power adapter	input 100-240V~, 50-60 Hz, 0.8A MAX output +12V --- 3A
Size	Depth : 200 mm (7.87 in) Width : 252 mm (9.92 in) Height : 114 mm (4.9 in)
Weight	1.2 kg (2.65 lb)
Technical characteristics	- Maximum 300 tests per hour - ID input via key board, PC or Barcode reader - Updating Urometer 120 software by internet access - Automatic calibration
Memory capacity	Maximum 2,000 test results
Print	Internal thermal printer
LCD	8 lines 21 characters
Interface	RS232C COM1 : Communication with PC COM2 : Communication with bar code system USB : Communication with PC

☐ Storage and Handling Environmental conditions

- Indoor use only : Temperature 5°C to 40°C, Maximum relative humidity 80% for temperature up to 30°C decreasing linearly to 50% relative humidity at 40°C

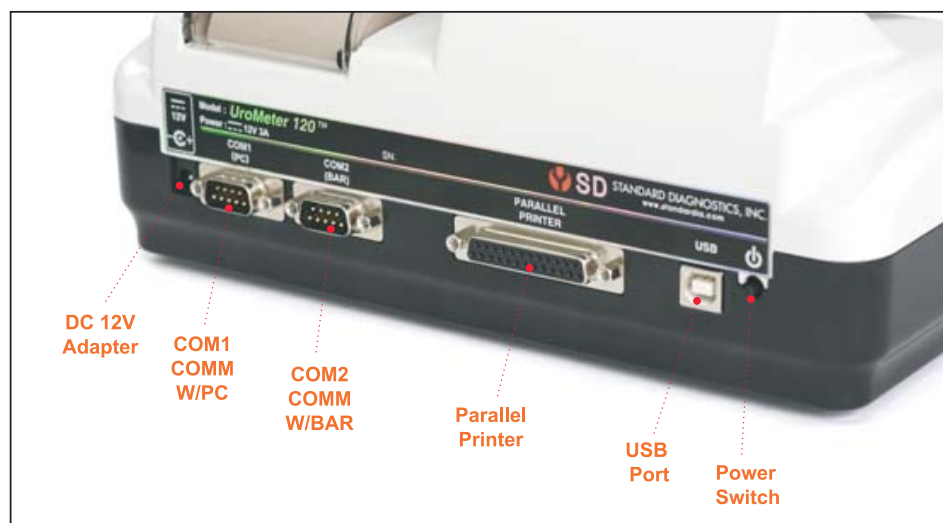


- Altitude up to 2000m
- Pollution degree 2
- In storage : Temperature 5 °C to 40 °C

1.3 Name of Components



[Fig 1.1] View from above



[Fig 1.2] View of rear



1. General Information of UroMeter 120

1.4 Warnings and precautions

- 1) If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
- 2) Read the UroMeter 120's user manual carefully before installation, operation, maintenance, transportation and storage, so as to ensure proper operation of the analyzer from the outset.
- 3) Treat all urine samples of human origin as being potentially infectious. Always wear protective gloves when handling and disposing of samples of human origin.
- 4) To ensure that urinalysis is carried out correctly, read the package insert of UroColor.
- 5) Be careful not to insert the finger into the moving part when you lay the test strip between strip loading plate and strip loading sensor.
- 6) Urine-wet loading plate and strip waste are potentially biologically hazardous. Always wear protective gloves if handling those materials.



2. System Installation

2.1 Components

After opening the packing box of UroMeter 120, check that all the items in the list below are available in the package.

Item	Quantity
1. UroMeter 120	1
2. Printing Paper	1
3. Power Cable & Adapter	1
4. RS232c Cable	1
5. USB Cable (AB type)	1
6. User Manual	1



USB Cable



RS232c Cable

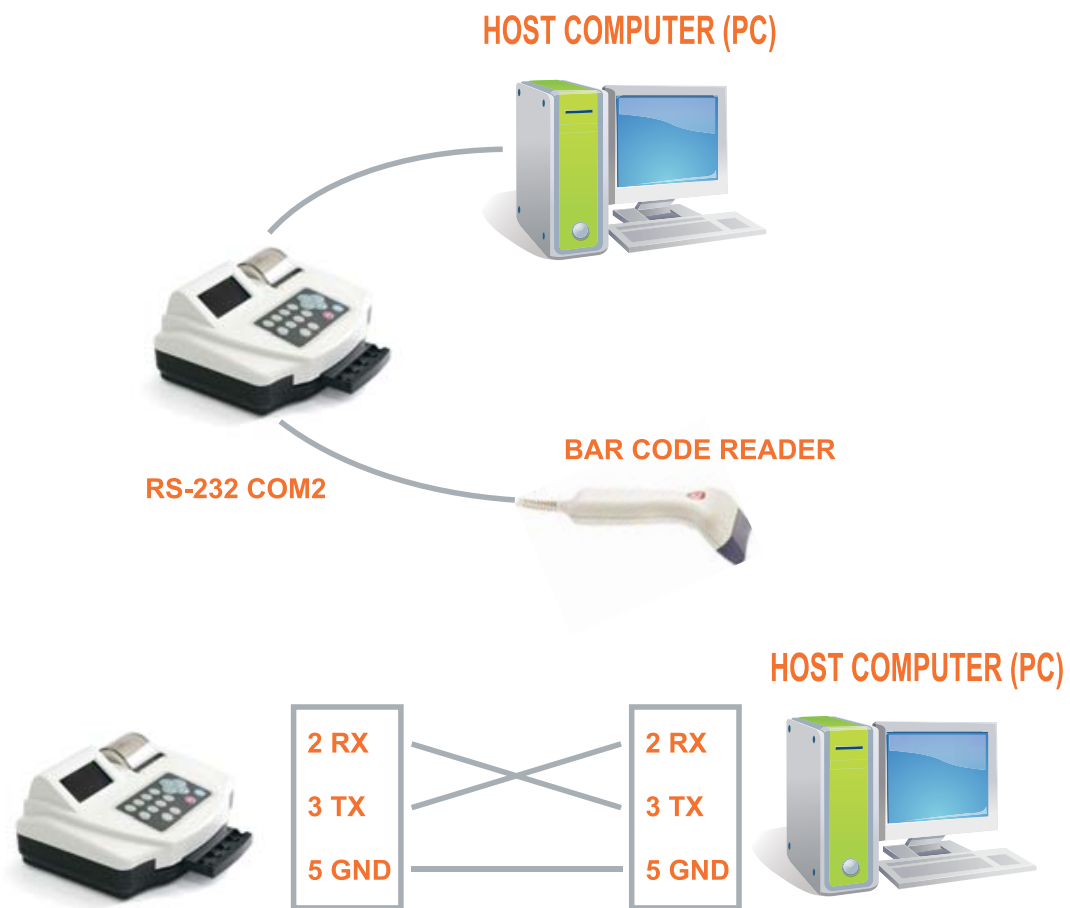
[Fig 2.1] Components of an UroMeter 120 set

2.2 Interfacing System to PC

- 1) Connecting Power Cable & Adapter to DC12IN at rear, left side of UroMeter 120.
- 2) Then connecting one end of RS232c Cable to PC and the other end to COM1 of UroMeter 120.
- 3) Or, connecting barcode reader to COM2 of UroMeter 120. (The baud rate of barcode reader should be 9600bps.)



2. System Installation



Connection diagram between UROMETER120 and Host Computer.

[Fig 2.2] Connection with PC



3. Components and Functions

3.1 Keyboard

Keyboard consists of 16 keypads. It is used to input data or set up each function.



[Fig 3.1] Key Board

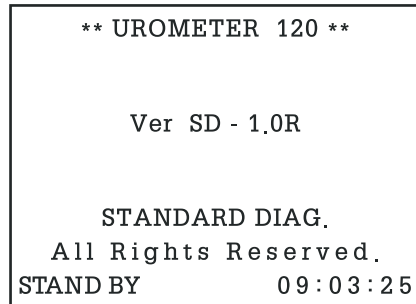
- 1) ENT Key
ENT Key is used to initiate testing or select a mode at each step.
- 2) ESC Key
ESC Key is used to terminate testing or escape from each step. At Standby mode, press ESC key twice, then System Control Mode will be shown.
- 3) ◀ ▶ ▲ and ▼ Key (Direction Keys)
Direction Keys are used to move to the left, right, up and down, respectively in each menu or to increase or decrease numbers in stead of Numeric Keys.
- 4) 0~9 (Numeric) Keys
Numeric Keys are used to select a mode at each step or input data such as patient's ID, Lot number, etc.



3. Components and Functions

3.2 LCD

LCD displays a current operating status of system and process steps to user.



[Fig 3.2] LCD

3.3 Printer

UroMeter 120 displays test results by printing.

- Setting the ON/OFF printer mode, optionally.
- When the printing papers are almost consumed, if a red line around the paper appears, replacement with a new printing paper should be made.

3.4 Strip Loading Plate

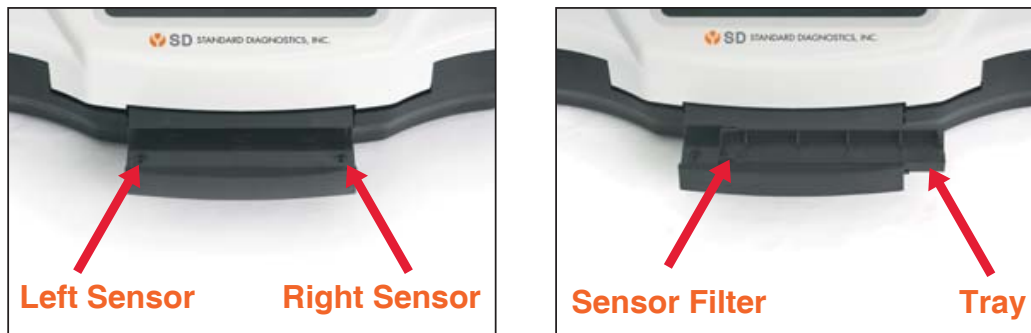
Everytime pressing ENT key, "Stand By Mode" changes to "Quick Mode", "Normal Mode" on LCD and loading plate comes out and into the unit.



[Fig 3.3] Strip Loading Plate



3.5 Strip Loading plate Component



[Fig 3.4] Strip Loading plate Component and Name

3.6 Changing direction Strip Loading plate

UroMeter120 is designed both right hand and left hand users. Push the tray right side, change the direction, and put it from left to right.



[Fig 3.5] Pull out Tray



3. Components and Functions



[Fig 3.6] Re-set Tray



[Fig 3.7] Strip Loading after set up stray



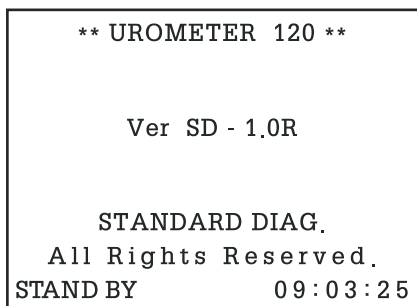
4. Brief Operating Instruction

- 1) Turn on the power switch at the rear of UroMeter 120.
 - System checking and calibration will be performed automatically and standby mode will be shown.
- 2) System configuration (5.5 System Configuration)
 - Set up the required environment such as Language, Display unit, Printer enable or not.
- 3) Set current time (5.3 System Clock Set)
- 4) Put Patient/Specimen ID (5.7 Registration)
- 5) Measurement (5.8 Measurement)
 - Put strip on the tray
- 6) Review test results stored in data base.

4.1 Preparation of Loading Plate

Prepare Loading Plate as following.

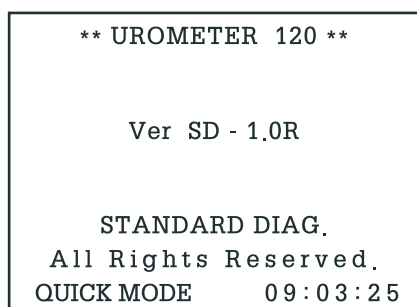
Everytime pressing "ENT" at "Stand By Mode", screen and loading plate show as below.



[Fig 4.1]



[Fig 4.2]



[Fig 4.3]



[Fig 4.4]



4. Brief Operating Instruction

** UROMETER 120 **

Ver SD - 1.0R

STANDARD DIAG.
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NORMAL MODE 09:03:25

[Fig 4.5]



[Fig 4.6]



5. Specific Operation Manual

5.1 System Initiation

Turn on Power

Stand By Mode, and auto calibration

```

** UROMETER 120 **

Ver SD - 1.0R

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All Rights Reserved.
STAND BY          09:03:25

```

[Fig 5.1] Stand By Mode

5.2 System Control

In Stand by Mode of [Fig.5.1], Press 2 times of "ESC" and then System Control status of [fig. 5.2] will be shown.

```

* System Control *

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

```

[Fig 5.2] System Control

5.3 System Clock Set

- 1) In System Control Mode of [Fig 5.2], press ① key and System Clock Set Mode of [Fig 5.3] will be shown as below.



5. Specific Operation Manual

* System Clock Set *		
YEAR	=	2007
MONTH	=	03
DATE	=	12
HOUR	=	07
MINUTE	=	27
SECOND	=	20

[Fig 5.3] System Clock Set

- 2) In the System Clock Set Mode, you can move to each item by using up/down (▲▼) keys and adjust the time by using left/right (◀▶) keys.
- 3) After adjusting local time, press ENT key for setting done. Date changes automatically along setting time.

5.4 System Calibration (Internal Quality Control)

- 1) The system of UroMeter 120 calibrates automatically, every time you turn power switch on. There is no need to check the system particularly.
- 2) When you turn on the power switch, system checking and calibration will be performed automatically.

5.5 System Configuration

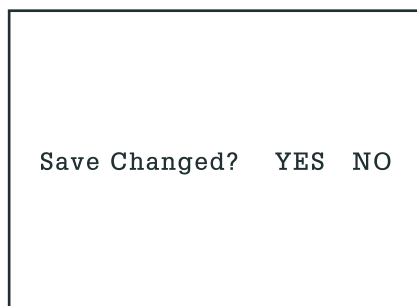
- 1) In System Control Mode of [Fig 5.2], press "2" key and System Configuration Mode of [Fig 5.4] will be shown as below. You can move to each item by using up/down (▲▼) keys and select by using left/right (◀▶) keys.

* System Config *		
Beep Enable	=	NO
Set Bps (PC)	=	115,2
Disp Unit	=	mg
Strip Type	=	SD 10
Language	=	Eng
Print Enable	=	YES
Disp I/O Cnt	=	NO

[Fig 5.4] System Configuration



- Beep Sound Enable (Beep or Silent)
If selecting YES, beep will sound while operating UroMeter 120.
 - Set Baud Rate (PC)
The speed rate can be selected while transferring data between UroMeter 120 and PC, each other. At normal condition, 115.2 should be selected.
 - Set Display Unit
The unit of test results can be set with mg or mol.
 - Strip Type
The strip type which you want among SD UroColor 4~11 can be selected.
 - Select Language
Selecting one language among 5 languages of English, French, German, Spanish and Italian.
Only, the name of each item changes to selected language on printing paper or on LCD display.
 - Printer Enable
Printer ON or OFF by selecting YES or NO.
If you select YES, test results will be shown on both LCD and printing paper.
 - Display I/O count
This is for displaying the number of loaded strips and analyzed strips on LCD with a large character.
- 2) When you finish selecting all conditions, press ESC key. If there is no change from last conditions, you will return to System Control Mode. But if there is any change, a question to confirm changed conditions will be shown on the display, as below.



[Fig 5.4.1]
System Configuration
Confirm Mode

If you select YES and press ENT key, you will go back to System Control Mode.



5. Specific Operation Manual

5.6 Printing Paper Loading

Open the cover and put roll paper.



[Fig 5.5] Paper Loading

- 1) Adjust both center projections to each hole of printing paper loading part of instrument, facing a rubber roller.
- 2) Pull the printer lever at an angle of 90°, facing you. Push the printing paper into the printer head.
- 3) In 2 seconds, the instrument recognizes the printing paper and initiates the paper's proper position, automatically.

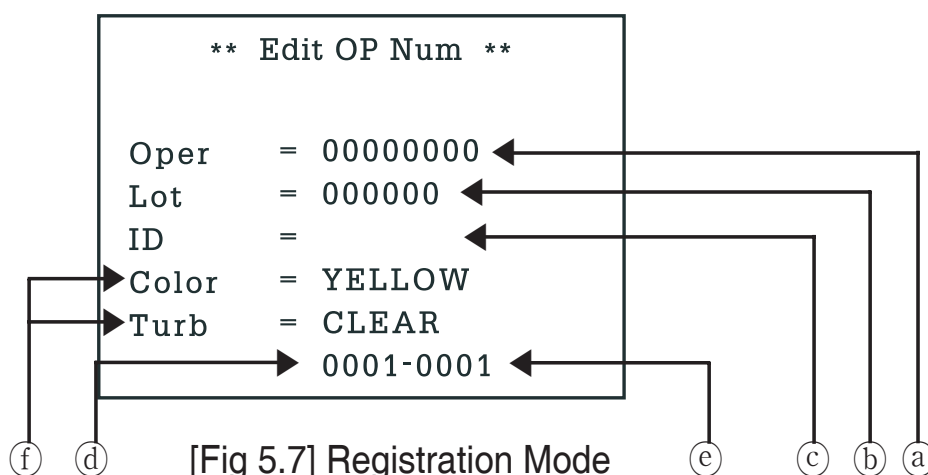


[Fig 5.6] Loading of Printing Paper



5.7 Registration (Input ID)

- 1) In System Control Mode of [Fig 5.2], press ③ key and Registration Mode of [Fig 5.7] will be shown as below. You can move to each item by using left/right (◀ / ▶) keys.



- 2) You can enter operator's ID in part ① and lot number of strip in part ②. If you don't need any records about operator's ID or lot number of strip, you may skip and leave it as blank.
 - 3) You can enter patient's/sample's ID in part ③ using numeric keys or a barcode reader.
 - 4) Press ENT key or up (▲) key to enter another patient's/sample's ID.
 - 5) If you want to change patient's/sample's ID, you can return to ID mode using up/down (▲▼) keys and enter new patient's /sample's ID, again.
 - 6) Press ESC key to System Control Mode.
 - Part ④ is a serial number of samples you are going to test. Part ⑤ is number of data that will be stored in data base after measurement.
 - Part ⑥ is for entering the color and turbidity of urine. It has no function in normal condition.
- * Color changes in order of YELLOW, DK YELLOW, STRAW, AMBER, RED, ORANGE, GREEN and OTHER, pressing



5. Specific Operation Manual

left/right (◀▶) Keys.

- * Turbidity changes in the order of CLEAR, SL CLOUDY, CLOUDY, TURBID and OTHER, pressing left/right (◀▶) Keys.- If patient's/sample's IDs are serial numbers, you may register - If
 - If patient's/sample's IDs are serial numbers, you may register only the first patient's/sample's ID. Then the others will be numbered in sequence, automatically.
 - If patient's/sample's ID includes letters, you should enter IDs one by one even though IDs are serial numbers.
 - In case you don't register patient's/sample's ID before a test, ID columns remain blank.

5.8 Measurement

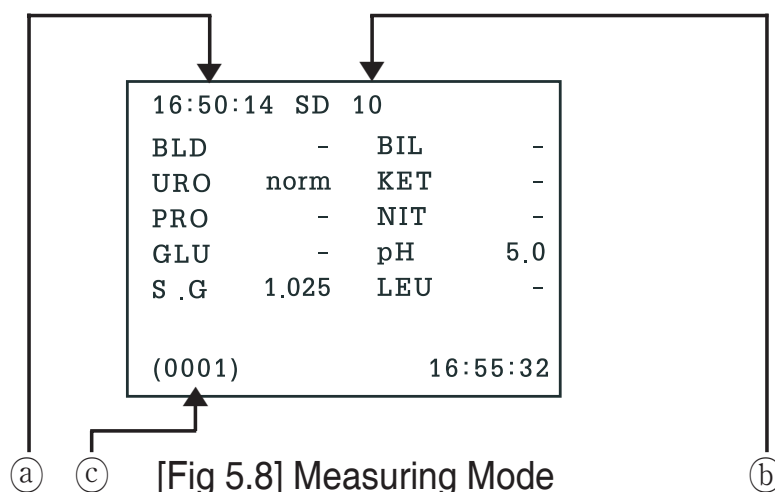
- 1) A measurement should be started in Quick Mode or Normal Model during Strip Loading Plate is out of the unit.
- 2) Dip a test strip into fresh urine sample for a few seconds and take it out.
- 3) Remove excessive urine by contacting the side of strip on the material such as soft tissue.
- 4) Lay a strip, there is buzz sound. After 3 seconds loading plate will enter the unit.
- 5) In Normal Mode, result will be shown on the screen and LCD after 100 seconds. In Quick Mode, result will be shown immediately.
- 6) Analyzer will stand by after the measurement. If there is no strip to be tested on the strip loading plate, the UroMeter 120 stops working.
- 7) Whenever press ENT, STAND BY MODE ▶ Quick Mode ▶ Normal Mode, Strp loading plate will move relatedly.

Precautions ;

- 1) You must use strips of SD UroColor 4~11 series manufactured by Standard Diagnostics, Inc.
- 2) Do not touch the strip pad by hand.



- 3) Be sure to use fresh urine sample.
- 4) You must lay one strip on the strip loading plate at a time.
- 5) As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- 6) In Quick Mode, consider reaction time at least 1 minutes
- 7) Excessive urine probably cause malfunction.



- (a) Time of measurement
- (b) Strip type
- (c) Sample's number tested and Data's number saved in data base



5. Specific Operation Manual

Test time	OCT/09/2006 13:03:15	
Patient Name	Name:	Sex:
Data's No	Ward:	Age:
	SD (10)	(0006)
	BLD -	neg
	BIL -	neg
	URO norm	0.1mg/dl
	KET -	neg
	PRO -	neg
	NIT -	neg
	GLU -	neg
	pH	5.0
	S.G	1.030
	LEU -	neg
Instrument Serial No.	(SN=60151215)	
Patient's sample No.	ID()	
Operator's ID No.	OP (00000000) LOT(000000)	
Strip Lot No.		

[Fig 5.9] Result Sheet

5.9 Data Base (How to use data base saved)

- 1) In System Control Mode of [Fig 5.2], press ⑥ key and Data Base Mode of [Fig 5.10] will be shown as below.

16:45:1	SD	10
BLD -	BIL -	
URO norm	KET -	
PRO -	NIT -	
GLU -	pH 5.0	
S.G 1.025	LEU -	
LOC (0001)		

(a) (c) (b)

[Fig 5.10] Data Base Mode



- 2) In part ③, enter the data's number you want to input. You can move to each item by using up/down (▲ ▼) keys.
- 3) Press ENT key. You can review the data's test result on LCD display.
- 4) You can print out the result on the display by pressing ENT key, once again.
 - ① shows the time of measurement.
 - ② shows the strip type.
 - ③ shows data's number saved in data base.
 - Data base can save up to memory of 2,000 test results. When the memory is full, all data will be transferred to main PC automatically if PC and the UroMeter 120 instrument is connected through RS232c cable. If they are not connected, previously saved data will be erased on the "first in first out" basis.
- 5) For the initiation of saved data, Set '9999' in part ③, and then press 'ENT'.

5.10 DB Block Control (Transferring and reprinting saved data)

- 1) In System Control Mode, press ⑦ key and Data Base Block Control Mode of [Fig 5.11] will be shown as below.

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

[Fig 5.11] Data Base Block Control Mode



5. Specific Operation Manual

- 2) You can upload the data of test results to PC through RS232C.
The data form uploaded is the same as paper printing style.
- 3) Uploading mode is for transferring data of the test results to PC in a lump.
Data input can be made by pressing numeric keys or direction keys (◀ / ▶). Press ENT key to operate a system.
- 4) Printing mode is for printing data of test results in a lump. You can input data, pressing numeric keys or direction keys (◀ / ▶). Press ENT key to operate a system. The printer capacity is limited to 50 test results at one time.
- 5) You can move to each item by using up/down (▲ / ▼) keys. if test memory is full (2,000 tests), 2,000 tests previously saved data is erased on a first in and first out basis. To erase all saved data in put the number of "9999" and press "ENT" key.
- 6) If data base is empty, an error message of "No Data in Data Base" will appear at the center of display and go back to previous mode. After all data processing is finished completely, a message of "OK Finish !" will appear on the screen.



6. How to store after using

6.1 Daily Check Up

Separate Strip loading plate from the instrument and wash them in water.

6.2 Cautions for Keeping

- 1) Avoid the places subject to high temperature, high humidity, direct sunlight and air containing dusts, salt and sulfur contents.
- 2) Avoid a slope or vibrating place for keeping.
- 3) Avoid any impact when instrument is moved.

6.3 Error, errors!

A bent strip will cause a jam inside of Strip loading plate of instrument. In this case, you take out the front cover and remove the strips jammed.

6.4 Error Messages and Troubleshooting

“Misplaced strip”	<p>Cause : No test strip is sensed by sensor or the strip is incorrectly positioned on the sensor.</p> <p>Action : Repeat the measurement with new strip</p>
“ERR Load Over Cnt”	<p>Cause : When you turn on the power switch, internal calibration will be performed automatically. In this process, if the strip loading plate is incorrectly inserted or out of working normally, this error message will be shown.</p> <p>Action : Please turn off and restart the machine. If it happen repeatedly, please contact your local technical Service.</p>



7. Display of Measured Concentration

7.1 Performance and limitations of use
















Urometer 120 prints the results in the following gradation of concentration in combination with Urocolor. To ensure that urinalysis is carried out correctly, read the package insert of Urocolor.

7.2 Presentation of analytical data

Test Area (Unit)		Results	Reading	Neg (-)	Trace (±)	Positive				
						+	++	+++	++++	
Blood	RBCs/ μl	Urocolor	Neg			10	50	250		
		Urometer	- Neg	+/- 5		+ 10	++ 50	+++ 250		
Bilirubin	mg/dl	Urocolor	Neg			0.5	1.0	3.0		
		Urometer	- Neg			+ 0.5	++ 1.0	+++ 3.0		
Urobilinogen	mg/dl	Urocolor	(normal) 0.1			(normal) 1	4	8	12	
		Urometer	norm 0.1			+ 1.0	++ 4.0	+++ 8.0	++++ 12	
Ketone	mg/dl	Urocolor	Neg	5		10	50	100		
		Urometer	- Neg	+/- 5		+ 10	++ 50	+++ 100		
Protein	mg/dl	Urocolor	Neg	10		30	100	300	1000	
		Urometer	- Neg	+/- 10		+ 30	++ 100	+++ 300	++++ 1000	
Nitrite	mg/dl	Urocolor	Neg	Positive		Positive				
		Urometer	- Neg	Pos 0.1		Pos 0.1				
Glucose	mg/dl	Urocolor	Neg	100		250	500	1000	2000	
		Urometer	- Neg	+/- 10		+ 250	++ 500	+++ 1000	++++ 2000	
pH	pH value	Urocolor	5.0	6.0		6.5	7.0	7.5	8.0	9.0
		Urometer	≤ 5.5 5.5	6.0		6.5	7.0	7.5	8.0	8.5 ≥ 8.5
Specific Gravity	S.G. value	Urocolor	1.000	1.005		1.010	1.015	1.020	1.025	1.030
		Urometer	≤ 1.005	1.005		1.010	1.015	1.020	1.025	≥ 1.025
Leucocyte	WBCs/ μl	Urocolor	Neg			25	75	500		
		Urometer	- Neg	+/- 10		+ 25	++ 75	+++ 500		
Ascorbic acid	mg/dl	Urocolor	Neg			10	25	50		
		Urometer	- Neg			+ 10	++ 25	+++ 50		



packaging material, the identification plate on the instrument and the user manual may contain the following symbols or abbreviations;

	<i>In vitro</i> diagnostic medical device		
	Please consult instructions for use		
	Attention consult accompanying documents/Caution, risk of danger		
	Manufactured by		Date of manufacture
	Store at 5~40 °C		
	Batch code		
	Serial number		
	Catalogue number		
	Fragile, handle with care		
	Keep dry		
	Direct current		
	Power On and Power Off		
	Alternating Current		
	Caution, risk of electric shock		

Technical Service : If you have any questions after reading the manual or if you need technical assistance including maintenance or change of consumables, please contact your local Standard Diagnostics, Inc. organization or e-mail (sales@standardia.com)



**** Very Important Cautions ****

If there is any burning smell, stop using instrument immediately, and contact the distributor so that specialist can take right service to the unit. If unspecialised technician disassembles and repairs the unit, it can cause severe malfunction and damage.





STANDARD DIAGNOSTICS, INC.

Manufacturer : Standard Diganotics, Inc.

Product : Urine Chemistry Analyzer

Model : UROMETER 120

Weight : Approx. 1.2 Kg

Address : 156-68 Hagal-dong, Giheung-gu,
Yongin-si, Kyonggi-do, Korea 446-930

Tel : 82-31-899-9730

Fax : 82-31-899-9740