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1.1 Product Introduction.

【Product name】 Portable urine analyzer

【Commodity product】 Labtouch urine analyzer

【Specifications and models】 PUA-120

【English name】 Portable Urine Analyzer

【Product structure and performance】

◎**Structure and composition:**Circuit boards, test components, function buttons, LCD screens, insertion point, casing, screen, battery and back cover

◎**Accessory:**test strip,pipettor,urine cup,battery

◎**Work environment:**

a)environment temperature:10℃-30℃

b)Relative humidity: ≤60%RH

c)Power: direct current 3.0V, 4 pieces 7#Alkaline battery

◎**Appearance:**

a)should be clean,no scratch,no Burr

b)letter symbol should clear

◎**Testing range:**

Item	Unit	Testing range
Ketone	mmol/L	0-16(0-160mg/dl)
Glucose	mmol/L	0-110(0-1980mg/dl)
Protein	g/L	0-20(0-2000mg/dl)
Microalbumin	mg/L	0-150(0-15mg/dl)

【Intended use】

The urine analyzer combines with the test strip check the content of Glucose,Ketone,protein,microalbumin from urine,the product use to Self-check.

The product use multiple wavelengths of light reflection measurement technology,can be if the urine have Glucose,Ketone,protein and microalbumin.it apply patients with diabetes, high blood pressure to self-checking at home,and Convenient to carry naked.we suggest you to read carefully before use,It is beneficial to understand the method of application.

Warning:the test result just use for reference,can't use to The diagnosis of certain diseases,, please do not make any treatment changes,without

the professional medical staff guidance.

【Instrument Principles】

This product uses dry chemical light reflection principles.

【Test strip principles】

PROTEIN:Applying principle of fuel combination protein error,protein of the samples can combine with the fuel to make up into complexes and make color changes.

KETONE:SNP can react with acetoacetate and acetone of urine into purple color.

GLUCOSE:Glucose is oxidized into glucuronic acid and hydrogen peroxide by glucose oxidase of the test strip,then the hydrogen peroxide release O under the peroxidase,O act on the propigment of the test block in strip cart and show color.

MICROALBUMIN:The test strip contain sulfonephthalein fuel,microalbumin can combine with fuel to make up into complexes and make color changes.

1.2 Package Contents

- 1.Labtouch portable urine analyzer(1 SET)
- 2.test strip(5pcs)
- 3.Pipettor(1 piece)
- 4.liquid absorption funnel
- 5.Operating instruction
- 6.Warranty card
- 7.Dry battery
- 8.Short guidance for use
- 9.One-single use urine cup

1.3 Exterior view of portable urine analyzer and test strip



2.1 Installation/Replace Battery

★Install instrument battery

1. Please turn around the instrument to the back and open the battery cover, you will see battery holder.
2. Please install as the positive and negative charges.
3. Close the battery cover till hear the noise 'ka'
4. Try to start up, if can't work, please check the battery installation.



★When should replace instrument battery

When need to replace the battery, battery symbol will be showed on the screen .

★Low battery

When screen show low battery symbol after starting up or during testing, it can't work as normal, please replace battery as soon.

After replacing the battery, memory values still exist.

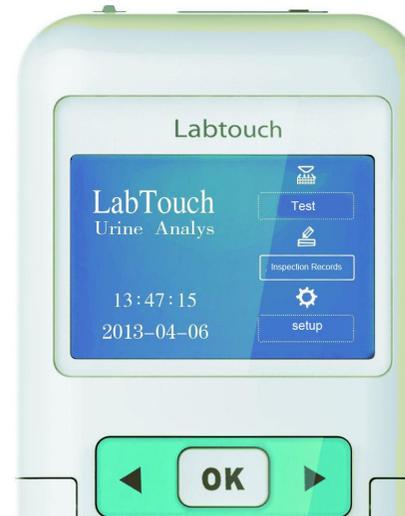
Please discard the old battery in accordance with the relevant regulations of local.

2.2 Instrument Setup

1. Press power switch  for 10 seconds, instrument will make a deep sound, the screen displays the splash screen, instrument get into test on itself.



2. After self-checking of the instrument, the screen will display the main menu.



3. Move the cursor to Options, press the "OK" key to enter the setup menu as follows:



Unit setting : Move the cursor to Unit set.,press the OK key to enter the setup menu. Use the left and right selection key to choose CI or SI. After finishing the setting, press right selection key to Exit.

Language setting: Move the cursor to LAN SET, press OK key to enter the setup menu. Use the left and right selection key to choose Chinese or English, then press OK key. After saving,the setting, exist to enter another language menu.



Time setting: Enter the Time menu, move the cursor to Date or Clock, press OK to enter and set up.



1.Date Setting: Move the cursor to the Date, press “OK” key to enter. Press “OK” key first, press “◀” “▶”to year, then press “◀” “▶”to increase or decrease. Take 2003 as example, press OK" key to determine.

Move“▶”key to middle position to set up the month. Press “OK” key first, then press“◀” “▶” to set up the month needed. Take April as example, press OK key to determine.

After the above operation, press“▶” to go on. Press “◀” “▶” to set up date needed. Press OK key to determine. After finishing the setting, press the “OK” key long to exist.



2. Clock Setting: Move the cursor to Clock, press OK key to enter, press the OK key first, press “◀” “▶” to hour, then press “◀” “▶” to increase or decrease. Take 10 o'clock(the default is 24 hours)k as example, press OK key to determine.

Press “▶” to middle position to set up the minute. Press OK key first, then press “◀” “▶” to set up the minute needed. Take 17 as example, press OK key to determine.

After the above operation, press “▶” to go on. Press “◀” “▶” to set up the second needed. Take 15 as example, press OK key to determine. After finishing the setting, press the OK key long to exist.



Sensibility: Move the cursor to Sensibility, press OK key to enter and there are four levels to choose from. Press OK key first, then press “▶” to increase and press “◀” to decrease. The default is level one.

Adjusting: Finished by professionals with professional adjusting card.

Factory setting: Factory has set this.

Serial number: The number has been generated automatically and recorded by factory.

Notice: After the power of instrument runs out, please replace new battery in time. Date and clock needs to be set up again after replacing new battery.

Chapter Three Urine Measurement

3.1 Preparation for the measurement

Please prepare the following items before measurement, and read the instructions to ensure the accuracy of the measuring process and result.

- ◎ Labtouch urine analyzer (please install the battery first)
- ◎ Strip package
- ◎ Quantitative urine-adding device.
- ◎ Urine absorption device
- ◎ Disposable urine cup or dry and clean container

Notice: The consumable items like strip, urine absorption device and urine cap can be bought from specified pharmacy after using up.

(1). Prepare the urine

Using a disposable urine cup (or dry clean container), reserving fresh urine, immediate detection.

(2) Prepare test strip

Take the strip out of test strip packaging, the test strip is individually packaged.

(3) Prepare pipettor

(4) Take the pipettor and pipette tip out of packaging, installing the pipette tip on the pipettor

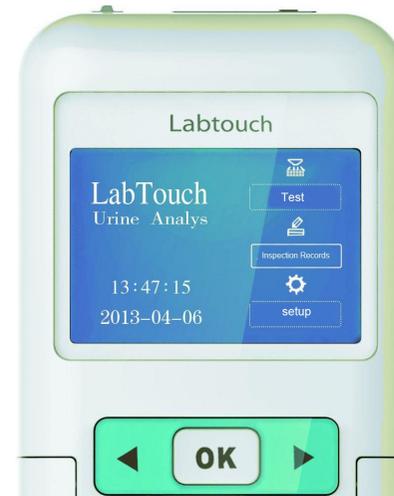
3.2 Measurement procedure

1. Starting up

Take out the urine analyzer, installed battery, press and hold the key to open the top left of the urine meter 10 seconds, hear a "beep" sound, urine analyzer power is turned on, and display self-test screen.

2. Enter the test image

Enter the main display screen after startup, use the bottom of the screen "OK" button and "◀" "▶" button, select "Test" and press "OK" button, the instrument "beep" three times into the test program.



3.Insert test strip

After entering the sample test program, the screen displays "Please insert test strip." Insert test strip (when inserting heard a slight sound that snapped into place.).



Note: When insert test strip, fingers do not touch the test strip test holes, to prevent pollution of strip, resulting in inaccurate measurements.



4.Urine measurement

After the test strip is inserted, the screen displays "Please open the lid"

Open the lid over the test strip, Instrument display please add urine“Δ”

Then accurately absorb urine 10μl with pipette.



Note: Pipette urine, according to the first gear position, avoid excessive fluid absorption.



Add the sample in to the center of the hole(one time for each hole),after add the sample,immediately shut the cover.



After shut the cover,when heard “deep”,the instrument begin test,45 seconds after the end of the countdown,when heard “deep”,the test finished and displaying the results.

Attention:Please do not open the cover in the process of test,In the period of 45 seconds-5seconds,if you open the lid.the instrument will display”the lid opened,please shut ”.In the period of 5 seconds-1 seconds,if you open the lid,the instrument will display”the lid opened,please exit test”Now need to restart testing,because the in countdown five seconds,the test system will check the test hole’s color change in the avoid light dark environment,if open the lid it is will effect the optic test.

5.The test results display and storage

The test will be finished in 45 seconds after add the urine sample and cover the lid.the instrument will display the glucose,ketones,protein and the microalbumin’s test result.press OK the instrument can storage the test result automatically,so the user can check the result at any time.

Discarded the used test strip into the proper container,to avoid pollution.

6.When finished test,If you do not need to continue another test,please press the OK key until it is return to the main interface screen and then press the power key turn off the instrument.

Attention:If do not continue the test or have other operation.the instrument’s backlight will shut after 3 minutes.and auto power-off after 5 minutes.

The following situation can cause inaccurate measurement result:

- ◎The urine’s drawing volume is not accurate.
- ◎The urine is not added to the reaction center hole position
- ◎The fluid’s volume more than once’s volume
- ◎Do not shut the lid immediately after add the urine.
- ◎When measuring, the environmental change is too big

©Do not use the accurate test paper.

The scope of application of urine test strip:

©The test strip is disposable use

©The test strip can only use for test urine

©Please use fresh urine

Attention: If test in different time even use the same test strip the test result maybe have difference.especially when test the urine sugar.because the in the process of urine's storge,Because the influence of the environment and chemical decomposition of itself,the chemical composition maybe change as the extension of storage time.

Chapter Four Inspection Records and Results Storage

4.1 Results Storage

The instrument can store 100 test results, shows the test results at the end of each measurement, press OK key to store test time and results. Next time you can view the test records and test time.

4.2 Check the Inspection Result

In the main screen, move the cursor to the inspection records, press the OK key to enter the inspection record menu, press the left or right button to move the cursor to “▲” or “▼”, press OK button to view inspection records of different time, “▲” is up, “▼” is down.

Chapter Five The Significance of the Test Results

The difference of results between Labtouch urine analyzer and traditional urine analyzer:the test results sign of traditional urine analyzer “+” “_”,is just a qualitative analysis,the concentration behind the “+” is a fixed value corresponds to the “+”,such as urine sugar “+” corresponds to a fixed value is 250 mg/dl (15mmol/L),”++” corresponds to 500mg/dl (30mmol/L),but the concentration between “+”~ “++”can not be detected.And the Labtouch urine analyzer make up the defect of traditional urine analyzer,the result both show qualitative sign “+” “_”,and quantitative density between “+” range.

Glucose

Urine sugar analysis is the simplest way to early diagnosis of diabetes.Normal person can have trace glucose in the urine,when urine discharge rate<2.8 mmol/24 h (< 50.4 mg/dl),using ordinary qualitative method checks were negative.On medicine,the lowest blood sugar level can occur in diabetes is called “renal glucose value”,blood sugar is higher than this value,in diabeters,is lower than this value, no diabetes.Normal person’s renal glucose value is 8.9~10mmol/L (160~180mg/dl).

Urine sugar increased:mainly in diabetes, hyperthyroidism, adrenocortical hyperfunction, chronic liver disease, etc.

Patients with diabetes who is in a stable condition,in order to avoid the inconvenience of frequent blood glucose test,can detect the urine glucose by themselves to get know of the condition changes,but it should not be refused to blood glucose detection on a regular basis.Because in general the appearance of urine glucose and severity is consistent with the rise of blood glucose,but in some special cases,urine glucose and blood glucose fluctuation relationship also can appear the phenomenon of “out of step”.

Blood glucose	Urine glucose
180-200mg/dl (8.9-10mmol/L)	± less than 250mg/dl(13.9mmol/L)
200-250mg/dl (10-13.9mmol/L)	+ 250-500mg/dl(13.9-127.8mmol/L)
250-300mg/dl (13.9-16.7mmol/L)	2+ 500-1000mg/dl(27.8-55.6mmol/L)
300-350mg/dl(16.7-19.4mmol/L)	3+ 1000-2000mg/dl(55.6-110mmol/L)
>350mg/dl(19.4mmol/L)	4+ >2000mg/dl(110mmol/L)

Protein

Urine protein positive both have physiological reasons and sick reasons,its positive degree is not necessarily proportional to the degree of renal damage. Urine protein positive continue to appear in diabetic’s urine,except for urinary tract infections, primary nephrotic, should consider the

possibility of diabetic nephropathy. Some experts believe that the early diabetic nephropathy proteinuria is intermittent, only for positive reaction in labor or after exercise. Therefore, urine protein test after exercise is of certain significance for early detection of diabetic nephropathy.

The clinical significance of urine protein quantitative detection: 24 hours urinary protein quantitative's normal reference value is 10-150 mg/L. If in 150~500mg/L, for the trace albuminuria. >500mg/L, for the clinical proteinuria. Trace albuminuria in diabetic nephropathy early, need to long-term control of blood glucose, has a certain significance to reverse or delay the occurrence of nephropathy and retinopathy.

Ketones

When the body can not use glucose as an energy source, it will use the fat decomposition to produce energy, while there is a substance called ketones, the body will cause serious consequences if ketones accumulate too much in the body, and even coma. Therefore, in patients with diabetes, especially in patients with type 1 diabetes should be able to self monitor urine ketones, in order to detect excessive accumulation of ketones in body.

Ketone positive appeared in:

1. There will be strong positive (more than +++) in diabetic patients, diabetic acidosis, at this time should be paid attention to, prone to poisoning coma, should take timely measures to treatment.
2. Severe vomiting, diarrhea, chronic malnutrition, starvation, after strenuous exercise.
3. Pregnant women with pregnancy reaction and severe vomiting, eclampsia, disorder of digestion and absorption.

When appear following situations, please self testing urine ketone: blood glucose more than 240mg/dl (13.3mmol/L), for various reasons to stop treatment, colds or physical discomfort, suffering from infectious diseases, before and after the operation, vomiting or stomach discomfort, pregnancy, extremely nervous and so on.

If the urine ketone more than “++” or 40mg/dl (3.9mmol/L), should be promptly to the hospital.

Micro albumin

Micro albuminuria positive in diabetic nephropathy, hypertension, preeclampsia, is a sensitive index for early renal injury.

Human metabolism under normal circumstances, the urine albumin rarely, specific to each ascending urine albumin does not exceed 20mg (<20mg/L), so called micro albumin. If found in the urine micro albumin in the 20mg/L-200mg/L range after examination, it belongs to the micro albumin urine.

When a patient has hypertension or diabetes or both of these two diseases (often occur simultaneously), renal vascular disease will occur, changes of kidney filtration protein (especially albumin) function, which makes the protein leakage into the urine. Micro albuminuria is an early sign of diabetic kidney, for diabetic nephropathy.

Signs of micro albuminuria is the whole vascular system, and can be considered to be the artery disease "window", because it is the early changes of renal and cardiovascular indications.

Please refer to the relevant literature or consult a doctor to get more detection significance.

Chapter Six Maintenance and Preservation of Test Strip and Urine Analyzer

6.1 How to save test strip

- ◎ Don't let the test strip directed irradiated by sunlight.
- ◎ Please note that the validity of mark on package before use, do not use expired test strip.
- ◎ Please use within 10 minutes after open the small package.
- ◎ Avoid finger direct contact with the test strip test hole.
- ◎ Test strip storage at room temperature in special bags, dry environment.
- ◎ Recommended for use in room temperature, dry environment.

6.2 How to maintain the urine analyzer

- ◎ Please wipe and cleaning the surface of equipment with the mild wet cloth or cleaning liquid, wipe test platform with a cotton swab.
- ◎ Please do not put other liquids into the test strip socket or down on the button of urine analyzer.
- ◎ Do not put the instrument into the water or any other liquid immersion.
- ◎ Recommended urine analyzer is stored in room temperature.

Chapter Seven Instructions and Troubleshooting

When the error occurs, the machine in poor condition or other unexpected situation, the display will appear relevant message to remind users to pay attention to what matters with this or how to eliminate these problems.

Chapter Eight Instrument specification

Product Model	PUA-120
Test range and display unit	Ketone: 0~16mmol/L(0~160mg/dl) Protein: 0~20mg/L(0~2000mg/dl) Glucose: 0~110mmol/L(0~1980mg/dl) Microalbumin: 0~150mg/L(0~15mg/dl)
Test time	45 seconds
Specimen amount	10µl /hole
Operating temperature range	10°C-30°C
Operating humidity range	≤ 60%RH
Memory Size	100 test results
Size	130×70×26mm
Weight	185g(Battery included)
Power	3.0V DC
Rated power	<10mW
Sample type	Only available fresh urine
Instrument storage environment	-20°C-50°C,RH≤ 90%
Please do not placed in direct sunlight or high temperature and wet places	
Do not fall instruments to the ground other hard objects to avoid collision	
Please do not remove any instrument	

Chapter Nine

The validity of the test strip and Symbol description of urine analyzer

9.1 The validity of the test strip

The validity of the test strip please refer to strip packaging labels

Please use within 10 minutes after opening

9.2 symbol description of urine

Symbol	Introduction
	Storage Temperature Range
	In vitro diagnosis
	Please read the instructions before use
	Note reference manual
	Prevent sun exposure
	Moistureproof

Chapter Ten Scope of Application, Taboo and Attention

10.1 Scope of application

The product is used with test strip, which is applied to test the glucose, ketones, protein and albumin levels in human urine. This product is for in vitro detection, and the test results is for reference only, not as a disease diagnostic tool.

10.2 Taboo

- ◎Who drink lots of water or severe dehydration.
- ◎Visual defect who can't operate the machine.
- ◎Unknown drugs who takes.

10.3 Matters needing attention

- ◎The machine must be operated in the environment of 10-30 °.
- ◎The product is used with test strip

◆Important information

Comparison the test results between Labtouch urine and clinical urine analyzer

Labtouch urine analyzer takes the principle of complete clinical urine analyzer, which is equivalent to the detection results of clinical urine analyzer, because of the environment, human action and other factors, Labtouch urine analyzer test results has slight error compared to the clinical urine analyzer.

Names and contents hazardous substances or elements in the product

		(Cr6+)	plumbum (Pb)	mercury (Hg)	Polybrominated biphenyls (PBB)	Polybrominated biphenyls ethers (PBDE)
body	O	O	O	O	O	O
battery	O	O	O	O	O	O
PCB/LCD	O	O	X	O	O	O

O: stands for the hazardous substance in of all homogeneous materials of the part is under the limited requirements in SJ/T11363-2006.

X: stands for the hazardous substance contained in at least one of the homogeneous materials of this part is beyond the limited requirement in SJ/T11363-2006.

Guarantee clause

1. Labtouch urine Analyzer, from the date of purchase, with the purchase invoice or membership card can enjoy three years free warranty.
But does not include the failure due to personal reasons caused by the user. Such as:
 - a) The fault caused by unauthorized dismounting and modification.
 - b) The fault caused by accidentally dropping in the process of using and handling.
 - c) The fault caused I by lack of reasonable care.
 - d) The fault caused not properly following the instructions carefully.
 - e) The fault caused by improper repairment of non-labtouch urine analyzer authorized repair shop, etc.
2. When required to provide warranty service, please take the product to the customer service network for maintenance.

After-sale Service Department:Shandong Yaohua Medical Device Technology Co.,Ltd.,Labtouch urine analyzer customer service department.

Address:No.5 of Zhujiang Street of High-Tech Zone of Laiwu City,Shandong Province,China

Zip Code:271199

Website:www.yaohua123.com

Production Enterprise:Shandong Yaohua Medical Device Technology Co.

Address:No.5 of Zhujiang Street of High-Tech Zone of Laiwu City,Shandong Province,China

Tel:86-634-8667211

Fax:86-634-8667311

Zip Code:271199

Sales Enterprise:Shandong Yaohua Medical Device Technology Co.

Address:No.5 of Zhujiang Street of High-Tech Zone of Laiwu City,Shandong Province,China

Tel:86-634-8667211

Zip Code:271199

Registration Certificate for Medical Device No.:

Production License No.:

Product Standard Code:

Date of Approval and Revise of Instructions:

The enterprise through ISO13485 quality management system certification.

Product Warranty Card

User Information

Product Model		Product Code	
Date of Purchase		Invoice No.	
Customer Name		Detail Address	
Zip Code		Telephone	

Warranty Record

Warranty Date	Troubleshooting Methods	Completion Date	Customer Signature

First,purchase this product,please fill out this card,read the following warranty terms carefully,to ensure the products effectively warranty.

1.User in the purchase of the product to keep this card,and requests the seller stamped confirmation.

2.When warranty is required to provide the warranty card.

3.Ensure fill out information is true,otherwise invalid.

4.Product warranty for one year,in the warranty period,if the product failure,belongs to the components quality or production problems,we provide free repair and replacement of parts.

Second,the causes of damage to the product can not be used normally,not under warranty.

1.Not in accordance with the instructions and the damage caused by the installation.

2.Damage to all man-made or the result of an accident.

3.Not approved by our company repair,modification,or sealing products stickers rupture.

Third,after the warranty period,the user can get the company to provide repair service,but need to pay the corresponding fees.