URINE ANALYZER

HT-115A

INSTRUCTION FOR USE

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Ⅰ. Introduction

Due to software changes, some screens on the instrument may appear slightly different from those in this manual.

The HT-115A urine analyzer is a semi-automated analyzer, composed of power system, strip tray system, strip collection system, measurement system, touch screen, print system and connection system, that intended for *in vitro* semi-quantitative determination of urine analysis.

The analyzer is designed to read and evaluate the results of urinalysis strips. These urinalysis strips are multiparameter strips used for the determination of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood and ascorbic acid in urine.

The analyzer can be set up to be as simple or sophisticated as you prefer. You may simply insert a dipped urinalysis strip into the analyzer and the result will be reported.

The analyzer can be used at least 5 years under routine maintenance.

Ⅱ. Scope of Application and Performance Specification

A. Scope of Application

The analyzer is designed to read and evaluate the results of Urine Test Strips for clinical routine examination of urine.

These urine test strips are multiparameter strips including:

Specific Gravity(SG) , pH, Leukocytes(LEU) , Nitrite(NIT) , Protein(PRO) , Glucose(GLU) , Ketone(KET) , Urobilinogen(URO) , Bilirubin(BIL) , Blood(BLD) and Ascorbic Acid(VC) .

⚠ Analyzer must use the urine test strip.

⚠ Before using, please make sure the expiration of urine test strip is within the validity period, and observe the color of every parameter whether it has been discolored. Discolored urine test strip can not be used.

⚠ The analyzer is a dedicated instrument, the operation must be carried out according to this Instruction for Use(IFU). The self protection of analyzer may be destroyed if it can not be used according to the IFU, and the accuracy of testing can not be guaranteed.

B. Performance Specification

Table Ⅱ B-1

Item	Specification
Measuring principle	The color change of urine test strip detected by reflective photometer, then it calculates the related concentration and outputs semi-quantitative results
Wavelength of Test	470mm, 525mm, 625mm
Speed of Test	514 Tests/Hour
Reporting	LCD, Serial output, Built-in 56mm thermal printer
Input	8-inch colorful touch screen
Storage of report	can store 10000 copies of the test report

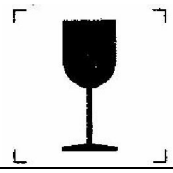
External Interface	Standard RS23 serial port, can be connected to the computer for data exchange
Operating Voltage	AC100-240V 50/60Hz
Power Consumption	Less than 45VA
Overvoltage Category	I
Pollution Level	II
Dimension	440*400*230mm
Weight	6.2kgs

C. Symbols

Symbols are used to help quickly locate and interpret information in this instruction for use. This section explains the formatting conventions used in this IFU.

The following symbols are used throughout this IFU:

Designation	Symbol	Explanation
BIOHAZARD		Indicates a potentially dangerous situation involving the presence of biohazardous material.
VOLTAGE SHOCK HAZARD		Indicates the electricity will cause harm or even death if any living organism comes in contact with the electricity
CAUTION, CONSULT ACCOMPANY DOCUMENTS		Attention, see instruction for use

PROTECTIVE EARTH(GROUND)		The ground connection wire must be connected to ground
FRAGILE		Contents of the transport package are fragile therefore it shall be handled with care
THIS WAY UP		Indicates correct upright position of the transport package
KEEP AWAY FROM RAIN		Transport package shall be kept away from rain
DO NOT ROLL		Transport package shall not be rolled
STACKING LIMIT BY NUMBER		Maximum number of identical packages which may be stacked on one another, where "n" is the limiting number
In vitro diagnostic medical device		*In vitro* diagnostic medical device

Ⅲ. Unpacking and Installation

A. Unpacking

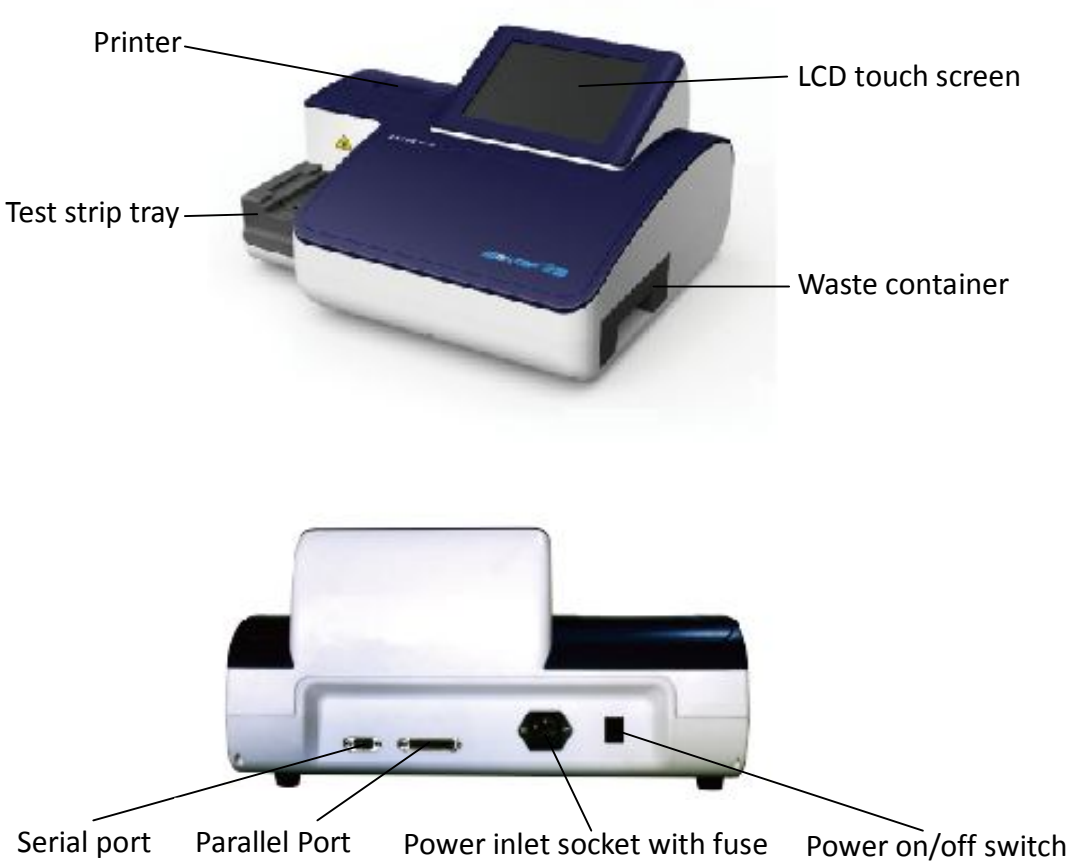
Check the carton and instrument for visible signs of damage, if seen, contact the carrier immediately.

Carefully remove the contents of the shipping carton, remove each of the wrappings and check the following items listed in Table 3.1.

Table ⅢA-1

No.	Item	Quantity
1	HT-115A Urine Analyzer	1 unit
2	Thermal Printing Paper Roll	1 unit
3	Serial Connection Cable	1 unit
4	USB-Serial Cable	1 unit
5	Power Cable	1 unit
6	Fuse	2 units
7	Warranty Card	2 units
8	Instruction for Use	1 unit
9	Certificate of Approval	1 unit
10	Urine Test Strip	Optional
11	Quick Guide	1 unit

B. Components



C. Working and storage condition

Table ⅢC-1

Item	Working Condition	Storage Condition
Temperature	5℃~40℃	0℃~40℃
Relative Humidity	≤80%	≤80%
Atmospheric Pressure	76-106Kpa	76-106Kpa
Condition	Indoor use, altitude < 2000m, place on a solid, , clean, airy surface, no strong direct light, no strong electromagnetic interference	

	power supply with good protective earth connection, power supply voltage fluctuation less than ±10% of nominal voltage

⚠ Power: voltage AC 220V, frequency 50Hz, the power socket protective grounding wire must be grounded to ensure the safety of users and the instrument working properly. Using extension cord to connect power is prohibited.

⚠ The analyzer is a dedicated instrument, do not open the outer casing without authorization. All components only provided by the manufacturer or authorized agent.

⚠ The location to place the instrument must enable to switch off the power or disconnect the power cable easily under emergency condition. Do not use wet hands to operate the power switch, there is danger of electric shock.

⚠ The where to place instrument should be solid and level. If found the four feet of the instrument can not stand on the desktop simultaneously, please adjust the left rear retractable foot of the instrument to make it standing solid.

⚠ Avoid using the instrument in the following locations:

- where there are direct sunlight,
- where there are flammable or explosive gas,
- where there is open window,
- where closed to heating or cooling devices,
- where closed to strong light source.

D. Plugging analyzer in

1. Plug the cable of the power supply into the power inlet socket located on the rear of the instrument.

2. Plug the other end of the power cord into a readily accessible AC electrical w0all

outlet.

E. Loading the paper roll

Open the printer cover by tapping and remove the printer roller out.

Take and remove the wrapping paper of the attached paper roll, put the paper roll into the hoop. Put the fixed roll into the compartment and pull out the first 8cm-10cm of paper just through and under the roller.

Pull out the paper head through the seam and close the cover again by tapping until it locks audibly into position.

The thermal paper must be put in right place, otherwise it will happen to paper deviate or paper jam in printing.

F. Powering up

Press the button " | " located at the rear of the instrument. The system starts with logo and "Self-checking".

The home page shows up after self-checking.

There are five buttons on the left side of main interface.

1. Home 

2. Detection 

3. Setting 

4. Search 

5. Strip Opt 

There are total sixty Sample ID with 6*10 rows on the right side of main interface.

No mark under the Sample ID indicates that the sample has not been tested,

 under the Sample ID indicates that the sample has been tested.

 under the Sample ID indicates that it is failed to test the sample.

It only shows the test results at the same day, all marks of results will be cleared in the following day when first powering up.

The upper right corner of main interface displays the current date and time.

The bottom of the main interface displays the printer status.

indicates that the printer will print automatically.

indicates that the printer will not print automatically

indicates that there is no paper roll in the compartment.

G. Powering down

Switch the button to "o" located at the rear of the instrument.

Do not remove the power cable while the instrument is operating, otherwise the data may be corrupted or the system may be compromised.

Before turning the analyzer off, always ensure that there is no strip on the test strip tray and that the tray is clean.

Ⅳ. Strip Option

"Strip Opt" means strip options, including "Reference Value" and "Strip Type", which relative to the choice of operation.

Press the button 

"Strip Opt" on the left side of main interface to enter next level that shows on the right side.

There are two buttons "Reference Value" and "Strip Type" that. The button will be raised once it is selected and shows relative contents below.

A. Reference value

Press the button of "Reference Value", the reference value for each parameters show up.

By clicking the reference value(cut-off value) on the corresponding parameter to modify the gradient and value, then click "OK" to save. (Note: If the button still on raised status indicates that the modification is not saved yet.)

The meaning of Reference Value(cut-off value) is when the result is higher than the reference value, the report will prompt the test results exceeded.

The modification by user is not recommended, if necessary, please contact the supplier.

B. Strip type

Press the button of "Strip Type", the selection interface shows up.

By clicking "HT-11A" or "HT-11B" to select the type of urine test strip, the selected strip type is marked by a blue dot.

Ⅴ. Search of Results

Press the button 

"Search" on the left side of main interface to enter the searching page that shows on the right side.

The testing date and sample quantity display on the left side of searching page.

By clicking  and  on the slider to flip up and down.

By clicking "Up" and "Dn" on the slider to flip to the first page and the last page.

By clicking the testing day to enter the data page of it. Or enter the testing day(*YYYY-MM-DD*) on the blank box under "By Date", then click "Search" to enter the data page of it.

The data page displays with testing day, sample ID and testing time.

By clicking  and  on the slider to flip up and down.

By clicking "Up" and "Dn" on the slider to flip to the first page and the last page.

By clicking the Sample ID to enter the results page of it. Or enter the Sample ID on the blank box under "By Sample ID", then click "Search" to enter the results page of it.

By clicking  and  to view the other ID's test results up and down at the same day.

By clicking 

to print the current test results that shown on the page.

By clicking 

to return to last page.

Ⅵ. Settings

The instrument has been set according to a conventional use and can be used directly without any modification generally. If the initial settings do not meet user's needs, it can be modified as needed.

Press the button 

"Settings" on the left side of main interface to enter the setting page that shows on the right side.

A. Serial port setting

By clicking the button 

to enter the serial port setting page.

By clicking the baud rate value("9600", "19200", "38400", "57600") to select the baud rate value, the selected baud rate value is marked by a blue dot, then click "OK" to save the change.

B. Print setting

By clicking the button 

to enter the print setting page.

By clicking the "Print" or "No Print" to whether prints automatically or not, the selected one is marked by a blue dot, then click "OK" to save the change.

"Print" means the test results will be printed synchronously once each testing finish, "No Print" on the contrary.

C. Date & Time setting

By clicking the button 

to enter the Date and Time setting page.

By clicking the button "Modified", the digital keyboard appears, modifying the date and time through the digital keyboard.

By clicking  to discard and back to Date and Time setting page.

By clicking 

to save and return to Date and Time setting page.

D. Language setting

By clicking the button 

to enter the Language setting page.

By clicking the "汉语" or "English" to select the Language, the one selected is marked by a blue dot, then click "OK" to save the change.

Ⅶ. Detection

A. Specimen collection

The urine sample should be collected by a clean container.

Test urine as soon as possible after collection to avoid deterioration of specimen, it is the best to test urine within *one* hour after collection.

The storage of urine after collection should not over *four* hour due to the instability of Urobilinogen and bilirubin.

The urine should be mixed thoroughly by capping container and swirling several times before testing to avoid incorrect results. Do not centrifuge or add preservatives to the urine specimen.

Instructions for collection of urine specimen may reference to the *Instruction for Use* for urine test strip.

B. Start detection

By clicking the button to enter the Date and Time setting page.

C. Detection

Press the button 

"Detection" on the left side of main interface to enter the detection page that shows on the right side.

There two parts of the detection page, the part above dotted line is the sample ID that is about to detect except the rightmost ID is under detecting. The part below dotted line is the latest sample ID and testing results that finished detection. (If the "*" appears in front of the value indicates the result has exceeded the reference value.)

D. Procedure

Dip the urine test strip briefly (one sec) in the urine sample. Draw the long edge of the test strip along the rim of the specimen container to remove excess urine. Touch

the long edge and the backside of the strip for one second to an absorbent paper to remove excess urine.

Immediately place the test strip, with the pads facing upward, on the test strip tray. While the confirmatory beep, the instrument has learned that the strip is correctly positioned. The test strip tray starts moving after a few seconds that to ensure enough reaction time for the test strip.

While the test strip moves inside the instrument, there is a confirmatory sensor to confirm whether there has test strip on the test stray or not. The detection will start only after this confirmation while the test strip moves to the test position.

After

⚠ The pads of test strip facing upward.

⚠ The test strip should be placed in the second row from the left on the test strip tray.

⚠ The end of the test strip should be over the upper groove and as close to the upper end of the test strip tray to prevent the strip moves.

⚠ To place the test strip on the tray should be immediately, in case that affects the detecting of the operation or touches the moving test strip.

⚠ Do not place test strip when the test tray is moving.

E. Error handling

During testing process, if the test tray is extracted out or removed, instrument prompts "Tray Error" ,please reinstall tray.

When the test tray is reset, conveyor belt moves 10-bit tooth position, push all the urinalysis reagent strip into waste container, at this point, the strip on tray is not tested, must be re-immersion, drained and tested.

During testing process, if the waste container is extracted out or removed, instrument prompts "Waste Container Error".

After waste container been placed well, push all the urinalysis reagent strip into

waste container, at this point, the strip on tray is not tested, must be re-immersion, drained and tested.

When the waste urinalysis reagent strip is accumulated to a certain extent, instrument prompts "Waste Container full".

The instrument continues to run until all the strips on tray are finished testing, then prompts "Waste Container Full" again. Please empty waste container and then test.

Ⅷ. Errors & Handling

Operate and maintain the instrument according to instruction for use to ensure the instrument work normally. When the instrument detects some abnormality, It will display error prompt message, so that the operator can resolve the issue according to prompt further or ask help to seller or manufacturer. The following is a list of error table Ⅷ-1.

Table Ⅷ-1

No.	Error Message	Issues and Handling Methods
1	Communication Error	Communication between the instrument cover and bottom case fails, please contact the supplier to fix.
2	Transfer Moto/Locate Error	Conveyor belt moves abnormally or positioning sensor is damaged, please contact the supplier to fix.
3	Strip Detector Error	Sensor of urinalysis reagent strip inside instrument fails, please contact the supplier to fix.
4	Detection Module Error	Test head origin sensor or driving motor fails, please contact the supplier to fix.
5	Tray Error	Replace the test tray, if not work, please contact the supplier to fix.
6	Waste Container Error	Replace waste container, if not work, please contact the supplier to fix.
7	Waste Container Full	When all strips placed inside are finished testing, take out the waster container, discard strip, replace, if not work, please contact the supplier to fix.

The following table Ⅷ-2 lists the problems may happen, but the instrument won't prompt.

Table Ⅷ-2

No.	Error Description	Issues and Handling Methods
1	When testing, no any reaction after put the strip on the test tray.	The cover of instrument is damaged, a strong light source around the instrument is working or instrument is explore to direct sunlight, please move instrument to dark, if don't happen above situation, please contact the supplier to fix.
2	Inaccurate detecting data	The cover of instrument is damaged, a strong light source around the instrument is working, instrument is explore to direct sunlight, the test tray is not cleaned up after a long time or instrument light is damaged, please move instrument to dark or clean up tray, if not work, please contact the supplier to fix.
3	Instrument can not be operated.	System halted, please restart, if not work, please contact the supplier to fix.
4	Boot the machine unresponsive	Fuse burned, unplug and replace the fuse, if not work, please contact the supplier to fix.

⚠ When instrument fails, handle according to the above or following prompts.

⚠ Operating voltage of instrument is AC 100-240V, if the voltage is overrun too high, the instrument may produce significant abnormal sound, or issue a burning smell or smoke, turn off the power switch immediately, unplug the power cable, and notify the manufacturer, re-use after overhaul.

⚠ Do not disassemble the instrument without permission. Before disassemble the instrument, cut off the power and unplug the power cable firstly. After opening the cover, pay particular attention to the inside warning signs, such as electric shock

warning, pay attention to protection, prevent the risk of electric shock.

⚠ If accidentally spill liquid into the instrument, cut off the power and unplug the power cable firstly immediately. Extract tray and waste paper box, check the situation of liquid entering, open the cover if necessary, In particular, the parts of switching power and circuit board, clear liquid immediately, stoving or natural drying, energize after confirm drying, any abnormal, cut off the power and unplug the power cable immediately.

⚠ The power cable must use the National Standard three-core wire which is equipped with the instrument, power source socket should have ground wire to ground reliably.

⚠ Serial cable which is equipped with instrument should be protected properly to use to connect with computer. Buy from the origin factory once lost or damaged, or purchase according to the original specifications.

⚠ Make sure that the tested urinalysis reagent strip is completely accordance with the model set in instrument and within expiry date, otherwise may cause wrong results.

⚠ Instrument should be moved gently, before move, had better pack with original package to avoid damage from severe shock. Before move, make sure that no any waste strip in tray or waste paper box, no residual liquid in waste liquid box, in case that the interior of instrument is polluted after upset or something is embedded inside to avoid normal work.

⚠ To transport a used instrument, before transportation, disinfect according to medical institutions internal norms, and mark "Disinfected", otherwise mark " Unsterile", remind the staff who receive the instrument to pay attention to protection. The packed well instrument should be stored at a room,0~40℃, relative humidity less than 80%,non-corrosive substances, well-ventilated.

Ⅸ. Maintenance

A. Routine maintenance and precautions

The instrument is a automated device, it has motion mechanism, expose to urine and so on. So has to set up good operation specifications and make maintenance regularly to extend its lifetime, the more important is to ensure the instrument to output correct results.

 Biohazard: Make prevention and treatment according to Urine Processing Specification formulated by medical institutions.

⚠ The instrument is professional and precision medical instruments, all the consumable and accessories should get from manufacturer or agency authorized by the manufacturer, accessories must be repaired or replaced by personnel specified by the manufacturer. We have right to refuse maintenance for such breakdown caused from dismantle or replace accessories by users themselves or users use consumables which are not from us.

B. Disassembly and cleaning tray

Clean the test tray with clear water every day.

Steps: Turn off the power switch, extract the tray, scrub with a soft cloth in water repeatedly, wash, dry and slot back into tray groove, note that have to align and slot into groove, exert uniformly, don't overexert, don't push hard in case of resistance, retreat back a little and push again, and please push the test tray in the end.

 Biohazard: Pay attention to prevention and treatment.

⚠ The test tray is an important part of the test system, must be maintained properly, can't use detergent or hot water, but can not bake heating, once deform, the test results will be affected.

C. Disassembly and cleaning of waste paper box

Clear up waste strips every day and clean waste container with clear water.

Steps: Turn off the power switch, pull out the waste paper box, discard waste strips, wash waste paper box with soft cloth or brush, plug it back to the instrument after wipe or dry in the air. Note to exert uniformly, the guide rail on box should align the guide groove on shell, push until you feel it has been put in place, at this time, the waste paper box should be on the same level with the shell surface.

 Biohazard: Pay attention to prevention and treatment.

⚠ Urinalysis reagent strips are disposable, non-reusable. Waste urinalysis reagent strips should be properly handled, can not be thrown away. Please handle according to your laboratory waste disposal handling specifications.

D. Disassembly and cleaning of waste liquid tray

Clear up the waste liquid in waste liquid tray every day and wash with clear water.

Steps: Turn off the power switch, pull out the waste paper box, stretch out your hand to the waste paper box position, hold on to the edge of waste liquid tray to pull out the tray. Wash waste liquid tray with clear water and brush, plug it back to the position of waste liquid tray after wipe or dry in the air, and then plug the waste paper box back to the original position.

 Biohazard: Pay attention to prevention and treatment.

E. Replace the fuse

Unplug the power cable, use a "—" screwdriver to pry open the fuse box, take out the fuse, confirm that it has been burned out, change new fuse and push back the fuse box.

⚠ Please use the fuse what is equipped with the instrument or such fuse with specifications: diameter 5mm,length 20mm, 250V/2A slow blow fuses(tube), T2AL250V.

F. Replacing the clock battery

The system uses the 3V button battery with model of "2032". When find the clock abnormal and it turns back to the year 2000 automatically, it indicates the battery has exhausted, need to replace.

Make the instrument upside down, remove the 7 units of M3x10 screws and 1 unit of M3 x8 screw with magnetic phillips screwdriver, collect well. Turn the instrument and put flatly, slowly open the top shell. At this moment you should see a battery holder on the bottom control board. Pull out the battery and at the same time, plug a new battery in the battery holder. Note the direction of the electrode, the positive upward.

Ⅹ. Appendix-Communicate with PC

The instrument communicates with PC via uncrossed serial cable. If the PC doesn't have serial port, Please use USB to serial cable instead of serial cable, at the same time, install USB-to-Serial driver, specific operation please refer to "PC software operation instruction".