

DIRUI

Urine Analyzer

(H-100)



User Manual

DIRUI INDUSTRIAL CO.,LTD.

This manual is applicable to the H Series Urine Analyzer (Model: H-100), hereinafter called “analyzer”.

Instructions

Dear users, thanks for purchasing H Series Urine Analyzer (Model: H-100).

Please read this User Manual carefully for correct operation.

Please keep User Manual safe for future use.

Manufacture Date: Refer to the label.

Use Limit: 7 years.

Version: REV. 06-2017.

Notice

- The analyzer shall be operated by clinical professionals, physicians, nurses, or lab assistants trained.
- The analyzer poses biological, chemical risk; the operator must receive training and use personal protection articles to reduce the risk.
- The operator must be trained before performing operation with danger, such as moving parts.
- Hospitals or clinical institutions should work out a maintenance plan and strictly follow it. Otherwise the analyzer malfunction may be caused.
- As for the usage and storage of reagent strip and Control, please refer to the relevant instructions. Confirm that they are within shelf life.
- Do not use expired reagent strips.
- Do not use turpentine, benzene or other organic solvent to clean the surface of the analyzer because this may cause housing color or shape change. Wipe with soft cloth or moistened cloth. In case of severe dirt, clean the analyzer with diluted alcohol.
- When transportation or storage ambient temperature is fairly low or relative humidity is more than 75%, keep the analyzer in the normal working environment for 24 hours and then start it up for tests.

Biohazard

- User should comply with the local and national regulations when discharging and disposing of reagents, waste solution, waste samples, and consumables etc.
- Samples, Control and waste solution have potential biological infectivity to irritate eyes, skin and mucosa. User should refer to the safety regulation for lab operation. Protective measures should be taken for user (Such as lab protective clothes and gloves).
- Do not use disposable goods repeatedly.

Warning

- If the user does not use the analyzer according to the manual, the protective measures offered by the analyzer may lose effectiveness.
- Do not pull/plug the electrical wire with wet hands. Electric shock may happen.
- Do not use broken wire and cable. Do not pull, stamp on, twist or drag the wire and cable. Otherwise fire may be caused.
- The analyzer should be operated in a good grounding condition.
- Confirm that input voltage is qualified. Use specified fuse.
- Confirm that analyzer switch is on [O] before power supply is connected.
- Do not use the analyzer in inflammable and explosive conditions.

Statement

DIRUI has the final interpretation of this user manual.

DIRUI is responsible for the security, reliability and performance of H Series Urine Analyzer(Model:H-100) after the following requirements are met:

- (1)Installation, debugging and repair are conducted by professionals from DIRUI.
- (2)Relevant electrical equipment is in line with the national standards.
- (3)Operation is subject to the user manual.

All software interfaces are subject to change without notice.

Contents

Chapter 1 General Introduction	1-1
1.1 General Description and Intended Use	1-1
1.2 Technical Specifications	1-1
1.3 Testing Principle	1-1
1.4 Analyzer Structure	1-2
1.5 Symbol	1-3
1.6 Introduction of the Keyboard.....	1-4
Chapter 2 Installation.....	2-1
2.1 Environment Requirements.....	2-1
2.2 Open Carton.....	2-1
2.3 Installation.....	2-1
2.3.1 Install printing paper	2-1
2.3.2 Install the strip holder and urine collector	2-1
2.3.3 Connect with computer.....	2-2
2.3.4 Install external stylus printer	2-2
2.3.5 Connect power cable	2-2
2.3.6 Connect with barcode reader	2-3
2.4 Carrying Method	2-3
Chapter 3 Functions and Setup	3-1
3.1 Function Block Diagram	3-1
3.2 Setup	3-2
3.2.1 Set Sequence Number	3-2
3.2.2 ID Edit.....	3-2
3.2.3 Data recall	3-3
3.2.4 Calibration and QC liquid	3-4
3.2.5 Set system.....	3-4
3.3 Test Strip Security Barcode Instruction	3-9
Chapter 4 Quality Control Monitoring.....	4-1
4.1 Calibration Strip Test.....	4-1
4.2 Quality Control Liquid Test	4-1
Chapter 5 Method of Operation	5-1

5.1 Checkup the Strip Table	5-1
5.2 Startup the Analyzer	5-1
5.3 Operation Method	5-1
5.3.1 Fast Mode.....	5-1
5.3.2 Slow Mode	5-2
Chapter 6 Cleaning and Maintenance	6-1
6.1 Daily Cleaning.....	6-1
6.2 Periodical Cleaning.....	6-1
6.3 Disinfection.....	6-2
6.4 Maintenance before stopping use of analyzer	6-2
6.5 Waste Treatment	6-2
6.6 Disposal of Scraped Analyzer	6-2
Chapter 7 Transportation and Storage.....	7-1
7.1 Transportation Requirement.....	7-1
7.2 Storage Requirement.....	7-1
Appendix A Manufacturer's Warranty	A-1
Appendix B Interface for Communicating with Computer	B-1
Appendix C Output Value.....	C-1
Appendix D Malfunction Information List	D-1
Appendix E Performance Indexes	E-1
Appendix F Accessories List	F-1

Chapter 1 General Introduction

1.1 General Description and Intended Use

H Series Urine Analyzer (Model: H-100) should be used together with Dirui urinalysis strips (model: H11-II, H10-II, H11-MA(N), H11-MA).

It can provide a qualitative or semi-quantitative result for Urobilinogen, Bilirubin, Ketone, Blood, Protein, Micro-albumin, Nitrite, Leucocytes, Glucose, Specific gravity, pH, and Vitamin C.

Adopting the advanced “high luminosity cold light source reflection determination” technology, H-100 urine analyzer gets the specialties of resisting the interference of the ambient light and has longer lifespan. It can finish the testes of biochemical components in urine within 30 seconds, and it also can revise the affects toward the test result which is caused by ambient temperature, ambient light, acid-base scale and abnormally colored sample. It can also connect with the urine sediments analyzer.

1.2 Technical Specifications

Performance Specification							
Test Items		Test Speed	Storage	Functions	Dimensions	Power	N/W
Urobilinogen	UBG	60 t/h or 120t/h	5000 records	Calibration	385mm×337mm× 166mm	40VA	3.9kg
Bilirubi	BIL			Database Query			
Ketone	KET			Speed Switch			
Blood	BLD			Sequence Setting			
Protein	PRO			Language Setting			
Microalbumin	MALB			Time Setting			
Nitrite	NIT			Status Setting			
Leucocytes	LEU			Date Format			
Glucose	GLU			Units Selection			
Specific Gravity	SG			Critical Value Setting			
pH	pH						
VitaminC	VC						

Normal Working Conditions:

- (1) Ambient Temperature: 15℃~35℃
- (2) Relative Humidity: no more than 75%
- (3) Atmospheric pressure: 76kPa~106kPa
- (4) Power Supply: 100-240V~, 50 /60Hz
- (5) Light: avoid direct sunlight.

1.3 Testing Principle

The analyzer uses the method of colorimetry of light against electronic signal, according to color changes of testing light against strip reflection pad to determine the biochemistry content of urine.

Four kinds of mono-light will scan the reaction area of strip, and then, change the signal into electronic signal. Electronic signal will execute A/D conversion, and adopt the convert data to calculate the reflectivity to determine the biochemistry content of urine.

Adopt double wavelength test mode in the application. That is to obtain the final test data by the ratio of the reflectivity (reflectivity refers to the reflex of mono-light on the strip pad). The formula is as follows:

$$R = \frac{T_m \times C_r}{T_r \times C_m}$$

Where,

R	Test data of strip pad
T_r	Reflection intensity of reference light against strip pad
C_r	Reflection intensity of reference light against white benchmark
T_m	Reflection intensity of testing light against strip pad
C_m	Reflection intensity of testing light against white benchmark

1.4 Analyzer Structure

This analyzer is composed of: control system, optical system, mechanical system and input & output system.

Control System: includes main control boards, CPLD boards, monitoring modules and built-in software.

Optical System: includes LED illumination section and data collection section to collect all the sample information shown by strips.

Mechanical System: includes housing, frame, drive motor, transmission gear, strip table, urine collector, strip holder, white-benchmark, etc. to fulfill the strips feeding.

Input & Output System: includes keyboard, LCD, thermal printer and output serial ports and external printer interface to control the commands input and test result output.

See the figure below to get a visual instruction of the analyzer:

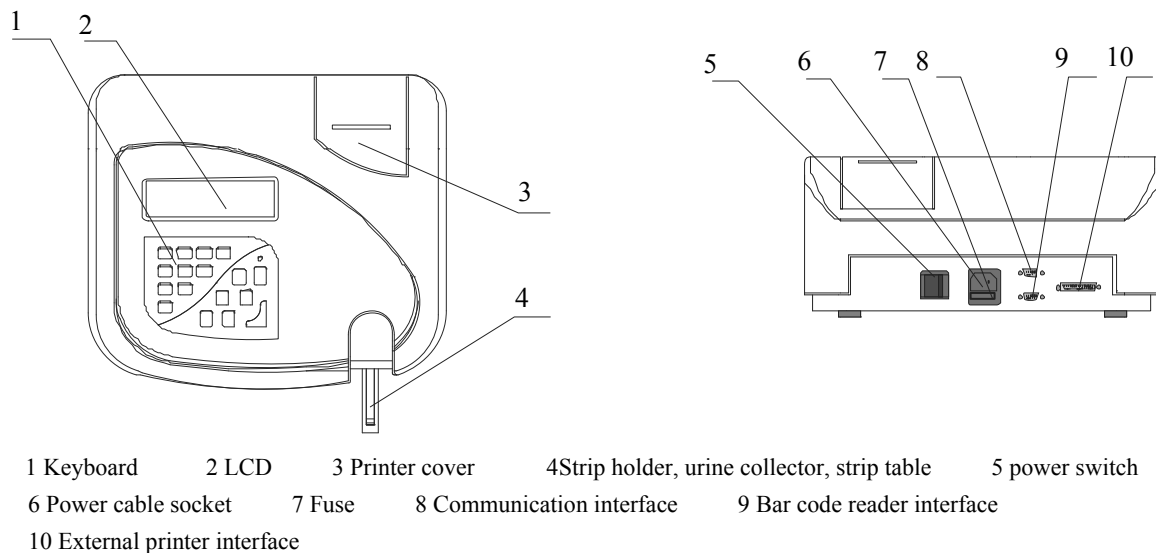


Figure 1-4-1

1.5 Symbol

Table 1-5-1

Symbol	Meaning
	Biohazard, reminding the user to pay attention; otherwise there is risk of potential bio-infectivity
	LASER, DANGER SYMBOL
	ALTERNATING CURRENT
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	BATCH CODE
	USE BY
	SERIAL NUMBER
	DATE OF MANUFACTURE
	PROTECTIVE GROUND
	MANUFACTURER
	CAUTION, REFER TO THE ACCOMPANYING FILES OR MARK DETAILED WARNING OR MATTERS NEEDING ATTENTION
	THE DEVICE MEETS THE REQUIREMENTS OF DIRECTIVE ON IN VITRO DIAGNOSTIC MEDICAL DEVICES
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	The symbol of the crossed out wheeled bin indicates that the product (electrical and electronic equipment) should not be placed in municipal waste. Please check local regulations for disposal of electronic products.
	CATALOGUE NUMBER
	“ON”(POWER)
	“OFF”(POWER)



The above symbol information is included on the analyzer, reagent strip and control.

1.6 Introduction of the Keyboard

Table 1-6-1

 (Number keys)	These number keys are used to enter the corresponding number.
 (Start)	After pressing the key, the analyzer will sound a warning tone to dip the test strip into urine. 40 seconds later it begins testing. No response when press the key during the testing time.
 (Menu)	Under the main menu, touching this key will make the screen turn to the main menu. Under the menu status, touching this key will make the screen return to the upper menu.
 (Enter)	Press this key to confirm the option under the menu status. Press the key before current test finished, the analyzer will stop testing after current test. Touching this key could check the result.
 (Clear)	Under the number input status, touching this key will turn the corresponding number to zero.
 (Up/Down)	Under the menu status, touching the two keys will move the cursor upward or downward. Under the data recall status, touching the two keys will turn to the previous or the next screen (the previous or the next record).
 (Print)	Under the date recall status, touching this key will print out the test data on the current screen.
 (Line)	Touching this key will make the printer to go ahead, leaving two lines blank.

Chapter 2 Installation

2.1 Environment Requirements

- (1) The analyzer should be located on a stable, flat, and vibration-free surface which can bear at least 4kg.
- (2) Keep away from chemicals and avoid the effect from corrosive gas and strong electromagnetic waves.
- (3) Keep out of direct sunshine, dampness and high temperature.
- (4) Ambient temperature range for operating is 15°C~35°C. (20°C~25°C would be the best); relative humidity $\leq 75\%$.
- (5) Keep a good ventilation status. If need be, a ventilation device can be used. However, do not make the device blow the analyzer directly. Otherwise, the test accuracy would be affected.

2.2 Open Carton

Please take out the H Series Urine Analyzer (Model: H-100) and its accessories, and check them with the packing list. If there is damage to the following parts, please contact the supplier immediately.

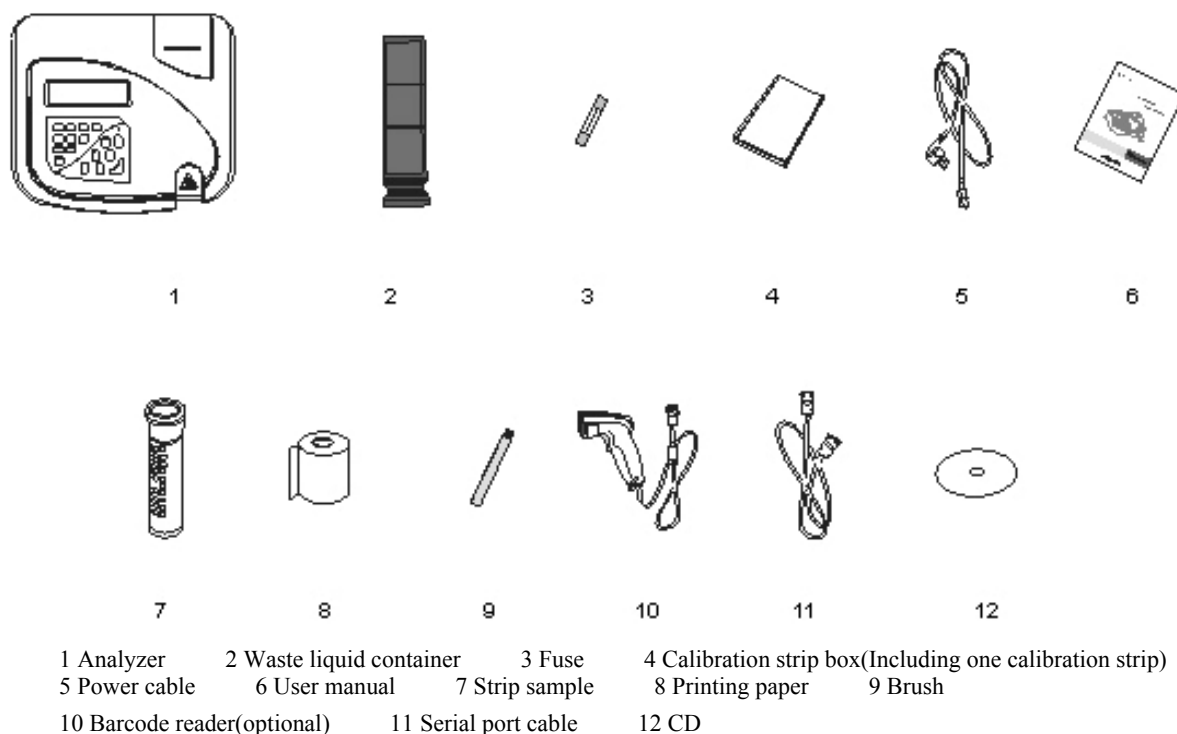


Figure 2-2-1

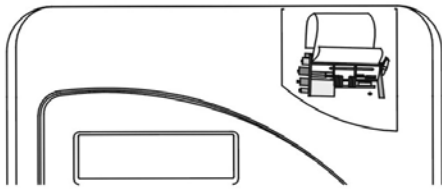
2.3 Installation

2.3.1 Install printing paper

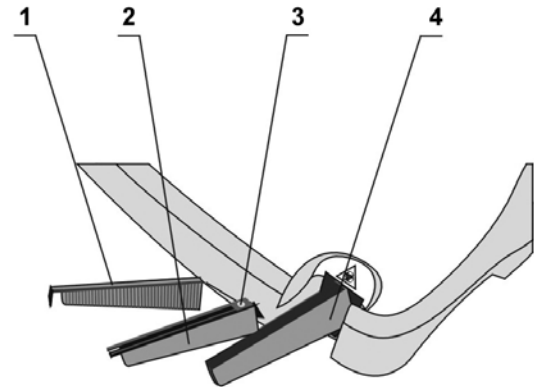
- (1) Obtain a roll of thermal printer paper (Figure 2-3-1) with width of 57mm and diameter less than 50mm.
- (2) Remove the cover of the printer.
- (3) Put the new roll of paper into the paper box and release the paper roll, with the end of the paper toward the near side of the analyzer.
- (4) Switch out the handle and feed the paper roll to the printer perpendicularly. Pull the paper up and down and press down the handle.
- (5) Pull the paper through the hole on the covering tab of the printer and set the covering tab back into position.

2.3.2 Install the strip holder and urine collector

According to the Figure 2-3-2, put the strip holder into the urine collector, put the urine collector into the strip table.



1 Strip holder



2 Urine collector

3 White bench-mark

4 Strip table

Figure 2-3-1

Figure 2-3-2

2.3.3 Connect with computer

The analyzer can be connected with the computer through the serial port cable. Insert one end of the serial port cable into the serial port at the back of the analyzer (Figure 2-3-3) and the other end into the serial port of the computer.

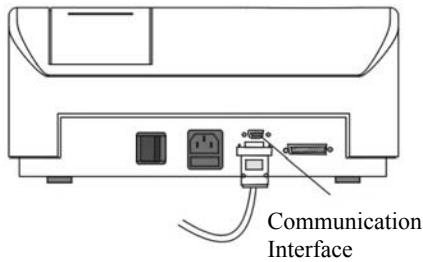


Figure 2-3-3

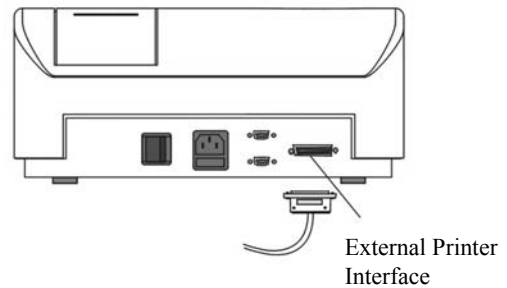


Figure 2-3-4

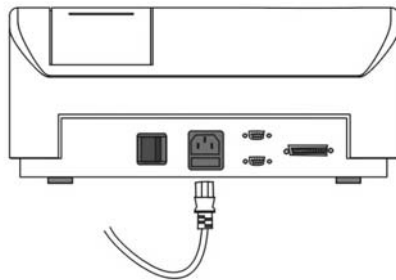


Figure 2-3-5

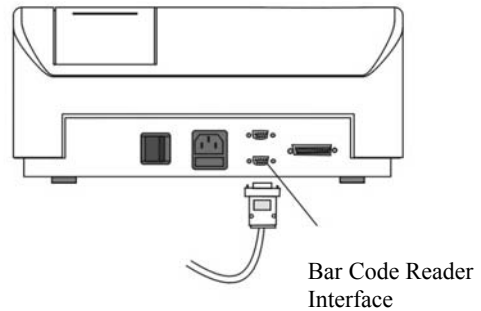


Figure 2-3-6

2.3.4 Install external stylus printer

Connect one end of the printer wire to the printer, the other end to the parallel port of the analyzer (Figure 2-3-4).



The analyzer can be connected to printers such as EPSON LQ1600K, EPSON LQ300K+.

2.3.5 Connect power cable

Power Requirement:

- (1)Voltage: 100-240V~, 50 /60Hz;
- (2)Power: 40VA;
- (3)Fuse: F1AL250V 5mm×20mm.



- The socket connecting the power cable should be fixed and grounded.
- The socket unit should be placed near the analyzer for an easy power-cut operation.

Connect the output terminal of the power cable with the socket at the back of the analyzer; Connect the input terminal of the power cable to AC power (Figure 2-3-5).

2.3.6 Connect with barcode reader

Urine analyzer can connect with bar code reader and receive the bar code scanned by bar code reader. Take out the barcode reader (optional part) from the box, connect the data cable of bar code reader, as shown in Figure 2-3-7, and connect the other end of the data cable (RS-232 port) with the barcode reader port of urine analyzer(Figure 2-3-6).



Figure 2-3-7



The analyzer uses a laser barcode reader (optional). Do not stare at the reading window of the barcode reader when the power is on.

2.4 Carrying Method

- (1)Keep the analyzer up-right during carrying.
- (2)Avoid vibration during carrying process, if happened, check and debug the analyzer prior to use.

Chapter 3 Functions and Setup

3.1 Function Block Diagram

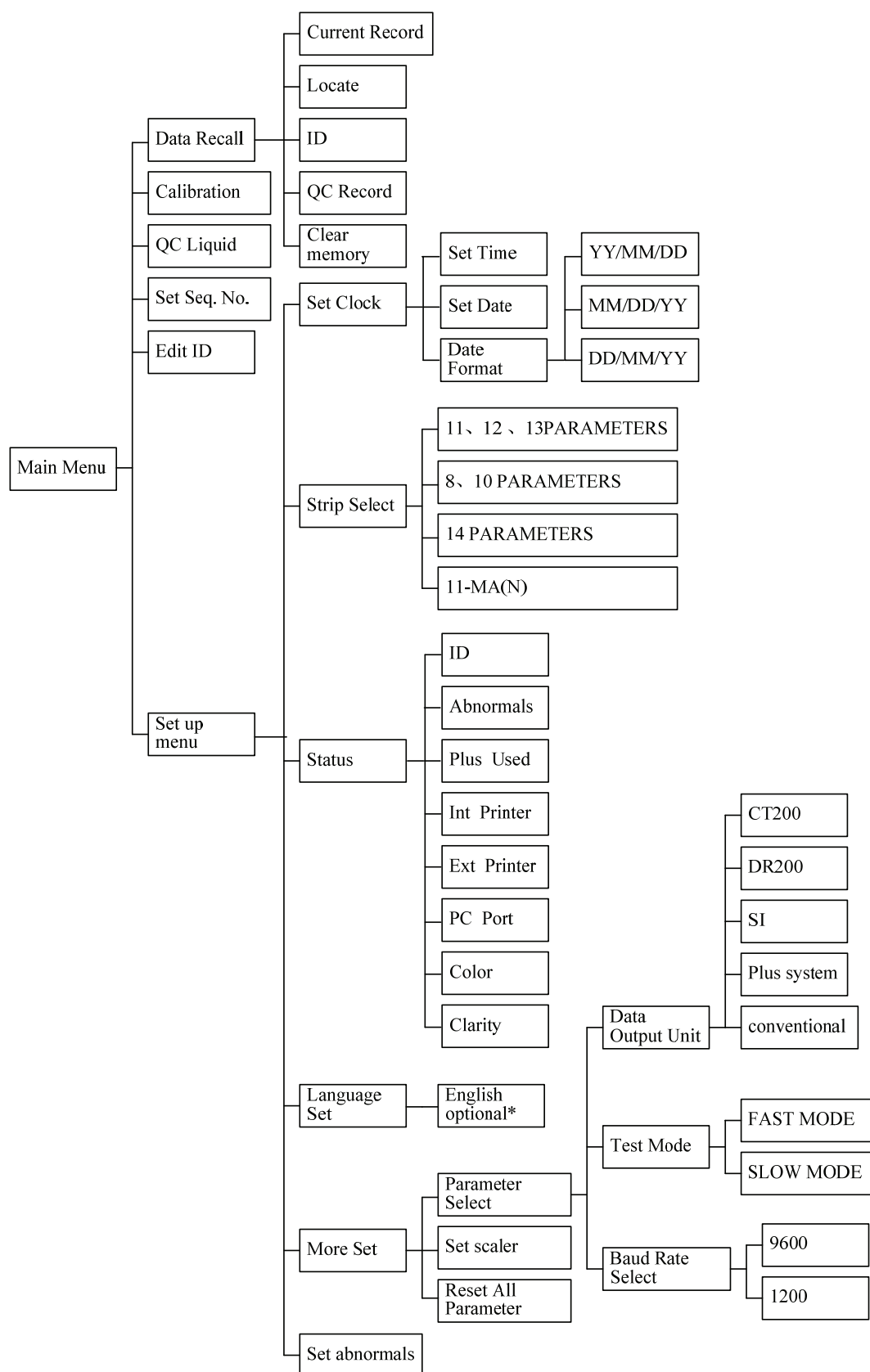


Figure 3-1-1

3.2 Setup

3.2.1 Set Sequence Number

URINE ANALYZER	10-01-01
#0001	12:00:00
VERSION	0118
MENU	START

Figure 3-2-1

In the main screen (Figure 3-2-1) press the key “Menu”, enter into the sequence number setup, the screen shows as follows:

MAIN	MENU
Data Recall	Set Seq No.
Calibration	Edit ID
QC Liquid	Set Up Menu

Figure 3-2-2

Press the key “Menu” return to the main screen (Figure 3-2-1).

Press the key “▲” and “▼” to move the cursor to the position of “Set Seq. No.”, press the key “Enter” for confirmation, and enter sequence number setup Submenu.

Please Input Sequence No.
Sequence NO. 0001

Figure 3-2-3

The sequence number can be any numerical value between 0001-9999, the sequence number will add 1 automatically after each test.

Press the number key “0” to “9” on the keyboard to setup the sequence number.

Press the key “Enter” to confirm and return to the upper menu.

Press the key “Menu” to discard changes and return to the upper menu.

3.2.2 ID Edit

Choose “Edit ID” in the Figure 3-2-2 and press “Enter” to confirm. In the ID interface, the display as follows:

Input ID:

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

Figure 3-2-4

Enter the number on the keyboard to input the number, press “Line”, the cursor will stay under the capital letter. Press “Line” again, the cursor will stay under the small letter. Press the key “▲” and “▼” to move the cursor. Choose the letter and press “Start” to input the letter. After input the ID, press “Enter” to confirm the ID, it displays main menu (Figure 3-2-2). Enter the next testing, the ID input will display in the printout.



The input limit is 30 ID number before testing.

3.2.3 Data recall

The analyzer can store 5000 pieces of records; each record includes data as time, sequence number, test result and so on. After each test, the analyzer stores the test result automatically. If the storage records exceeds 5000, the analyzer will display “Memory full, please clear the records!”. Test can not be conducted if the records are not cleared.

In main menu (Figure 3-2-2), press the key “▲” and “▼” to select the “Data Recall”, press the key “Enter” to confirm, the screen will show as follows:

Data Recall:	
Current Record	QC Record
Locate	Clear Memory
ID	

Figure 3-2-5

The user may check the test result by four ways: current record, Locate, QC Record and ID.

3.2.3.1 Current record recall

Select Current Record and press “Enter”, the screen will show current records. Press the key “Line” could turn record page and press the key “▲” and “▼” to select the corresponding record. Press the key “Print” to print the showed record.

3.2.3.2 Sequence number Recall

Select the “Locate” and press the key “Enter” to confirm, the screen will show as follows:

Please Input Sequence No.
Sequence NO.0001

Figure 3-2-6

The cursor stops at the first number, enter the recall sequence number through the number key. And then, press the key “Enter” to check the result by the sequence number. If there is record in the analyzer, the screen will display the record. If there is no such record, the screen will display “Record Not Found!”(Figure 3-2-7).

Record Not Found!

Figure 3-2-7

Press the key “Menu” to return to the Figure 3-2-5.

3.2.3.3 ID record

Choose “ID” in Figure3-2-5 and press “Enter” to confirm. The display as follows:

Input ID:

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

Figure 3-2-8

Enter the number on the keyboard to input the number, press “Line”, the cursor will stay under the capital letter. Press “Line” again, the cursor will stay under the small letter. Press the key “▲” and “▼” to move the cursor. Choose the letter and press “Start” to input the letter. Press the Line for the third time, Figures could be input.

After input the ID, press “Enter” to confirm the ID. If there is ID, the record will be displayed. If not, “Record Not Found!” will be displayed.

3.2.3.4 Quality Control Record

The analyzer could store 50 pieces QC records. Choose “QC Record” in Figure 3-2-5 and then press “Enter” key to confirm. Press the key Line could turn record page and press the key “▲” and “▼” to select the corresponding record. Press the key “Print” to print the showed record. Press “Menu” to return.

3.2.3.5 Clear memory

Select “Clear Memory” in Figure 3-2-5 and press the key “Enter”, the screen displays as follows:



Figure 3-2-9

Select “No”, the screen will return to the upper menu, select “Yes” and press the key “Enter”, all the records will be cleared, the sequence number set as 0001 automatically.

3.2.4 Calibration and QC liquid

Refer “Calibration” and “QC liquid” in Chapter 4 “Quality Control Monitoring”.

3.2.5 Set system

Select “Set up Menu” in main menu (Figure 3-2-2), press the key “Enter” to confirm, the screen shows as follows:

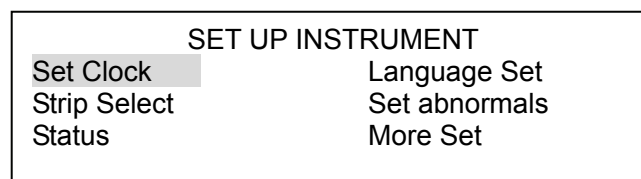


Figure 3-2-10

Press the key “▲” or “▼” to move the cursor to the item which the operator want to change, press the key “Enter” to confirm, the screen will show the corresponding display. Press the key “Menu” to return the upper screen after setup.

3.2.5.1 Set clock

Select “Set Clock” in the Figure 3-2-10, press the key “Enter” to confirm, the screen shows as follows:

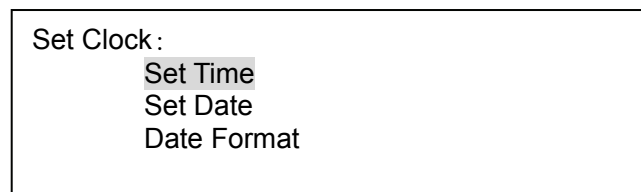


Figure 3-2-11

(1)Set time

Select “Set Time” in Figure 3-2-11, press the key “Enter” to confirm, the screen shows as follows:

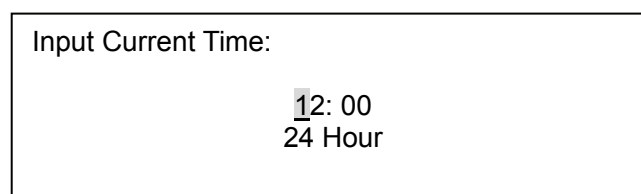


Figure 3-2-12

The cursor stop at the position of the first number, press the corresponding number key to enter the current time, press “Menu” could give up setup and back to upper menu.

After each entering, the cursor will move to the number next to its right. After the last number has been entered, the cursor will return to the first number. After operation, press the key “Enter” to confirm and return to the upper menu (Figure 3-2-11).

If the number entered is less than 10, add “0” to its front.

(2) Set date

Select “Set Date” in Figure 3-2-11, press the key “Enter” to confirm, the screen shows as follows:

Input Current Date:

10/01/01

YY/MM/DD

Figure 3-2-13

The cursor stop at the position of the first number, press the corresponding number key to enter the current time. After each entering, the cursor will move to the number next to its right. After the last number has been entered, the cursor will return to the first number. After operation, press the key “Enter” to confirm and return to the upper menu.

If the number entered is less than 10, add “0” to its front.

(3)Data Format

Select “Date Format” in Figure 3-2-11, press the key “Enter” to confirm, the screen shows as follows:

Date Format Select:

YY/MM/DD

MM/DD/YY

DD/MM/YY

Figure 3-2-14

Press the key “▲” or “▼” to select the format.

Press the key “Enter” to confirm and return to the upper menu.

Press the key “Menu” to discard changes and return to the upper menu.



Date format displayed in Figure 3-2-13 should be the same with the set date format in Figure 3-2-14

3.2.5.2 Strip Select

Select “Strip Select” in Figure 3-2-10, press the key “Enter” to confirm, the screen shows as follows:

Strip select:

8 PARAMETERS	11 PARAMETERS
10 PARAMETERS	12 PARAMETERS
11-MA (N)	13 PARAMETERS

Figure 3-2-15



- H Series Urine Analyzer (Model: H-100) can use DIRUI H11-II, H10-II, H11-MA(N), H11-MA urinalysis strips. Other strips can not be used.
- Strip selection function is only available after supplier’s authorization.

In the original setting of the analyzer, if the strip option setting is only 13 parameters, the analyzer can conduct

switch setting for any parameter of the 13 testing parameters when selecting “Strip Select” from Figure 3-2-10 and clicking the “Enter” key, as shown in Figure 3-2-16:

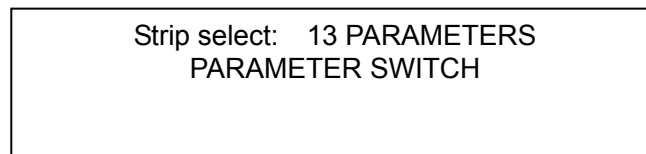


Figure 3-2-16

Select “PARAMETERS SWITCH”, and click the “Enter”, as shown in Figure 3-2-17:

UBG	ON	BLD	ON
BIL	ON	PRO	ON
KET	ON	MALB	ON
CRE	ON	NIT	ON

Figure 3-2-17

Click the “” key, and turn to the next page, as shown in Figure 3-2-18:

LEU	ON	VC	ON
GLU	ON	SG	ON
PH	ON		

Figure 3-2-18

When the cursor moves to the selected item, click the “Enter” key to change the “On”, “Off” status of the item.

3.2.5.3 Set Status

Select “Status” in Figure 3-2-10, press the key “Enter” to confirm, the screen shows as follows:

ID	ON	Ext Printer	OFF
Abnormals	ON	PC Port	ON
Plus Used	ON	Color	OFF
Int Printer	ON	Clarity	OFF

Figure 3-2-19

In this menu, the operator can change the status of “ID”, “Abnormals”, “Plus Used”, “Int Printer”, “Ext Printer”, “PC Port”, “color” and “Clarity”.

(1)ID: when “ID” is “ON” and the connected bar code reader could scan the bar code on tube, the output display ID as Figure 3-2-20. When “ID” is “OFF”, the output not display ID as Figure 3-2-21, The following explanation take H13-Cr strip as example.



Each scanning limit is less than 30 samples. The over parts are invalid code, the length of the bar code should be less than 15 character. Operator could scan bar code when waiting for put in strip and printing result. The scanned bar code during the strip table moving is invalid. Without tone response from the scanner, the scanned result is invalid.

Date :	2010-01-01	11:40
No.	0494	
ID:	000015214810234	
UBG	Normal	3.4μmol/L
BIL	Neg	
KET	Neg	
CRE	4.4	mmol/L
* BLD	2+	Ca80 Ery/μL
PRO	Neg	
MALB	10	mg/L
* NIT	Pos	
* LEU	3+	>=Ca500Leu/μL
* GLU	1+	5.6 mmol/L
SG		1.020
pH		5.5
VC		2.8 mmol/L
A:C	<3.4mg/mmol	Normal

Figure 3-2-20

Date :	2010-01-01	11:40
No.	0494	
UBG	Normal	3.4μmol/L
BIL	Neg	
KET	Neg	
CRE	4.4	mmol/L
BLD		Ca80 Ery/μL
PRO	Neg	
MALB	10	mg/L
NIT	Pos	
LEU		>=Ca500Leu/μL
GLU		5.6 mmol/L
SG		1.020
pH		5.5
VC		2.8 mmol/L
A:C	<3.4mg/mmol	Normal

Figure 3-2-21

(2)Abnormals: When Abnormals is “ON”, if the test result of a certain item is more than or equal to the set critical value, the symbol “*” will appear on the report (Figure 3-2-20) otherwise the “*” will not print out. (Figure 3-2-21).

(3)Plus Used: When the “plus Used” is “ON”, the test result will print the “+” together with the relative test value under the current unit select (Figure 3-2-20). When the plus system is “OFF”, the “+” will not print out (Figure 3-2-21).

(4)Internal Print: When “Int. printer” is “ON”, the internal printer will print the result, otherwise it will not print.

(5)External Print: When “Ext. printer” is “ON”, the external printer will print the result, otherwise it will not print.

(6)Computer Interface: when “PC Port” is “ON”, analyzer can transmit data to computer; otherwise it can not.

(7)Color and Clarity

When “Color” is “ON”, the printed test result will show “Color” Item, when “Clarity” is “ON”, the printed test result will show “Clarity” item. Operator could write the relevant color and Clarity results. When they are “OFF”, “Color” and “Clarity” will not show in the result.

3.2.5.4 Set Language

In Figure 3-2-10, select the “Language Set”, press the key “Enter” to confirm, the screen will show as follows:

	French
Language Select	English
	Russian

Figure 3-2-22

Nine languages are available according to the requirement of clients: English, Russian, Polish, Italian, Spanish, Portuguese, Turkish, German, and French.

Press the key “▲” and “▼” to select language, press the key “Enter” to confirm and return the upper menu.

3.2.5.5 Set abnormals

Select “Set abnormals” in Figure 3-2-10, press the key “Enter” to confirm, the screen will show as follows:

UBG	PRO
BIL	NIT
KET	LEU
BLD	GLU

Figure 3-2-23

By pressing the key “▲” or “▼” to move the cursor to the selected item, press the key “Enter”. For example, to change the critical value of urobilinogen, move the cursor to the “UBG” item, press the key “Enter”. The screen will show as follows:

Normal	17μmol / L
1+	34μmol / L
2+	68μmol / L
3+	>=135μmol / L

Figure 3-2-24

The cursor will stop at the current critical value. Press the key “▲” or “▼” to Move the cursor to the needed critical value, and press the key “Enter” for confirmation and return to the upper menu.

When one of the test item in the test result is higher than the set abnormal value. “*” will appear in the output result.

3.2.5.6 More setup

In Figure 3-2-10, choose “More set”, press “Enter” to confirm, the screen displays as follows:

Set Options:
Parameter Select
Set Scaler
Reset All Parameters

Figure 3-2-25

(1) Choose “Parameter Select”, Press “Enter” to confirm, the screen displays as follows:

Data Output Unit	SI
Test Mode	FAST MODE
Baud Rate Select	9600

Figure 3-2-26

a) Data Output Unit: In Figure 3-2-26, choose “Data Output Unit”, press “Enter” the screen will show the option one by one as follows:

Table 3-2-1

1	SI
2	CT200
3	DR200
4	Plus System
5	Conventional



When the strip option is 13 or 14 PARAMETERS, Results Units can only choose SI, Conventional and Plus System; When the strip option is 12 PARAMETERS, 11 PARAMETERS, 10 PARAMETERS, 8 PARAMETERS, 11-MA(N), all five units are able to choose.

b) The test mode: Select the “Test Mode” in Figure 3-2-26, press the key “Enter” to confirm, the screen will show the option one by one between two modes: The test mode including “FAST MODE” and “SLOW MODE”.

Under fast mode, put the next strip on the table without pressing other key after testing one strip. The fast mode

is suitable for the continuous test of large quantity of urine samples, the test rate for each strip is 30 seconds. Under slow mode, the analyzer will stop after complete one test. Press the key “Start” if the next test is conducted. The slow mode is suitable for the non-continuous test, the test rate for each strip is 60 seconds.

c)Baud rate select: It is used to set up the transmission speed of urine analyzer. In Figure 3-2-26, select “Baud Rate Select” and press the key “Enter”, the content after “Baud Rate Select” will be switched between “9600” and “1200”.

(2)Set Scaler: Values are related to the accuracy of the tests, users should not change these values at will.

(3)Reset All Parameters: Choose “Reset All Parameters” in Figure 3-2-25, press “Enter” to confirm.

It will goes back to Figure 3-2-25 after a sound. The scaler value of the analyzer is reset the factory default.

3.3 Test Strip Security Barcode Instruction

Press “Enter” of the keyboard, as shown in Figure 3-2-27 shows:

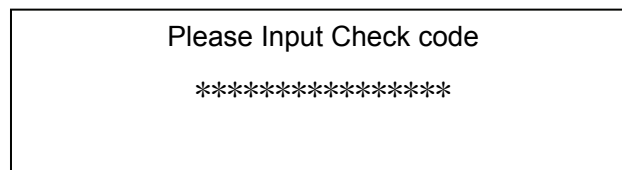


Figure 3-2-27

Enter the valid barcode on the test strip canister manually or by scanning before test.

The existence of the following situations may occur in the process of entering the barcode:

(1)If the barcode entered has been used, press “Enter” key, and a prompt “USED CHECKCODE” will pop up.

(2)When entering manually, if entering barcode error occurs, press “Enter” key, and a prompt “Invalid Check Code” will pop up.

(3)If entered barcode is overdue (test strip is out of expiry date), press “Enter” key, and a prompt “Expired Check Code” will pop up.



- The security code can be input singly or continuously.
- 120 test strips can be tested by input a security bar code. The number of test paper is displayed on the right side of the main interface. The number will increase by continuous input (As shown in Figure 3-2-1 “0118”).
- If the right side of the main interface displays 0000, the analyzer can not test. A new security bar code should be input before testing.

Chapter 4 Quality Control Monitoring

4.1 Calibration Strip Test



- Do not dip the calibration strip into water or any other liquid when testing.
- In the process of test, make sure the calibration strip do not deviate the test position.
- There are two calibration strips accompany with the analyzer.
- If the calibration strip has besmirched or damaged, please contact with the supplier, do not continue to use this calibration strip to test the urine analyzer.

In order to make sure to get correct test result, it is recommended to test the analyzer by the calibration strip every one or two weeks.

Test Method:

Select “Calibration” in Figure 3-2-2, put the calibration strip on the center of the strip holder, and push it forward until the strip touch the end of the strip holder, press the key “Enter”, the analyzer will conduct the test.

The screen will show as follows:

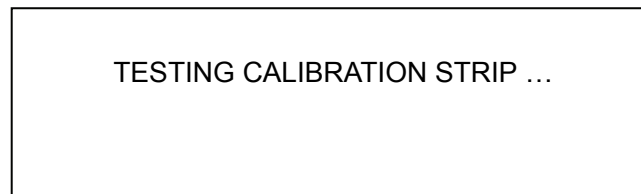


Figure 4-1-1



If the urine analyzer has passed the test, the test result is “Calibration OK”, otherwise the result is “Calibration Not OK”.

If the calibration failed, please execute calibration again. If it still failed, contact Dirui customer service department or the distributor.

4.2 Quality Control Liquid Test

In order to make sure the correctness of the test result, the positive and negative quality control liquor manufactured by Dirui Industrial Co., Ltd. should be often used to test the urine analyzer and the reagent strip.

The quality control monitoring might be conducted under the following conditions:

- (1) At the time before daily test.
- (2) At the time when replace another tube of strips.
- (3) At the time when the operator is changed.
- (4) At the time when there is query in the test result.

Test the urine analysis quality control liquor in the same process of testing the urine sample.

Then compare the result with the reference value in the control liquor manual.

Test Method:

In the main menu (Figure 3-2-2) select “QC liquid”. Put the strip that dipped by QC on the strip holder and press “Enter” as follows:

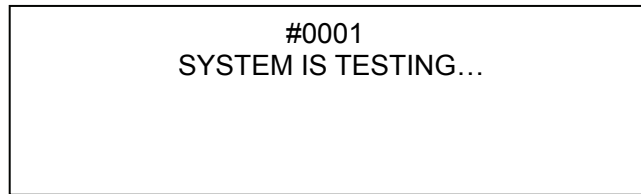


Figure 4-2-1

After the testing, the QC result will be displayed. Refer to the QC result in the manual.

If QC failed, please use control liquid of another lot number and execute QC testing again. If it still failed, contact Dirui customer service department or the distributor.

Chapter 5 Method of Operation



- The urine sample may have potential infectivity, please wear protective gloves when testing, cleaning, or doing maintenances to the analyzer.
- Please dispose of the urine sample and the abandoned strip according to the local lab regulation.

This chapter introduces the method that the urine analyzer conducts the conventional urine analysis. Before the test, please carefully read the “Chapter 3 Functions and Setup of the H Series Urine Analyzer(Model:H-100)”.



- When the analyzer did not pass the self-testing, the screen displays the error information code.
- Do not place the analyzer in the place where there is direct projection of the sunshine.
- Please check the type of the strip before test, in order to avoid the mistaken test result caused by the mistaken strip type.
- Do not use the strip which has passed the expiration date or deterioration.

5.1 Checkup the Strip Table

Make sure the strip holder and the white benchmark is clean and without any foreign matter. The strip holder, urine collector and the white benchmark can be cleaned according to the relative content in the “Chapter 6 Cleaning and Maintenance”.

5.2 Startup the Analyzer

After the analyzer is installed, turn on the power switch, the system is conducting self-testing. The screen display as follows and the strip table moves out.

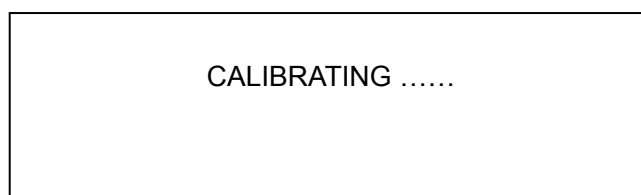


Figure 5-2-1

After the self-check, the screen displays as followed:

URINE ANALYZER	10-01-01
#0001	12:00:00
VERSION	0118
MENU	START

Figure 5-2-2

5.3 Operation Method

The test includes the fast test mode and the slow mode test.

5.3.1 Fast Mode

The test can be conducted continuously, the test rate for each strip is 30 seconds (the first strip is 60 seconds), the operation methods are as follows:

(1) Press the key “Start” around 2 seconds in main screen, the analyzer make a tone for dipping the strip into the urine sample. On hearing the warning tone, dip the reagent area of the strip into the urine sample which is fresh, fully mixed and not centrifugal, then place the strip on the center of the strip holder, and push it forward until the strip touch the end of the strip holder (this one is marked as the first strip).

(2) On hearing next warning tone, dip another strip into the next sample, and then move out the strip quickly and

put it on the absorbent paper to wait to be tested (this one is marked as the second strip).

(3)On hearing the warning tone for the third time, the fist strip has been tested and its test result is printed out, the strip table moves out; dip another strip and put it on the absorbent paper, remove the first strip from the strip holder and put the second strip on the holder to conduct test.

(4)When hearing the warning tone, repeat the operation in 3).



If want to stop the test, please take the following measures:

- Press the key “Enter” before the strip table comes out.
- Remove the strip from the strip holder.

5.3.2 Slow Mode

The test rate for each strip is 60 seconds, the operation methods are as follows:

Under the main screen, press the key “Start” for 2 seconds, when hearing the warning tone, completely dip the reagent part of the strip into the urine sample which is fresh, fully mixed and uncentrifuged, and then take the strip out immediately. Then put it on the center of the strip holder and push the strip forward until it reaches the strip holder top(for the first strip). After 40 seconds, the analyzer starts testing. When the test completes, print out the test result and the strip table moves out. The analyzer returns to the main interface. Click the “Start” key again to test next sample.



- The tested strip must be placed in the right place before the strip table moves.
- If no strip is placed on the strip holder, the analyzer will automatically stop testing. The display will show information as in the following picture. The strip table moves out. Touch the key “Start” to continue the test.

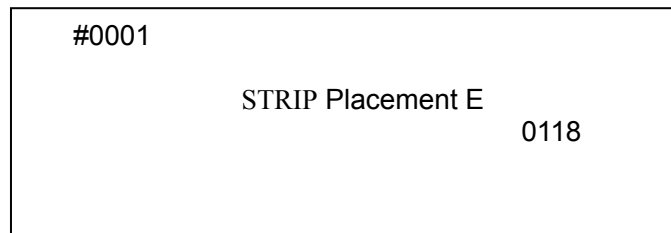


Figure 5-3-1

- During the test process, the keyboard is ineffective, press any key will get no response.
- During the test process, do not hit the strip table.

Chapter 6 Cleaning and Maintenance



- **Don't spill water, urine samples and other liquid over the mechanical parts or electrical parts of the analyzer, so as to avoid damaging it.**
- **While working, the operator needs to take protective action, wearing protective gloves and putting on working clothes to avoid being infected by contaminated liquid. In case of contact with contaminated liquid, wash with water and perform sterilization immediately.**
- **If the accessories used by the analyzer is not manufactured or recommended by the manufacturer, or the analyzer is not used in the manner specified by the manufacturer, the protection offered by the analyzer may be weakened.**
- **During cleaning and maintenance, failure of spare parts holding liquid may lead to danger.**

6.1 Daily Cleaning

To keep the analyzer clean and tidy, the surface of the analyzer should be cleaned regularly. Wipe it with moistened cloth or gauze. If necessary, wipe with soft dry cloth or soft cloth with little 75% alcohol; but do not use any organic solvent, so as not to damage the shell. The LCD can be wiped by soft and no abrasion cloth. In order to make the analyzer work normally and provide correct test result, the strip holder must keep clean.

The methods of cleaning the strip holder are as follows:

Draw out the strip holder, urine collector from the strip table. After wash it with water, wipe the strip with soft cloth or absorbent paper.

Check whether the white benchmark is clean or not, if there is dust or besmirsch, wipe them clean by soft cloth.

During the cleaning process, the operator must pay attention to:

- (1) If the hazardous substance leaks on the surface of the equipment or enters the equipment, proper disinfection should be taken. (wipe with soft cloth with little 75% alcohol for disinfection)
- (2) It is not possible to use a cleaning agent or disinfectant that causes a hazard in the chemical reaction with the material that the equipment parts or equipment contains.
- (3) Consult the manufacturer or its agent if there is any doubt as to the compatibility of the disinfectant or cleaning agent with the material that the equipment parts or equipment contains.



- **Do not clean the analyzer when the power is turned on.**
- **Do not use any organic solvent such as petrol, thinner lacquer, benzene compounds and things that may erode the analyzer to wipe it.**
- **Do not clean the LCD with water.**
- **Do not use anything that may scrap the strip holder and white benchmark to wipe the strip holder.**
- **Do not use any solvent to clean the white benchmark.**
- **If there is apparent scrape on the white benchmark, contact with the supplier.**

6.2 Periodical Cleaning

If there is accumulated dirt on the strip holder, urine collector and the waste liquid plate, cleaning can be done according to the following procedures:

- (1) Prepare a little 0.1mol/L NaOH solution.
- (2) Draw the strip holder from the analyzer gently. Wipe the strip holder thoroughly by the cotton bar dipped with 0.1 mol/L NaOH solution.
- (3) Clean the remains of the NaOH solution on the strip holder by water.
- (4) Wipe and dry the strip holder and white benchmark with soft cloth.
- (5) Install the strip holder and urine collector.
- (6) Restart the analyzer and conduct self-check.



Do not touch the white benchmark with the NaOH solution. Daily cleaning is recommended.

6.3 Disinfection

Because the strip holder, urine collector and the waste liquid plate contact with the urine sample, it should be disinfected.

The following solutions can be used to conduct disinfection.

(1) 2% glutaric dialdehyde solution

(2) 5% javel water

The steps are as follows:

(1) Pouring disinfects liquid of 10cm into an appropriate container.

(2) Immerge the strip holder, urine collector and the waste liquid plate into the disinfect liquid, and make sure the white benchmark does not contact the liquid.

(3) Immerge the strip holder for 10 minutes.

(4) Wash cleaning the disinfect liquid that remain on the strip holder after removing it from the disinfect liquid.

(5) Wipe and dry the strip holder and the white benchmark with a soft cloth.

(6) Reinstall the strip holder and urine collector.

(7) Restart the analyzer and conduct self-testing.



The white benchmark does not contact the liquid.

6.4 Maintenance before stopping use of analyzer

Before stopping use due to repair or treatment, the following should be performed for the analyzer:

(1) Remove waste strips from the strip holder.

(2) Clean and sterilize the strip holder, urine collector, and waste tray. For detailed operation, refer to 6.2 and 6.3.

(3) Wipe the strip table with a wet cloth or soft absorbent paper.

6.5 Waste Treatment

The analyzer while working will produce used disposable test tubes, waste strips, waste samples, and other waste materials.

According to the state laws and regulations, wastes must be sterilized:

(1) The used disposable test tubes and waste strips should be stored in the container with the mark of pollutant, and then autoclaved or incinerated.

(2) The remaining urine samples may contain infectious substances such as bacteria and viruses. To avoid contamination of the environment, proceed as follows: put 100mL of 10g/L peroxyacetic acid or an appropriate amount of bleaching powder in a large container (such as plastic bucket, ceramic pool, etc.) and then pour the remaining samples and wastes into the container. Before discharge, they should be mixed and sterilized for more than 1 hour.



The risk of biological and chemical contamination of the waste discharging from the analyzer should be handled as required.

6.6 Disposal of Scraped Analyzer

After the expiry date, the analyzer cannot be discarded at random and can be disposed of by the manufacturer.

Chapter 7 Transportation and Storage

7.1 Transportation Requirement

The analyzer should be transported according to the contract. Avoid violent shaking and pressing during transportation. Gently handle it when loading and unloading.

7.2 Storage Requirement

The analyzer should be stored in the room where there is no chemical drugs, corrosive gas, and has a good ventilation and sanitation condition; the ambient temperature $-40^{\circ}\text{C}\sim 50^{\circ}\text{C}$; and the relative humidity is no more than 80%.

Appendix A Manufacturer's Warranty

Dear consumer:

Thank you for purchasing the H-100 urine analyzer. Our company provides the following services for you:

- (1) Technical consultations are provided at any time.
- (2) Maintenance free of charge within a year from the day you purchase the analyzer.
- (3) Maintenance will be charged in the following conditions:
 - a) Product which has passed the date for free maintenance.
 - b) Damage caused by accidental factor or improper use.
 - c) Damage caused by the operation that not according to the instruction manual.
 - d) Damage caused by your own repair that without our company's permission.

With the development of technology, DIRUI will supply the service of analyzer update.

If you need any technological service, please reach us according to the following address:

For technique support, contact the following address and telephone:

Register/Manufacturer: DIRUI INDUSTRIAL CO., LTD.

Register/ Manufacturer Address:

95 Yunhe Street, New & High Tech. Development Zone, Changchun, Jilin 130012, the People's Republic of China

Headquarter Address:

3333 Yiju Street, New & High Tech. Development Zone Changchun, Jilin 130103, the People's Republic of China

Factory Address:

95 Yunhe Street, New & High Tech. Development Zone Changchun, Jilin 130012, the People's Republic of China

Tel: 400 811 6695 400 811 6605

Website: <http://www.dirui.com.cn>

E-mail: dirui@dirui.com.cn

For complaint: +86(431)81935326 85177245

Fax: +86(431)85173354

After-Sale Service From: DIRUI INDUSTRIAL CO., LTD.

International customer service hotline: +86 400 808 7597

International customer service e-mail: service@dirui.com.cn

Domestic customer service hotline: 400 811 6695 400 811 6605

Domestic fax: +86(431)85100405

Domestic customer service e-mail: service.ch@dirui.com.cn

Appendix B Interface for Communicating with Computer

H-100 Urine analyzer links with computer through RS-232 standard serial port. The communication agreements are as follows:

Baud rate: 9600 or 1200

Data bit: 8 bits

Stop bit: 1 bit

Verification: none

Hardware held hands: none

Start character: 02H

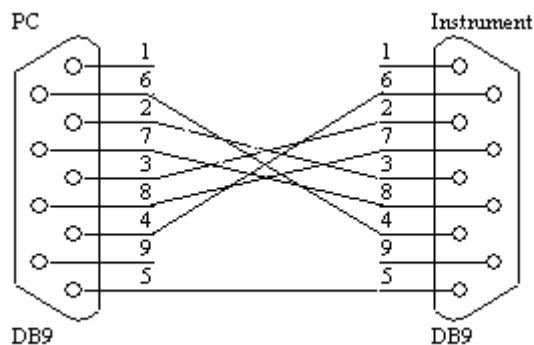
2byte space: 20H

3byte space: ABH

Line-change character: 0DH0AH

Ending character: 03H

Connection between Urine analyzer and computer:



International Unit, conventional, plus system transmission format(Bar Code reader is Off)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
STX	CR	LF																					
SP	D	a	t	e	:	x	x	x	x	-	x	x	-	x	x	SP	x	x	:	x	x	CR	LF
SP	N	o	.	SP	x	x	x	x	CR	LF													
SP	U	B	G	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	B	I	L	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	K	E	T	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	C	R	E	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	B	L	D	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	P	R	O	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	A	L	B	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	N	I	T	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	L	E	U	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	G	L	U	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	S	G	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	P	H	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	V	C	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	C	a	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	A	:	C	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	R	T	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
ETX																							

International Unit, conventional, plus system transmission format(Bar Code reader is ON):

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
STX	CR	LF																					
SP	D	a	t	e	:	x	x	x	x	-	x	x	-	x	x	SP	x	x	:	x	x	CR	LF
SP	N	o	.	SP	x	x	x	x	CR	LF													
SP	I	D	:	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF
SP	U	B	G	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	B	I	L	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	K	E	T	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	C	R	E	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	B	L	D	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	P	R	O	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	A	L	B	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	N	I	T	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	L	E	U	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	G	L	U	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	S	G	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	P	H	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	V	C	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	C	a	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	A	:	C	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	R	T	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
ETX																							

STX=0X02 CR=0X0D LF=0X0A SP=0X20
 SP1=0XAB ETX=0X03 -=0X2D X= Any ASCII character

Appendix C Output Value

Item	Conventional unit			International unit			Plus system unit
	Plus -ON		Plus -OFF	Plus -ON		Plus -OFF	
UBG	Normal	0.2 mg/dL	0.2 mg/dL	Normal	3.4μmol/L	3.4μmol/L	Normal
	Normal	1 mg/dL	1 mg/dL	Normal	17 μmol/L	17 μmol/L	Normal
	1+	2 mg/dL	2 mg/dL	1+	34 μmol/L	34 μmol/L	1+
	2+	4 mg/dL	4 mg/dL	2+	68 μmol/L	68 μmol/L	2+
	3+	>=8 mg/dL	>=8 mg/dL	3+	>=135 μmol/L	>=135 μmol/L	3+
BIL	Neg		Neg	Neg		Neg	Neg
	1+	1 mg/dL	1 mg/dL	1+	17 μmol/L	17 μmol/L	1+
	2+	3 mg/dL	3 mg/dL	2+	51 μmol/L	51 μmol/L	2+
	3+	>=6 mg/dL	>=6 mg/dL	3+	>=103 μmol/L	>=103 μmol/L	3+
KET	Neg		Neg	Neg		Neg	Neg
	+-	5 mg/dL	5 mg/dL	+-	0.5 mmol/L	0.5 mmol/L	+-
	1+	15 mg/dL	15 mg/dL	1+	1.5 mmol/L	1.5 mmol/L	1+
	2+	40 mg/dL	40 mg/dL	2+	3.9 mmol/L	3.9 mmol/L	2+
	3+	>=80 mg/dL	>=80 mg/dL	3+	>=7.8 mmol/L	>=7.8 mmol/L	3+
CRE		10 mg/dL	10 mg/dL		0.9 mmol/L	0.9 mmol/L	0.9 mmol/L
		50 mg/dL	50 mg/dL		4.4 mmol/L	4.4 mmol/L	4.4 mmol/L
		100 mg/dL	100 mg/dL		8.8 mmol/L	8.8 mmol/L	8.8 mmol/L
		200 mg/dL	200 mg/dL		17.7 mmol/L	17.7 mmol/L	17.7 mmol/L
		300 mg/dL	300 mg/dL		26.5 mmol/L	26.5 mmol/L	26.5 mmol/L
BLD	Neg		Neg	Neg		Neg	Neg
	+-	Ca10 Ery/μL	Ca10 Ery/μL	+-	Ca10 Ery/μL	Ca10 Ery/μL	+-
	1+	Ca25 Ery/μL	Ca25 Ery/μL	1+	Ca25 Ery/μL	Ca25 Ery/μL	1+
	2+	Ca80 Ery/μL	Ca80 Ery/μL	2+	Ca80 Ery/μL	Ca80 Ery/μL	2+
	3+	>= Ca200 Ery/μL	>= Ca200 Ery/μL	3+	>= Ca200 Ery/μL	>= Ca200 Ery/μL	3+
PRO	Neg		Neg	Neg		Neg	Neg
	Trace	Trace	Trace	Trace	Trace	Trace	Trace
	1+	30 mg/dL	30 mg/dL	1+	0.3 g/L	0.3 g/L	1+
	2+	100 mg/dL	100 mg/dL	2+	1.0 g/L	1.0 g/L	2+
	3+	>=300 mg/dL	>=300 mg/dL	3+	>=3.0 g/L	>=3.0 g/L	3+
MALB		10 mg/L	10 mg/L		10 mg/L	10 mg/L	10 mg/L
		30 mg/L	30 mg/L		30 mg/L	30 mg/L	30 mg/L
		80 mg/L	80 mg/L		80 mg/L	80 mg/L	80 mg/L
		150 mg/L	150 mg/L		150 mg/L	150 mg/L	150 mg/L
NIT		Neg	Neg		Neg	Neg	Neg
		Pos	Pos		Pos	Pos	Pos
LEU	Neg		Neg	Neg		Neg	Neg
	+-	Ca15 Leu/μL	Ca15 Leu/μL	+-	Ca15 Leu/μL	Ca15 Leu/μL	+-
	1+	Ca70 Leu/μL	Ca70 Leu/μL	1+	Ca70 Leu/μL	Ca70 Leu/μL	1+
	2+	Ca125 Leu/μL	Ca125 Leu/μL	2+	Ca125 Leu/μL	Ca125 Leu/μL	2+
	3+	>=Ca500 Leu/μL	>=Ca500 Leu/μL	3+	>=Ca500 Leu/μL	>=Ca500 Leu/μL	3+

Item	Conventional unit		International unit		Plus system unit
	Plus -ON	Plus -OFF	Plus -ON	Plus -OFF	
GLU	Neg	Neg	Neg	Neg	Neg
	+- 50 mg/dL	50 mg/dL	+- 2.8mmol/L	2.8mmol/L	+-
	1+ 100 mg/dL	100 mg/dL	1+ 5.6 mmol/L	5.6 mmol/L	1+
	2+ 250 mg/dL	250 mg/dL	2+ 14 mmol/L	14 mmol/L	2+
	3+ 500 mg/dL	500 mg/dL	3+ 28 mmol/L	28 mmol/L	3+
	4+ >=1000 mg/dL	>=1000 mg/dL	4+ >=56 mmol/L	>=56 mmol/L	4+
SG	<=1.005	<=1.005	<=1.005	<=1.005	<=1.005
	1.010	1.010	1.010	1.010	1.010
	1.015	1.015	1.015	1.015	1.015
	1.020	1.020	1.020	1.020	1.020
	1.025	1.025	1.025	1.025	1.025
	>=1.030	>=1.030	>=1.030	>=1.030	>=1.030
pH	<=5.0	<=5.0	<=5.0	<=5.0	<=5.0
	5.5	5.5	5.5	5.5	5.5
	6.0	6.0	6.0	6.0	6.0
	6.5	6.5	6.5	6.5	6.5
	7.0	7.0	7.0	7.0	7.0
	7.5	7.5	7.5	7.5	7.5
	8.0	8.0	8.0	8.0	8.0
	8.5	8.5	8.5	8.5	8.5
VC	>=9.0	>=9.0	>=9.0	>=9.0	>=9.0
	0 mg/dL	0 mg/dL	0 mmol/L	0 mmol/L	0 mmol/L
	10 mg/dL	10 mg/dL	0.6 mmol/L	0.6 mmol/L	0.6 mmol/L
	25 mg/dL	25 mg/dL	1.4 mmol/L	1.4 mmol/L	1.4 mmol/L
	50 mg/dL	50 mg/dL	2.8 mmol/L	2.8 mmol/L	2.8 mmol/L
	>=100 mg/dL	>=100 mg/dL	>=5.7 mmol/L	>=5.7 mmol/L	>=5.7 mmol/L
Ca	<=4mg/dL	<=4mg/dL	<=1.0 mmol/L	<=1.0 mmol/L	<=1.0 mol/L
	10mg/dL	10mg/dL	2.5 mmol/L	2.5 mmol/L	2.5 mmol/L
	20mg/dL	20mg/dL	5.0 mmol/L	5.0 mmol/L	5.0 mmol/L
	30mg/dL	30mg/dL	7.5 mmol/L	7.5 mmol/L	7.5 mmol/L
	>=40 mg/dL	>=40 mg/dL	>=10.0l mmol/L	>=10.0 mmol/L	>=10.0 mmol/L
A:C	<30mg/g	<30mg/g	<3.4mg/mmol	<3.4mg/mmol	<3.4mg/mmol
	Normal	Normal	Normal	Normal	Normal
	30-300 mg/g	30-300 mg/g	3.4-33.9 mg/mmol	3.4-33.9 mg/mmol	3.4-33.9 mg/mmol
	Abnormal	Abnormal	Abnormal	Abnormal	Abnormal
	>300 mg/g	>300 mg/g	>33.9 mg/mmol	>33.9 mg/mmol	>33.9 mg/mmol
	High abnormal	High abnormal	High abnormal	High abnormal	High abnormal

Appendix D Malfunction Information List

No.	Message	Cause	Solutions
1	No display on the screen	Power supply does not switch on CPU trouble	(1)Check if the power supply works (2)If method 1 cannot solve the problem, please contact with supplier
2	Strip table moving trouble	Engine moving suffocated	(1)Check if there is fraise in front of strip table (2)Check if there is fraise in mechanical part (3)Press “Start” to retest
3	Clock trouble	Clock chip trouble or no electricity of the battery	Change a new clock chip and battery
4	Screen shows “No strip”	No strip in the strip holder	(1)Place reagent strip (2)Press “Start” to retest
5	Screen shows “Strip mistake”	(1)Strip placing incorrect (2)Strip does not dip sample totally	(1)Take out some new strips and place in the right position (2)Immerge strips into sample totally (3)Press “Start” to retest
6	White benchmark trouble	White benchmark dirty	(1)Wipe the white benchmark (2)Restart the analyzer to self-testing (3)If methods 1 and 2 do not work, contact with supplier
7	Ambient light abnormal	Analyzer is exposed in sunlight	(1)Keep the analyzer away from direct sunlight (2)Restart the analyzer
8	Printing paper missing	No printing paper installed	Set a roll of printing paper
9	Test result of the calibration strip is “Calibration Not OK”	White benchmark dirty LED aging Calibration strip dirty	(1)Wipe white benchmark (2)Replace strip holder (3)Replace calibration strip
10	Memory is full	Memory has reached 5000 pieces	Clear the memory
11	103,107	525nm cable trouble	Please contact with supplier
12	102,106	572nm cable trouble	
13	101,105	610nm cable trouble	
14	100,104	660nm cable trouble	

Note:

No other notice is to be given if the manual has been changed for it is only used to provide with info.

Appendix E Performance Indexes

E.1 Analyzer Repeatability

Analyzer reflectance test result coefficient of variation (CV, %) ≤ 1.0 .

E.2 Applied Urinalysis Strips Accuracy

The difference between the test result and the labeled value of the corresponding reference solution should not exceed one order of magnitude in the same direction. Opposite direction difference is not allowed. No negative result for positive reference solution and no positive result for negative reference solution.

E.3 Analyzer Stability

Within 8 hours after power on, reflectance test result coefficient of variation (CV, %) ≤ 1.0 .

Appendix F Accessories List

The accessories list includes accessories, fittings, and consumables.

Name	Position	Replacement Cycle	Replacement Method	Remarks
Strip Holder	Mechanical Unit	5 years	2.3.2	
Urine Collector	Mechanical Unit	2 years	2.3.2	
Strip	Strip Holder	Timely		
Thermal Printing Paper	Internal Printer	Timely	2.3.1	
Calibration Strip	Strip Holder	Timely		



www.dirui.com.cn

DIRUI INDUSTRIAL CO.,LTD.

Address for headquarters:

3333 Yiju Street, New&High Tech. Development Zone Changchun, Jilin 130103, P.R.China

Address for factory:

95 Yunhe Street, New&High Tech. Development Zone Changchun, Jilin 130012, P.R.China

Website: <http://www.dirui.com.cn>

E-mail: dirui@dirui.com.cn **Fax:** +86(431)85173354

Telephone for complaint: +86(431)81935326 85177245

International customer service hotline: +86 400 808 7597

International customer service e-mail: service@dirui.com.cn

Domestic customer service hotline: 4008116695 4008116605

Domestic fax: +86(431)85100405

Domestic customer service e-mail: service.ch@dirui.com.cn



Certified to
ISO 9001:2008 and
ISO 13485:2003



EMERGO EUROPE

Prinsessegracht 20
2514 AP The Hague
The Netherlands