

Content

Chapter 1 General Introduction of H-100 Urine Analyzer	1
1.1 General Description and Intended Use	1
1.2 Technical Specifications	1
1.3 Testing Principle	2
1.4 Structure of the Instrument	2
1.5 Biological Hazard Symbol.....	3
1.6 Introduction of the Keyboard	3
Chapter 2 Installation of the H-100 Urine Analyzer.....	4
2.1 Environment Requirements.....	4
2.2 Open Carton	4
2.3 Installation	5
2.3.1 Install printing paper (Figure 2-2).....	5
2.3.2 Install the strip table and collect slot	5
2.3.3 Connect with computer.....	5
2.3.4 Install external stylus printer.....	6
2.3.5 Install power wire.....	6
2.3.6 Connect with bar code reader	6
Chapter 3 Functions and Setup of H-100 Urine Analyzer	7
3.1 Function Block Diagram	7
3.2 Setup	8
3.2.1 Set Sequence Number.....	8
3.2.2 ID Edit.....	8
3.2.3 Data recall	9
3.2.4 Calibration and QC liquid.....	10
3.2.5 Set system	10
3.3 Test Strip Security Barcode Instruction	15
Chapter 4 Quality Control Monitoring	17
4.1 Calibration Strip Test.....	17
4.2 Quality Control Liquid Test.....	17
Chapter 5 Method of Operation.....	19
5.1 Checkup the Strip Table	19
5.2 Startup the Instrument	19
5.3 Operation Method	20
Chapter 6 Cleaning and Maintenance.....	21
6.1 Daily Cleaning	21
6.2 Periodical Cleaning	21
6.3 Disinfection	21
Chapter 7 Transportation and Storage	23
7.1 Transportation Requirement.....	23
7.2 Storage Requirement	23
Appendix A	24
Appendix B	25

Appendix C28
Appendix D30

Chapter 1 General Introduction of H-100 Urine Analyzer

1.1 General Description and Intended Use

DIRUI H-100 urine analyzer is a kind of semi-automatic opto-electronic color comparator that can be used together with the H8、H10、H11-MA(N)、H11、H12、H13 urine analysis reagent strip manufactured by Dirui Industrial Co., Ltd. It can provide a qualitative or semi-quantitative result for Urobilinogen, Bilirubin, Ketone, Creatinine, Blood, Protein, Micro-albumin, Nitrite, Leucocytes, Glucose, Specific gravity, pH and Vitamin C of the urine sample according to the color change caused by the interaction between the reagent areas and the biochemical components in urine.

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 up to 13 kinds of biochemical components in urine, 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.

H-100 urine analyzer is professional used in vitro-diagnostic device (IVD).

1.2 Technical Specifications

Light Wavelength	525nm 572nm 610nm 660nm
Test Items	Urobilinogen(UBG) Bilirubin (BIL) Ketone(KET) Blood(BLD) Protein(PRO) Nitrite(NIT) Leucocytes(LEU) Glucose(GLU) Specific Gravity(SG) pH(pH) Vitamin C(VC) Microalbumin (MALB) Creatinine (CRE)
Test Speed	Fast mode: 120 specimens/hour Slow mode:60 specimens/hour
Data Memory	1,000 patient results, 50 quality control records
Language	English, Russian, Polish, Italian, Spanish, Portuguese, Turkish, German, French
Environment Requirements	Required temperature range is 15℃-35℃, optimal temperature 20℃-25℃ relative humidity ≤75%
Communication Interface	RS-232 serial interface, parallel printing interface
Bar Code	connecting with bar code reader
Baud Rate	9600 bps, 1200 bps
Power Supply	AC 100V~240V, 50/60Hz
Fuse	250V 1A
Power	40VA
Net Weight	3.60kg
Dimensions	376mm × 316mm ×170mm
Printer	Inner thermal printer, outer stylus printer is available
Adopted Reagent Strip	H8、H10、H11-MA(N)、H11、H12、H13 strips

NOTE:

Urine Analyzer H-100 can connect with barcode reader which can identify the code of EAN-13,EAN-8,Code-39,Code-128.

1.3 Testing Principle

H-100 urine analyzer adopts the principle of opto-electronic color comparison to test the quantity of biochemical component according to the color change caused by the urinalysis strips react with the biochemical components in urine.

The instrument uses four kinds of monochromatic light to scan the reagent areas one after another, and the scanning system converts the optical signal to electric signal. After treatment, the reflection rate of the reagent area can be calculated according to the strength of the electric signal. The amount of the biochemical component in the urine sample can be calculated according to the reflective rate. Optics system principle is as follows.

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

In the principle:

R ----- The reflection rate.

T_r ----- The reflected intensity of the blocks on the strips under the reference light.

C_r ----- The reflected intensity of the blank block under the reference light.

T_m ----- The reflected intensity of the blocks on the strips under the predetermined light.

C_m -----The reflected intensity of the blank block under the predetermined light.

1.4 Structure of the Instrument

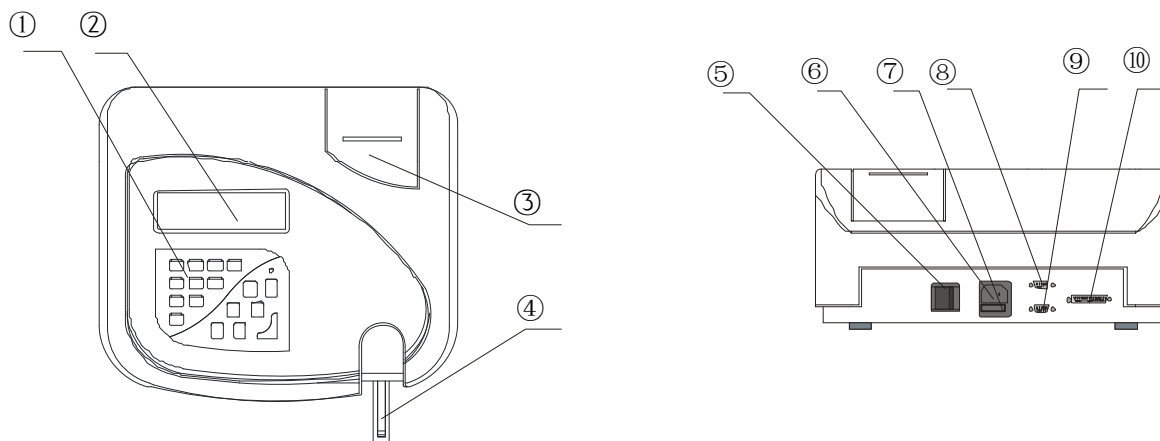


Figure 1-1

- | | | | | |
|-----------------------------|------------------------------|---------------------------|---------------|----------------|
| ① Keyboard | ② LCD | ③ Printer cover | ④ Strip table | ⑤ power switch |
| ⑥ Power wire socket | ⑦ Fuse | ⑧ Communication interface | | |
| ⑨ Bar code reader interface | ⑩ External printer interface | | | |

1.5 Biological Hazard Symbol



The Biological Hazard Symbol can be seen in the figure 1-2.

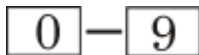
- The urine sample may have potential infectivity, protective measures should be taken when testing, cleaning or doing maintenance to the instrument.
- Please dispose the urine sample and the waste strips according to the local lab regulation.



Biological Hazard Symbol

Figure 1-2

1.6 Introduction of the Keyboard



These number keys are used to enter the corresponding number.

(Number keys)



(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.



(Line)

Touching this key will make the printer to go ahead, leaving two lines blank.



(Print)

Under the date recall status, touching this key will print out the test data on the current screen.



(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).

Chapter 2 Installation of the H-100 Urine Analyzer

2.1 Environment Requirements

Please put the instrument on a stable and flat table-board, do not put it together with vibrative source such as the centrifuge.

Please do not put the instrument in the place where it can be affected by chemical staffs, corrosive gas or strong electromagnetic interference.

Please don't put it in insulation, high temperature and high humidity places.

The temperature range for operating the instrument is 15℃~35℃, the optimal temperature range is 20℃~25℃, the humidity range for operating the instrument is ≤75%.

2.2 Open Carton

Please take out the H-100 Urine Analyzer and its accessories, and check them with encasement listing. Observe if the package carton or analyzer is damaged, if there is damage in the analyzer, please contact with supplier immediately.

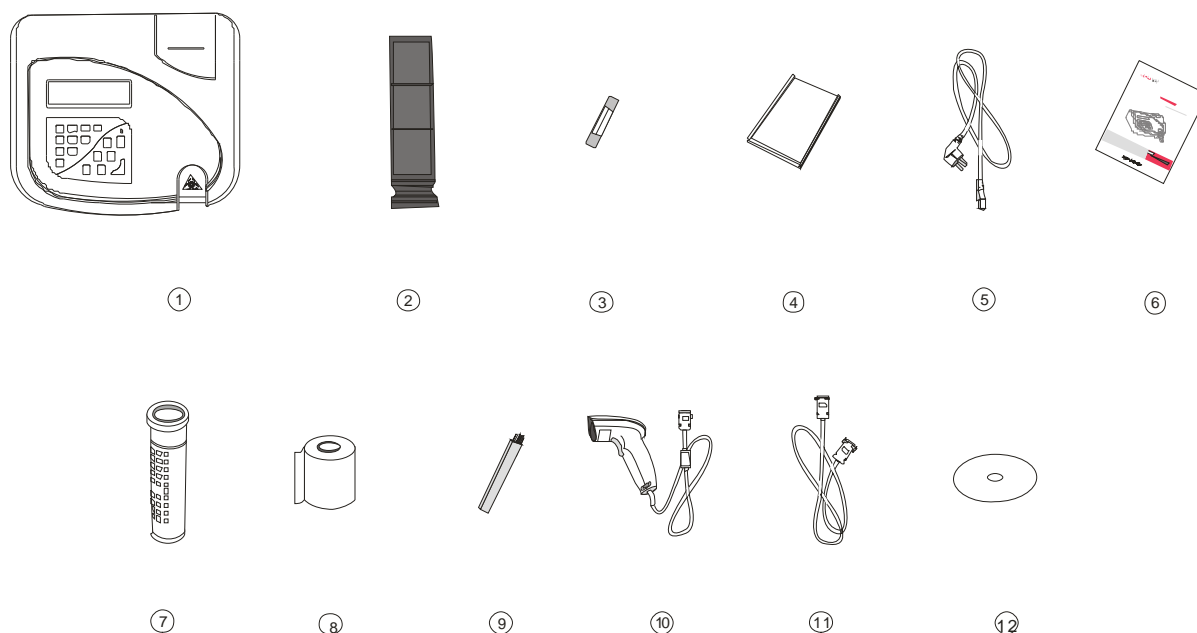


Figure 2-1

- ①H-100 Urine analyzer ②Waste liquid plate ③Fuse
 ④Calibration strip box (Including two calibration strips) ⑤Power wire ⑥Operation manual
 ⑦Reagent strip sample ⑧Printing paper ⑨Brush ⑩Barcode reader(Accessary) ⑪Communicate cable ⑫CD

2.3 Installation

2.3.1 Install printing paper (Figure 2-2)

- a) Obtain a roll of thermal printer paper with width of 57mm and diameter less than 50mm.
- b) Remove the cover of the printer.
- c) 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 instrument.
- d) Witch out the handle and feed the paper roll to the printer perpendicularly. Pull the paper up and down and press down the handle.
- e) 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 table and collect slot

According to the figure 2-3, put the testing slot into the collect slot, put the collect slot into the strip table.

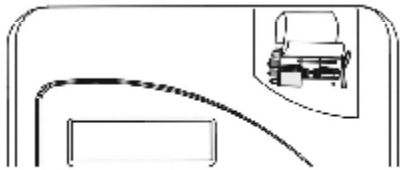
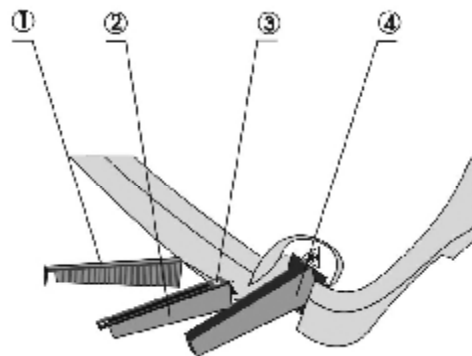


Figure 2-2



① Strip seat ②Collect slot ③White bench-mark ④Stage

Figure 2-3

2.3.3 Connect with computer

H-100 urine analyzer can be connected with the computer through the RS-232 serial port. Insert one end of the communicate cable into the serial port at the back of the instrument (figure 2-4) and the other end into the serial port of the computer.

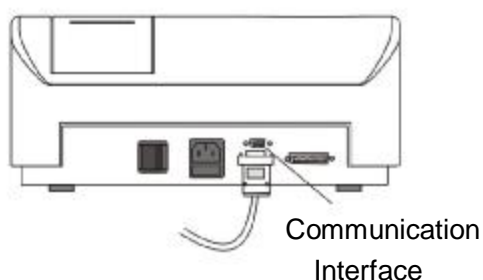


Figure 2-4

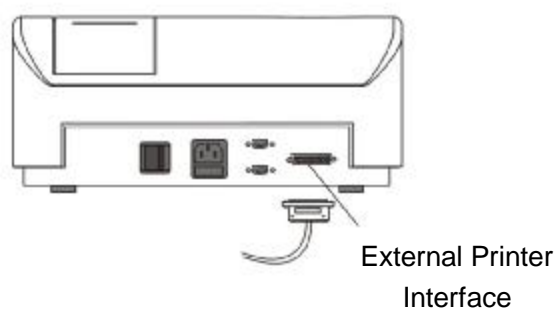


Figure 2-5

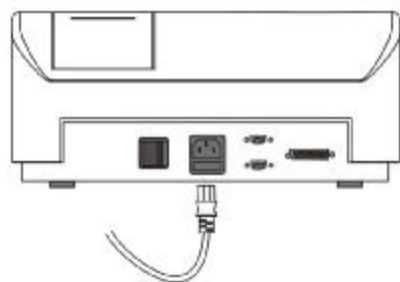


Figure 2-6

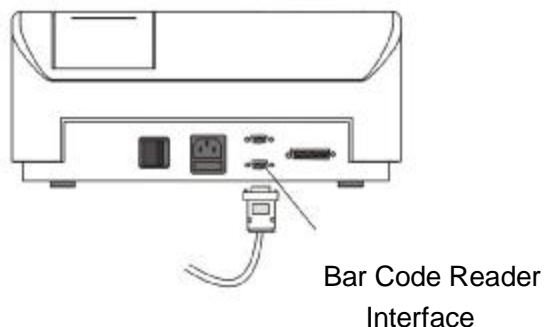


Figure 2-7

2.3.4 Install external stylus printer

Connect one end of the printer wire to the printer, the other end to the serial port of the outer printer outside the instrument (figure 2-5).

Note:

H-100 can connect to printers such as EPSON LQ1600K, EPSON LQ300K+.

2.3.5 Install power wire

Connect the input terminal of the power wire with the instrument; Insert the entry terminal of the power wire into the power socket (figure 2-6).

2.3.6 Connect with bar code reader

Urine analyzer can connect with bar code reader and receive the bar code scanned by bar code reader. Take out the barcode reader from the box, connect the data cable of bar code reader, as shown in Figure 2-8, and connect the other end of the data cable (RS-232 port) with the barcode reader port of urine analyzer(Figure 2-7).



Figure 2-8

Chapter 3 Functions and Setup of H-100 Urine Analyzer

3.1 Function Block Diagram

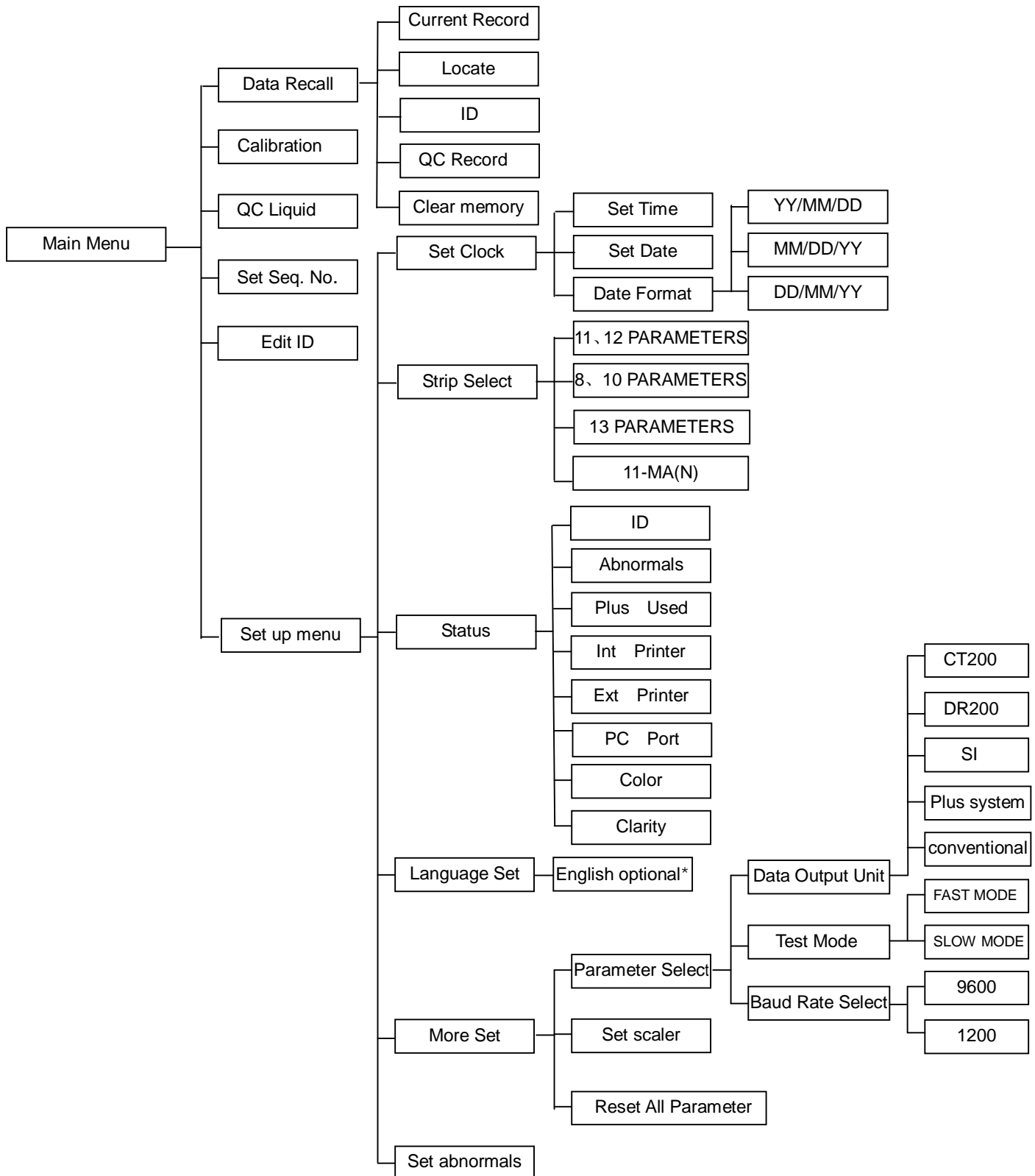


Figure 3-1

3.2 Setup

3.2.1 Set Sequence Number

URINE ANALYZER	10-01-01
#0001	12:00:00
VERSION 8.00	0118
MENU	START

Figure 3-2

In the main screen (Figure 3-2) 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 3-3

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

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 3-4

The sequence number can be any numerical value between 0001-1000, 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 3-3 and press “Enter” to confirm. In the ID interface, the display as follows:

Input ID:

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

Figure 3-5

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 3-3). Enter the next testing, the ID input will display in the printout.

Note: the input limit is 30 ID number before testing.

3.2.3 Data recall

The instrument can store 1000 pieces of records, each record includes data as time, sequence number, test result and so on. After each test, the instrument stores the test result automatically. If the storage records exceeds 1000, the instrument will display “Memory full, please clear the records !”. Test can not be conducted if the records are not cleared.

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

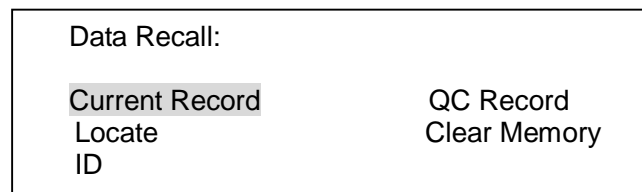


Figure 3-6

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:

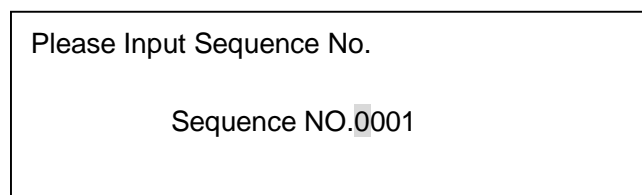


Figure 3-7

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 instrument, the screen will display the record. If there is no such record, the screen will display “Record Not Found!” (Figure 3-8).

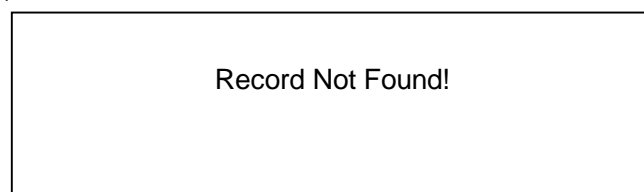


Figure 3-8

Press the key “Menu” to return to the figure 3-6.

3.2.3.3 ID record

Choose “ID” in figure3-6 and press “Enter” to confirm. The display as follows:

Input ID:

ABCDEFGHIJKLMNOPQRSTUVWXYZ

abcdefghijklmnopqrstuvwxyz

Figure 3-9

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

Analyzer could store 50 pieces QC records. Choose “QC Record” in figure 3-6 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 3-6 and press the key “Enter”, the screen displays as follows:

Clear Memory?

No

Yes

Figure 3-10

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

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

3.2.5 Set system

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

SET UP INSTRUMENT

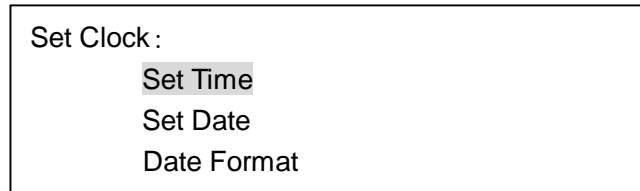
Set Clock	Language Set
Strip Select	Set abnormalities
Status	More Set

Figure 3-11

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 3-11, press the key “Enter” to confirm, the screen shows as follows:



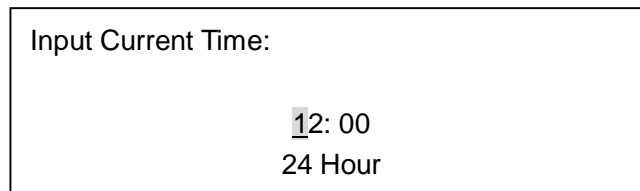
```

Set Clock :
  Set Time
  Set Date
  Date Format
    
```

Figure 3-12

● Set time

Select “Set Time” in figure 3-12, press the key “Enter” to confirm, the screen shows as follows:



```

Input Current Time:

  12: 00
  24 Hour
    
```

Figure 3-13

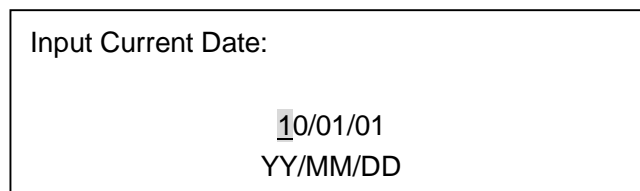
The cursor stop at the position of the first number, press the corresponding number key to enter the current time, press “Menu” could give up setup and back to upper menu.

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 3-12).

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

● Set date

Select “Set Date” in figure 3-12, press the key “Enter” to confirm, the screen shows as follows:



```

Input Current Date:

  10/01/01
  YY/MM/DD
    
```

Figure 3-14

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.

● Data Format

Select "Date Format" in figure 3-12, press the key "Enter" to confirm, the screen shows as follows:

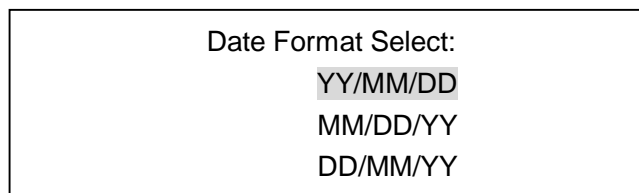


Figure 3-15

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.

3.2.5.2 Strip Select

Select "Strip Select" in figure 3-11, press the key "Enter" to confirm, the screen shows as follows:

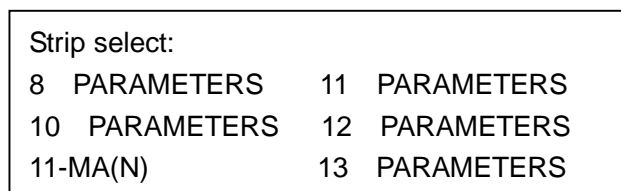


Figure 3-16

•H-100 Urine Analyzer can use DIRUI H8、H10、H11-MA(N)、H11、H12、H13 urinalysis strips. Other strips can not be used.

• Strip selection function is only available after supplier's authorization.

3.2.5.3 Set Status

Select "Status" in figure 3-11, 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 3-17

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

● ID: when "ID" is "ON" and the connected bar code reader could scan the bar code on tube, the output display ID as figure 3-18. When "ID" is "OFF", the output not display ID as figure 3-19, The following explanation take H13-Cr strip as example.

Note:

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 3-18

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 3-19

● **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 (3-18) otherwise no report will be printed out (3-19).

● **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 3-18). When the plus system is “OFF”, the “+” will not print out (figure 3-19).

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

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

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

● 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 3-11, select the “Language Set”, press the key “Enter” to confirm, the screen will show as follows:

	French
Language Select	English
	Russian

Figure 3-20

Ten kinds language interface is provided according to the requirement of clients:English、Russian、Polish、Italian、Spanish、Portuguese、Turkish、German、French.

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

3.2.5.5 Set abnormalities

Select "Set abnormalities" in figure 3-11, press the key "Enter" to confirm, the screen will show as follows:

UBG	PRO
BIL	NIT
KET	LEU
BLD	GLU

Figure 3-21

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

Figure 3-22

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 setted abnormal value. "✱" will appear in the output result.

3.2.5.6 More setup

In figure3-11, choose "More set", press "Enter" to confirm, the screen displays as follows:

Set Options:
Parameter Select
Set Scaler
Reset All Parameter

Figure 3-23

a) 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 3-24

● **Data Output Unit:** In figure 3-24, choose "Data Output Unit", press "Enter" the screen will show the option one by one as follows:

1	SI
2	Plus System
3	conventional
4	CT200
5	DR200

Table 3-1

Note:

When the strip option is 13 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.

● **The test mode:** Select the “Test Mode” in figure 3-24, 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 instrument 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.

● **Baud rate select:** It is used to set up the transmission speed of urine analyzer. In figure 3-24, select “Baud Rate Select” and press the key “Enter”, the content after “Baud Rate Select” will be switched between “9600” and “1200”.

3.3 Test Strip Security Barcode Instruction

1. Press “Enter” of the keyboard, as shown in figure 3-25 shows:

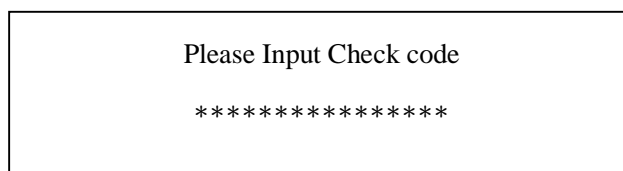


Figure 3-25

2. 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:

- (a) If the barcode entered has been used, press “Enter” key, and a prompt “USED CHECKCODE” will pop up.
- (b) When entering manually, if entering barcode error occurs, press “Enter” key, and a prompt “Invalid Check Code” will pop up.
- (c) If entered barcode is overdue(test strip is out of expiry date), press “Enter” key, and a prompt “Expired Check Code” will pop up.

Note:

1、The security code can be input singly or continuously.

2、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 "0118").

- 3、 If the right side of the main interface displays 0000, the instrument can not test. A new security bar code should be input before testing.

Chapter 4 Quality Control Monitoring

4.1 Calibration Strip Test

Note:

- 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 instrument.
- 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 urine analyzer by the calibration strip every one or two weeks.

Test Method:

Select “Calibration” in figure 3-3, put the calibration strip on the center of the strip table, press the key “Enter” to conduct testing test toward the urine analyzer. The screen will show as follows:

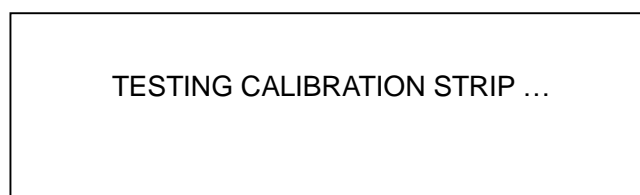


Figure 4-1

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

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:

- I At the time before daily test.
- I At the time when replace another tube of strips.
- I At the time when the operator is changed.
- I 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 3-3) select “QC liquid”. Put the strip that dipped by QC on the strip table and press “Enter” as follows:

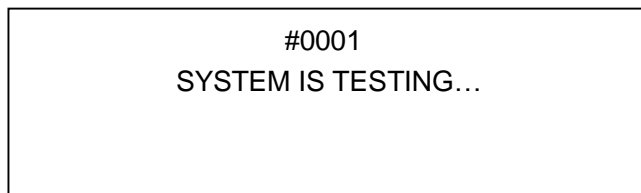


Figure 4-2

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

Chapter 5 Method of Operation



Warnings

- The urine sample may have potential infectivity, please wear protective gloves when testing, cleaning, or doing maintenances to the instrument.
- Please dispose 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-100 Urine Analyzer**”.

Note:

- When the instrument did not pass the self-testing, the screen displays the error information code.
- Do not place the instrument 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 table and the white benchmark is clean and without any foreign matter. The test slot, collect slot and the white benchmark can be cleaned according to the relative content in the “**Chapter 6 Cleaning and Maintenance**”.

5.2 Startup the Instrument

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

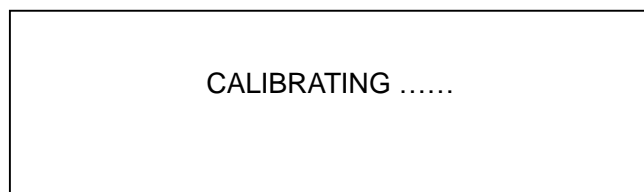


Figure 5-1

After the calibrating, the screen displays as followed:

URINE ANALYZER	10-01-01
#0001	12:00:00
VERSION 8.00	0118
MENU	START

Figure 5-2

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 instrument 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 table, and push it forward until the strip touch the end of the strip table (this one is marked as the first strip).
- 2) On hearing next warning tone, dip another strip into the urine 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 first 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 table and put the second strip on the table to conduct test.
- 4) When hearing the warning tone, repeat the operation in 3).

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

- (1) Press the key “Enter” before the strip table come out.
- (2) Remove the strip from the strip table.

5.3.2 Slow Mode

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

First step: Under the main screen, press the key “Start”, on hearing the warning tone, dip the strip into the urine sample and put it on the strip table according to the procedure in Slow mode, wait for 40 seconds, the instrument start testing. After the test complete, print out the test result, the strip table moves out.

Second step: Repeat the operation in the first step put the strip that is to be tested on the strip table.

Note:

- The tested strip must be placed in the right place before the strip table moves.
- If no strip is placed on the testing slot, the instrument 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.

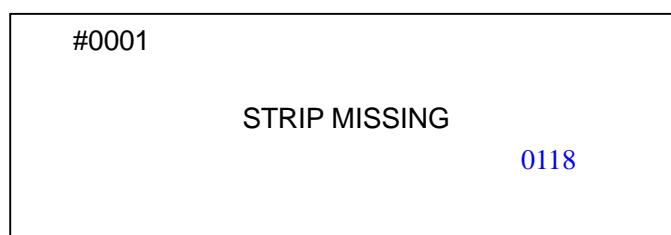


Figure 5-3

- 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

6.1 Daily Cleaning

The instrument can be wiped by soft cloth with gentle eradicator to keep it clean the LCD can be wiped by soft and no abrasion cloth. In order to make the instrument work normally and provide correct test result, the strip table must keep clean.

The methods of cleaning the strip table are as follows:

Draw out the test slot, select slot from the instrument gently. 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 besmirch, wipe them clean by soft cloth.

Note:

- Do not clean the instrument 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 instrument to wipe it.
- Do not clean the LCD with water.
- Do not use anything that may scrap the strip table and white benchmark to wipe the strip table.
- 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 test slot, select slot and the select plate, cleaning can be done according to the following procedures:

- (1) Prepare a little 0.1N NaOH solution.
- (2) Draw the strip table from the instrument gently. Wipe the strip table thoroughly by the cotton bar dipped with 0.1N NaOH solution.
- (3) Clean the remains of the NaOH solution on the strip table by water.
- (4) Wipe and dry the strip table and white benchmark with soft cloth.
- (5) Install the strip table according to the content in the 2.3 in the instruction manual.
- (6) Restart the instrument and conduct self-testing.

Note:

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

6.3 Disinfection

Because the test slot, select slot and the select plate contact with the urine sample, it should be disinfected.

The following solutions can be used to conduct disinfection.

- a) 2% glutaric dialdehyde solution
- b) 5% hypochlorite natrium solution

- (1) Inpouring disinfects liquid of 10cm into an appropriate container.
- (2) Immerge the test slot, select slot and the select plate into the disinfect liquid, and make sure the white benchmark does not contact the liquid.
- (3) Immerge the strip table for 10 minutes.
- (4) Wash cleaning the disinfect liquid that remain on the strip table after remove it from the disinfect liquid.
- (5) Wipe and dry the strip table and the white benchmark with a soft cloth.
- (6) Reinstall the strip table and collect slot.
- (7) Restart the instrument and conduct self-testing.

Note:

The white benchmark does not contact the liquid.

Chapter 7 Transportation and Storage

7.1 Transportation Requirement

In the transportation, the instrument should be damp proofed, water proofed, and avoid to be vibrated or extruded strongly. The instrument should be hold and put gently.

7.2 Storage Requirement

The instrument should be stored in the room where there is no chemical drugs, corrosive gas, and has a good ventilation and sanitation condition, storage temperature is -40°C \rightarrow $+50^{\circ}\text{C}$.

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 instrument.
3. Maintenance will be charged in the following conditions:
 - 1) Product which has pass the date for free maintenance.
 - 2) Damage caused by accidental factor or improper use.
 - 3) Damage caused by the operation that not according to the instruction manual.
 - 4) Damage caused by your own repair that without our company's permission.
4. With the development of technology, DIRUI will supply the service of update of analyzers.

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

DIRUI INDUSTRIAL CO., LTD.

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

Tel: +86(431) 85100409

Fax: +86(431) 85172581

E-mail: dirui@dirui.com.cn

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

Europe Authorised Representative

Emergo Europe

Molenstraat 15

2513 BH The Hague

The Netherlands

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 ,1200

Data bit: 8 bits

Stop bit: 1 bit

Verification: none

Hardware held hands: none

Start character: 02H

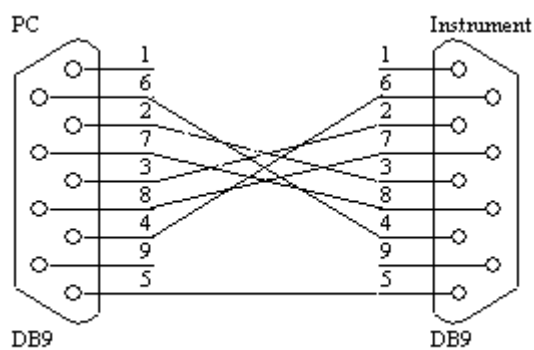
2byte space: 20H

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	:	×	×	×	×	-	×	×	-	×	×	SP	×	×	:	×	×	CR	LF
SP	N	o	.	SP	×	×	×	×	CR	LF													
SP	U	B	G	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	B	I	L	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	K	E	T	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	C	R	E	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	B	L	D	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	P	R	O	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	A	L	B	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	N	I	T	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	L	E	U	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	G	L	U	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	S	G	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	P	H	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	V	C	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	A	:	C	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP	R	T	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	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	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 of H-100 Urine Analyzer

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	3.4 μmol/L	3.4 μmol/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	
	+-	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+	
GLU	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+	
SG	4+	>=1000 mg/dL	>=1000 mg/dL	4+	>=56 mmol/L	>=56 mmol/L	4+	
		<=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
pH		1.025	1.025		1.025	1.025		1.025
		>=1.030	>=1.030		>=1.030	>=1.030		>=1.030
		<=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
VC		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
A:C		>=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
A:C		>=100 mg/dL	>=100 mg/dL		>=5.7 mmol/L	>=5.7 mmol/L		>=5.7 mmol/L
		<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
A:C		>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.	Trouble information	Possible reasons	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 can not solve the problem, please contact with supplier
2	Strips 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 table	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 Radiant tube aging Calibration strip dirty	Wipe white benchmark Replace strip table Replace calibration strip
10	Memory is full	Memory has reached 1000 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. Please call for free if you have any question: 8008468578 or 0431-85100409.

Rev. 08/2011