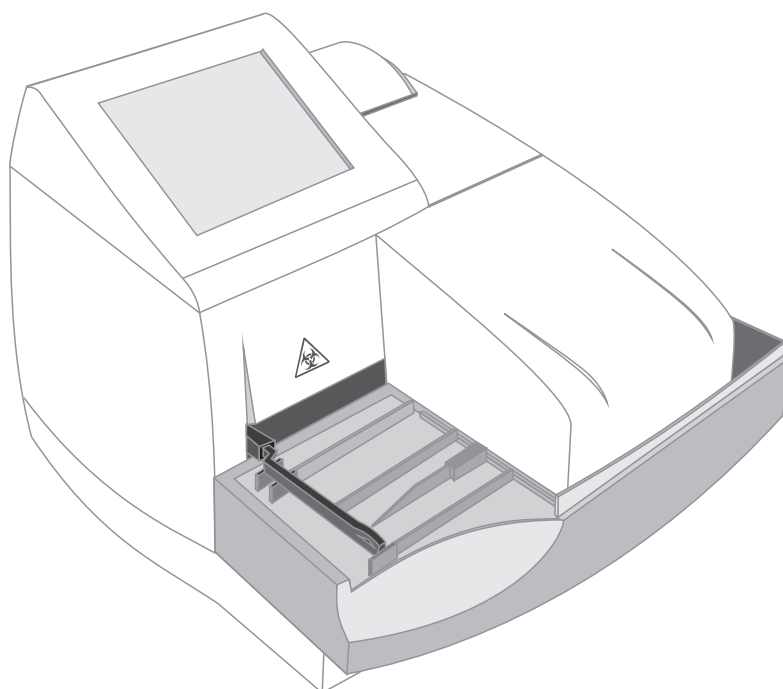# DIRUI

Urine Analyzer

(H-500)

User Manual

DIRUI INDUSTRIAL CO.,LTD.

This manual is applicable to H Series Urine Analyzer (Model: H-500), hereinafter called "analyzer".

Instructions

Dear users, thanks for purchasing H Series Urine Analyzer (Model: H-500).

Please read the User Manual thoroughly prior to operation so as to properly use the analyzer.

Please keep User Manual safe for future use.

Manufacture Date: refer to the label.

Use Limit: 7 years.

Version: REV. 06-2017.

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 tread on, twist or drag the wire and cable. Do not use broken 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 the analyzer switch is on [o] before power on.

● Do not use the analyzer in inflammable and explosive conditions.

Biohazard

● User should comply with local or national regulations when discharging and disposing of reagents, waste solution, waste samples and consumables.

● Samples, control materials and waste test strips have potential biological infectivity to irritate eyes, skin and mucosa. User should refer to safety regulation for lab operation. Protective measures should be taken for user (such as gloves and mouth-muffle).

● Do not use disposable goods repeatedly.

Caution

● 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.

● Regularly maintain the analyzer in strict accordance with the User Manual, otherwise analyzer failure may happen.

● As for the usage and storage of reagent strip and control, please refer to the relevant instructions. Confirm that they are within shelf life.

● Don't use expired strips.

● Do not use turpentine, benzene or other organic solvent to clean the surface of the analyzer because they may cause housing color or shape change. Wipe with soft cloth or moistened cloth. In case of severe dirt, diluted alcohol can be used to clean it.

● When transportation or storage temperature is fairly low or relative humidity is more than 75%, keep the analyzer in the normal work environment for 24 hours and then start it up for testing.

Statement

DIRUI has the final interpretation of this user manual.

DIRUI is responsible for the security, reliability and performance of H-500 urine analyzer 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 General Description and Intended Use

The H Series Urine Analyzer (Model: H-500) should be used together with Dirui urine analysis reagent strips(model: H11-II, H10-II, H11-MA(N), H11-MA).

The analyzer will qualitatively or semi-quantitatively determine the content of Urobilinogen, Bilirubin, Ketone, Blood, Protein, Microablumin, Nitrite, Leucocytes, Glucose, Specific gravity, pH and Vitamin C in the urine sample.

With the measuring and testing technique of cold light source, the H Series Urine Analyzer (Model: H-500) boasts long service life. It can determine biochemical components of the urine sample during 7 seconds; revise the effects toward the test result which is caused by pH value, hematuresis and abnormally colored sample; and connect with the urine sediment analyzer.

1.2 Technical Specifications

Model	Performance Specification							
	Test Items		Test Speed	Storage	Functions	Dimensions	Power	N/W
H-500	Urobilinogen Bilirubi Ketone Blood Protein Microalbumin Nitrite Leucocytes Glucose Specific Gravity pH VitaminC	UBG BIL KET BLD PRO MALB NIT LEU GLU SG pH VC	514t/h	5000 records	Calibration Database Query Sequence Setting Language Setting Time Setting Status Setting Date Format Units Selection Critical Value Setting Work Table Auto-Judgment	395mm×382mm×304mm	40VA	7.4kg

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 Working Principle

H Series Urine Analyzer(Model:H-500) 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 mono-light will scan the reaction area of strip, then, change the signal into electronic signal. Electronic signal will execute A/D conversion, 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).

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

In equation:

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

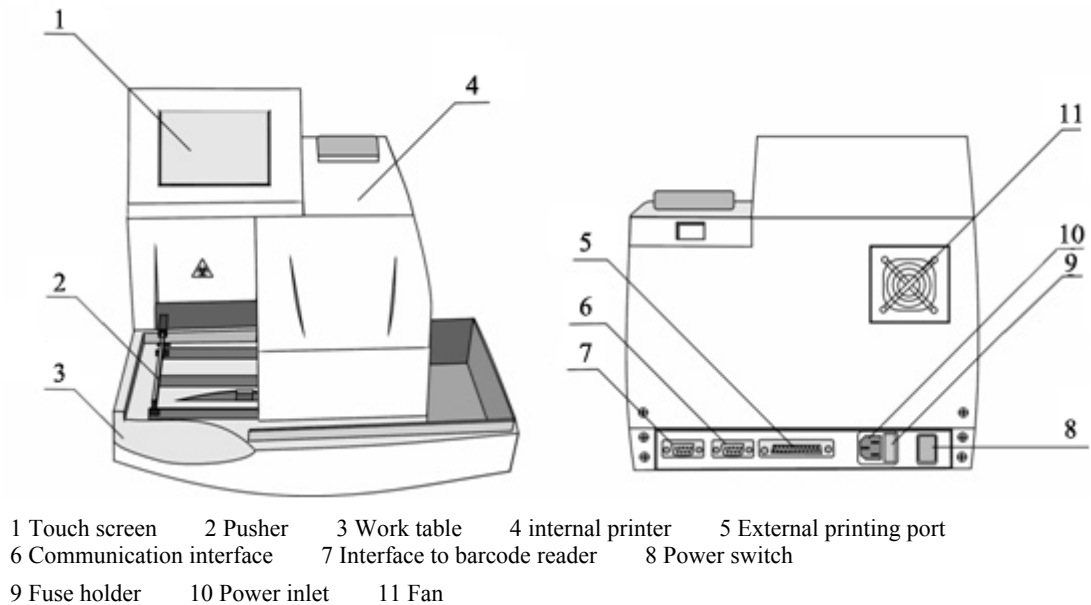The main structure of the analyzer is shown in Figure 1-4-1:

1 Touch screen   2 Pusher   3 Work table   4 internal printer   5 External printing port
6 Communication interface   7 Interface to barcode reader   8 Power switch
9 Fuse holder   10 Power inlet   11 Fan

Figure 1-4-1

1.5 Symbol

Table 1-5-1

Symbol	Meaning
	BIOLOGICAL RISKS
	LASER, DANGER SYMBOL
	ALTERNATING CURRENT
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE
	USE BY
SN	SERIAL NUMBER

Symbol	Meaning
�	DATE OF MANUFACTURE
⏚	PROTECTIVE GROUND
▰	MANUFACTURER
⚠	CAUTION, REFER TO THE ACCOMPANYING FILES OR MARK DETAILED WARNING OR MATTERS NEEDING ATTENTION
CE	THE DEVICE MEETS THE REQUIREMENTS OF DIRECTIVE ON IN VITRO DIAGNOSTIC MEDICAL DEVICES
EC REP	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.
REF	CATALOGUE NUMBER
│	"ON"(POWER)
◯	"OFF"(POWER)

⚠

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

1-4

Chapter 2 Installation

2.1 Environment Requirements

(1)Please put the analyzer on a stable, flat, and vibration-free surface which can bear at least 8kg.

(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℃~35℃. (20℃~25℃ would be the best); relative humidity ≤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-500) and its accessories, and then check them with packing list to see whether the following parts have been damaged or not. If there are some damages, please contact the supplier immediately.
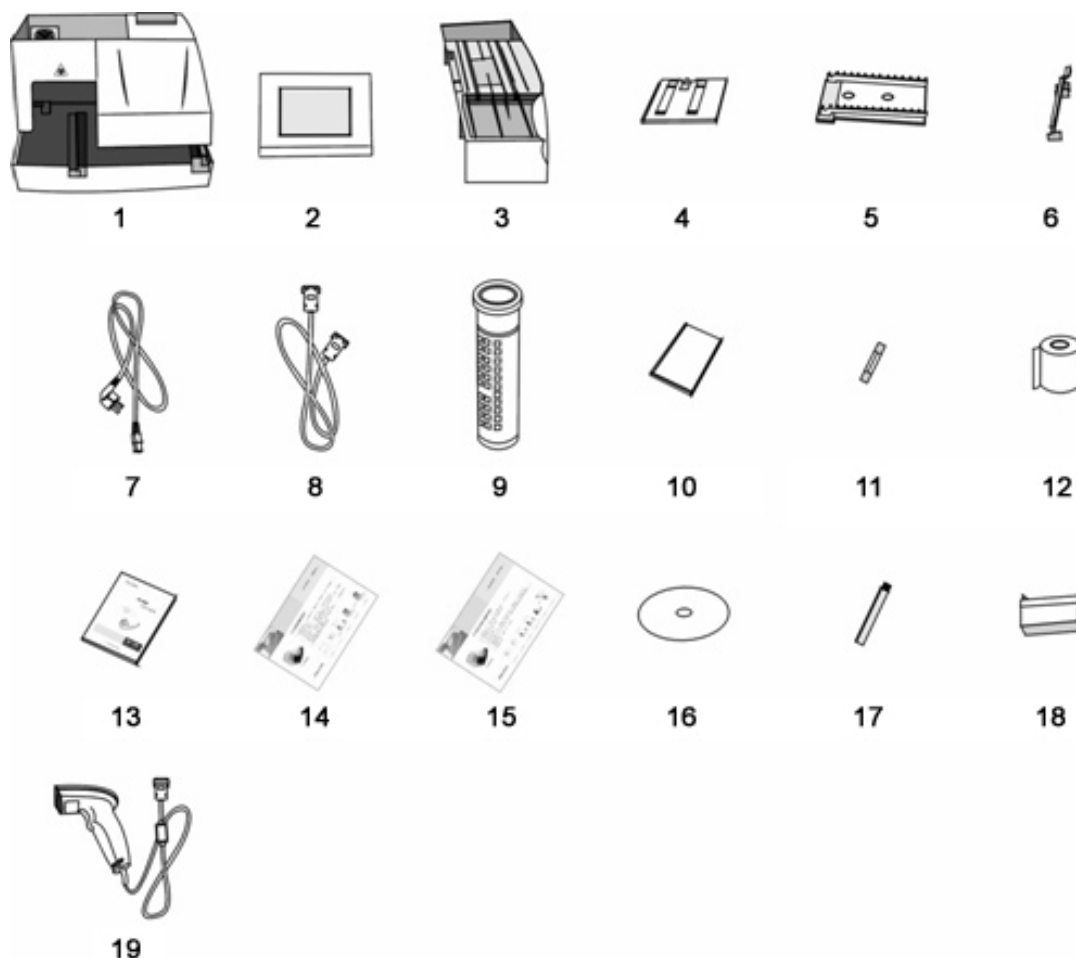
1 Main body   2 Screen   3 Worktable   4 Cover board   5 Stepping board   6 Pusher

7 Power cable   8 Serial port cable   9 Reagent strip sample

10 Calibration strip box (with 1 calibration strips)   11 Fuse   12 Printing paper   13 User Manual

14 Operation procedure   15 Maintenance procedure   16 CD   17 Brush   18 Waste box

19 Barcode reader (optional fitting(s))

Figure 2-2-1

2.3 Installation of the Analyzer

2.3.1 Install Screen

(1)As Figure 2-3-1, connect the wire of the screen with the corresponding socket on the main body;

(2)As Figure 2-3-2, insert the screen into the main body. Block the lock slot in front of the screen to the corresponding fix site on up-shell of the main board, then make the corresponding site of the site-limiting card behind the screen, and push the up-shell of the main board.
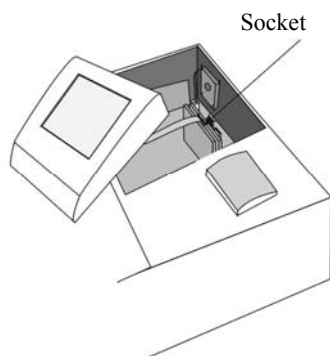
Socket   Lock slot
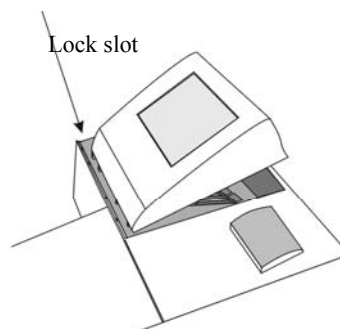
Figure 2-3-1   Figure 2-3-2

2.3.2 Install Stepping Board

Hold the stepping board with the saw tooth upside, and connect the board with the side with rectangle overhang facing the analyzer. Push the guide slot parallel on the two sides of the lower part of stepping board to the locked side through the guide on the two sides of connecting board (Figure 2-3-3).
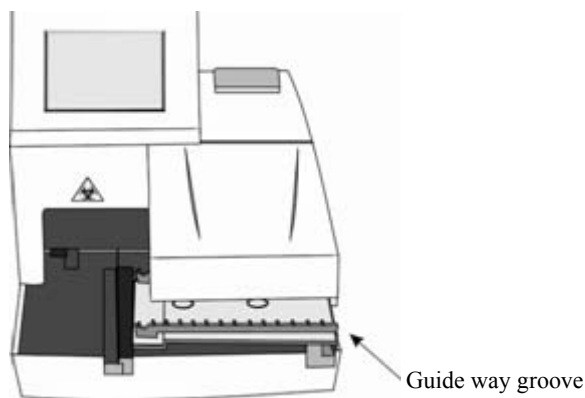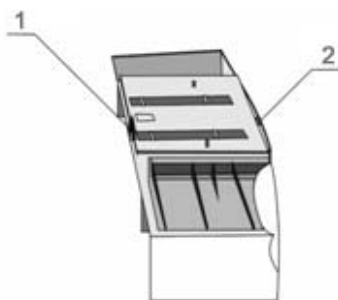
Guide way groove

Figure 2-3-3

2.3.3 Install Cover Board

(1)Insert the lower protruding cylinder of the cover board into the round hole of the worktable (2 in Figure 2-3-4);

(2)Press the upper protruding part of the cover board into the lock slot of the worktable (1 in Figure 2-3-4).

1 Lock slot   2 Round hole

Figure 2-3-4

2.3.4 Install Worktable

Before installing the worktable, please cut the nylon string around the frame of pusher and take down the safety holder (Figure 2-3-5).
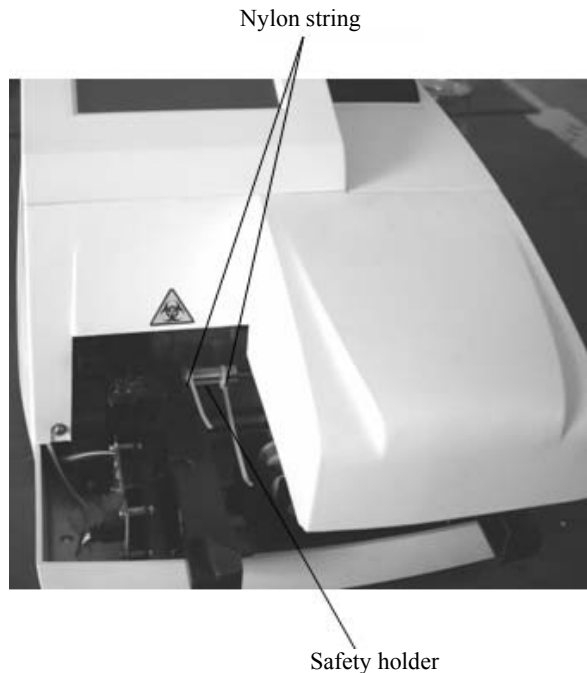
Nylon string

Safety holder

Figure 2-3-5

Align the guide rail of the worktable (with the cover board) with the guide way groove of the main body, and push the worktable into the main board in parallel, just near the main board (Figure 2-3-6).
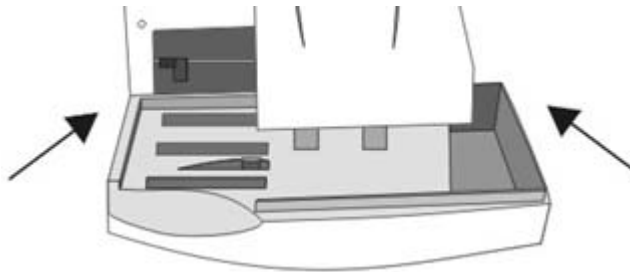

Figure 2-3-6

⚠️

Worktable can't be taken down only until the stepping board reaches the lowest point.

2.3.5 Install Pusher

Hold the end of the pusher, and insert the pusher into the mounting hole of the pusher on the slide support. Press the end of the pusher to the horizontal position (Figure 2-3-7).
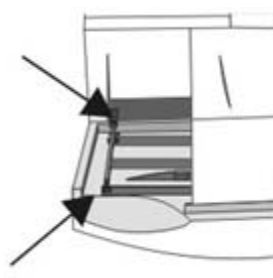

Figure 2-3-7

2.3.6 Install Printing Paper

(1)Choose the thermal printing paper with a width of 57mm and a diameter less than 50mm;

(2)Press the hook at the back of the printer cover, and then lift the cover and take it off (Figure 2-3-8);

(3)Put the printing paper in the box; unfold the printing paper to make the paper end close to inside of analyzer;

(4)Pull the paper installation hand and insert the printing paper into the printer. Pull the printing paper up and down and put down the hand when the printing paper moves smoothly; (The printing paper can be automatically pulled out by the printer when the analyzer is electrified.)

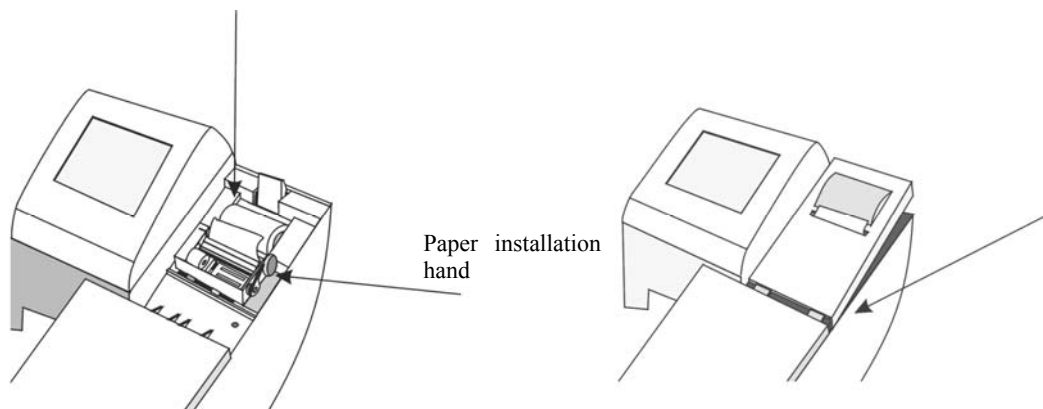(5)Put the paper through the outlet of the printer cover. Close the cover of printer.

Paper installation hand

Figure 2-3-8

⚠

When installing the printing paper, pull out the printing paper with shiny side up (Figure 2-3-8). Otherwise the test data cannot be printed.

2.3.7 Connect with Barcode Reader

H Series Urine Analyzer(Model: H-500) can be connected with the barcode reader to scan the barcode on the sample tube. Take out the barcode reader (optional part) from the box and connect the data cable of the barcode reader (Figure 2-3-9).

Figure 2-3-9

As shown in Figure 2-3-10, connect the other end of the data cable (RS-232 port) with the barcode reader port of urine analyze.
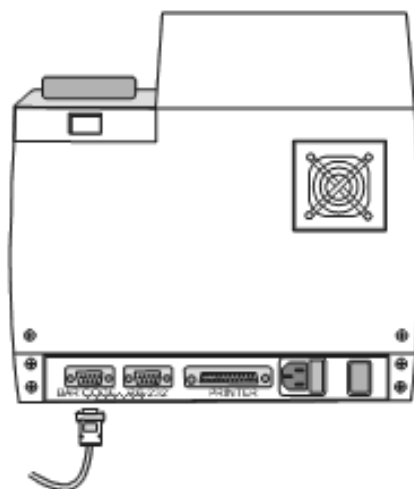
Figure 2-3-10

⚠️

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

2.3.8 Connect with Computer

H Series Urine Analyzer (Model: H-500) can be connected with the computer to communicate data to the computer. Insert one end of the communication cable into the serial port at the back of the analyzer (Figure 2-3-11), with the other end into the serial port of the computer.
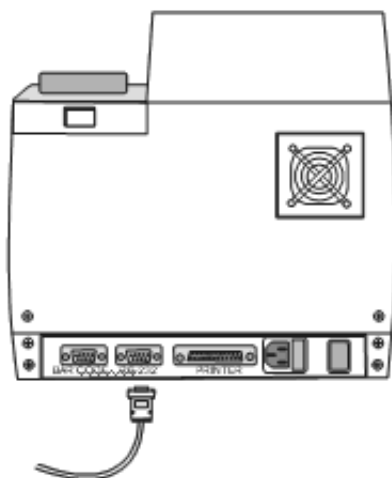

Figure 2-3-11

2.3.9 Connect with External Printer

Connect one end of the printer wire with the external parallel port for the external printer at the back of the analyzer (Figure 2-3-12), and the other end with the external printer.
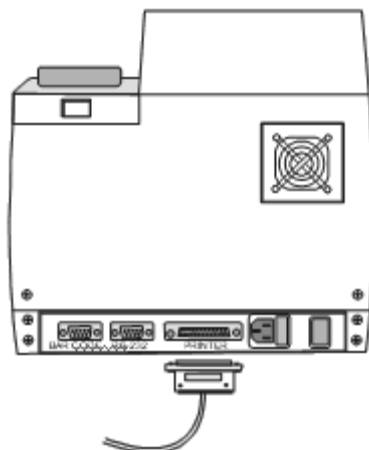
Figure 2-3-12

⚠

H Series Urine Analyzer (Model: H-500) can connect with EPSON LQ1600K Series and EPSON LQ300K+ Series needle printer.

2.3.10 Install Power Cable

Power Requirement:

(1)Voltage: 100-240V~, 50 /60Hz;

(2)Power: 40VA;

(3)Fuse: F1.6AL250V   5mm×20mm.

Connect the input terminal of the power cable with the power socket at the back of the analyzer (Figure 2-3-13), and the other end with the alternating power.
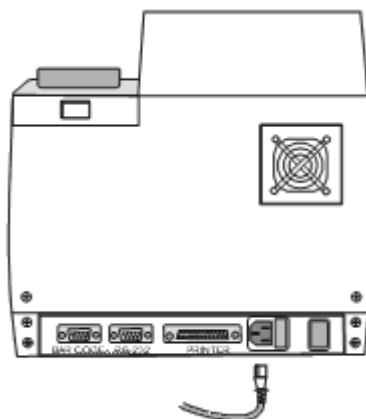

Figure2-3-13

⚠

● **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.**

2.4 Inspection for the First Use

After installation, the first inspection should be done. Please contact the supplier if there is any problem or error.

2.4.1 Power on Self-test

When the power is on, the fan and pusher start to work. The screen will display "System Initializing..." and the analyzer is performing self-test. If the printer has not installed the paper, the analyzer will display "NO PRINTING PAPER" during self-test.

The main menu (Figure 2-4-1) will appear after the self-test:

Figure 2-4-1

In the Figure 2-4-1:

(1)"Tech ID: 00000" meaning code name of the technician.

(2)"Jun. 1, 2006 18:58:46" refers to current date and time.

(3)"23℃" refers to current temperature.

2.4.2 Usage of Security Barcode of Reagent Strip

Press the key [key icon] in Figure 2-4-1, and the interface is shown in Figure 2-4-2:

Figure 2-4-2

Scan or manually input the effective barcode on the reagent strip canister. Press the key [enter key icon] in Figure 2-4-2 and start the test when "Correct Check Code" appears.

Following circumstances may occur when inputting the barcode:

(1)Barcode on every reagent strip canister can only be used for once. For reused barcode, the analyzer will display

"Used Code" when pressing the [enter key icon] key;

(2)For wrong manual input, the analyzer will display "Invalid Code" when pressing the ⏎ key;

(3)If the reagent strip is out of expiration, the analyzer will display "Overdue Code" when pressing the ⏎ key.

2.4.3 Paper Skip

Pressing the corresponding key "Paper out" as in Figure 2-4-1 ⏺, the printer will perform as per the specified value.

2.4.4 Notes for Usage

(1)Immerse the reagent strip into a urine sample, and then take it out by running the edge of the strip against the rim of the container to remove excessive urine.

(2)Put the strip in the test area of the analyzer with reagent area upward (Figure 2-4-3). The pusher will push the reagent strip to the testing area once the strip is sensed. Testing result will be printed out after test.

⚠

Do not touch any part of the screen when testing, otherwise errors will occur.
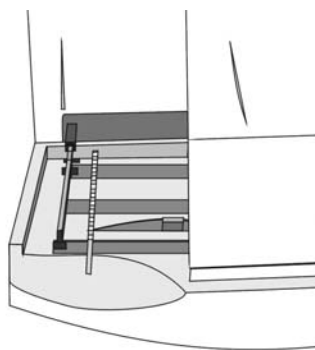
Figure 2-4-3

(3)Please reset the relevant items according to Chapter 3 if the display does not show as expected or the results do not accord with the anticipated value.

2.5 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 Function and Setup

3.1 General Description

Operator can touch the main screen to control and use H Series Urine Analyzer(Model:H-500). Relative options, parameters for setup and touch-keys will display on the main screen. Operator just needs to touch the keys to operate this analyzer.

Do not use hard or sharp articles to touch the screen.

3.2 Function of Keys

The function of keys is explained as follows:

(1)Name: Return key

Icon:

Function: Once pressed, the display will return to the upper menu or ignore the current correction and then return to the upper menu.

Location: Upper right of the screen.

Note: The function of key is to make the display return to the upper menu. If there is key on the current screen, the function of is to ignore the current correction and return to the upper menu.

(2)Name: Page down key

Icon:

Function: Go forward to next page. It is effective only when there is a next page, otherwise, it will only make a twinkling on the current page.

Location: Lower right of the screen.

(3)Name: Page up key

Icon:

Function: Go back to the former page. It is effective only when there is a former page, otherwise, it will only make a twinkling on the current page.

Location: Lower right of the screen.

(4)Name: Enter key

Icon:

Function: Confirm the current correction and exit from the current page.

Location: Bottom of the screen.

Note: It appears on the screen with number keys, being used together with the key . When the user input numbers, touch the key to store the current correction (e.g. No., date, time) and exit from the current page. Touch the key to ignore the current correction and exit from the current screen. The original setup remains.

(5)Name: Left-moving key for cursor

Icon:

Function: To get the cursor move left in one letter distance. It appears on the screen of number key. It is void when the cursor stays at the end of the left side.

Location: Right side of the screen.

(6)Name: Right-moving key for cursor

Icon: ➡️

Function: To get the cursor move right in one letter distance. It appears on the screen of number key. It is void when the cursor stays at the end of the right side.

Location: Right side of the screen.

(7)Name: Up-moving key for cursor

Icon: ⬆️

Function: To get the cursor move upward in one letter distance. It appears on the screen of number key. It is void when the cursor stays atop line.

Location: Right side of the screen.

⚠️

It is used to search last record (the sequence number is current number minus one) in the menu of research key.

(8)Name: Down-moving key for cursor

Icon: ⬇️

Function: To get the cursor move downward in one letter distance. It appears on the screen of number key. It is void when the cursor stays at the bottom line.

Location: Right side of the screen.

⚠️

It is used to search next record (the sequence number is the current number plus one) in the menu of research key.

(9)Name: Delete key

Icon: Del

Function: Be used to delete the number where the cursor is.

Location: Bottom of the screen.

(10)Name: Number keys

Icon: 0 1 2 3 4 5 6 7 8 9

Function: Be used to input corresponding numbers.

(11)Name: Printing key

Icon: 🖨️

Function: Be used to print the current test records on the screen.

Location: Right side of the screen.

(12)Name: Research key

Icon: A

Function: Be used to search test records stored in the analyzer. Press this key, the screen turns to the screen of number key. The user can press the number key for the sequence number in the range of 0001 and 9999. Press the

key , the screen will show corresponding record matched with the input sequence number; if there is no record, the screen will show blank record.

Location: Right side of the screen.

(13)Name: Sub-menu key

Icon:

Function: Be used to enter a sub-menu of the selected item. Press this key, the screen will show content of the sub-menu selected.

(14)Name: Cycling key

Icon:

Function: Touch it to display next setup data under current setup item. It can be used to switch corresponding setup items circularly among internal setup selection items.

(15)Name: Enter key

Icon:

Function: Be used to confirm the current operation, i.e. "Yes". It appears when some important operation (e.g. storing a corrected setup value or abbr. value) is made to remind the user of confirming the correction.

(16)Name: Cancel key

Icon:

Function: Be used to cancel the current operation, i.e. "No". When it appears together with on the same screen, touching it means canceling the selected operation.

3.3 Menu Setting

3.3.1 Setting of Sequence Number

Click on sub-interface key corresponding to "SEQ#" in the main interface (Figure 2-4-1), and enter the sub-interface of S/N setting as shown in Figure 3-3-1:

Figure 3-3-1

Users can set up sequence number of record in Figure 3-3-1.

Press number key, input sequence number, press the key [⏎] to confirm and save the change and then go back to the menu of the main interface. The newly set sequence number will be applied; press the key [⬆] to cancel the change and go back to the menu of the main interface. The original sequence number remains.

Serial number displayed on the screen represents a test record number of next paper to be tested, and it will add 1 to it automatically upon each test completion.

⚠️

● **Sample No. cannot be set as 0.**

● **The user can change the number between 0001 and 9999.**

3.3.2 Menu Setting

Press sub-interface key [◉] corresponding to "Menu" of the main interface and enter the sub-interface of the menu as shown in Figure 3-3-2. Users can set up each option here.

```
┌─────────────────────────────────────────┐
│                                          │
│          Set options.          ⬆         │
│                                          │
│   ◉    Tech ID                           │
│                                          │
│   ◉    Manufacturer setup                │
│                                          │
│   ◉    Setup                             │
│                                          │
│   ◉    Recall                            │
│                                          │
└─────────────────────────────────────────┘
```
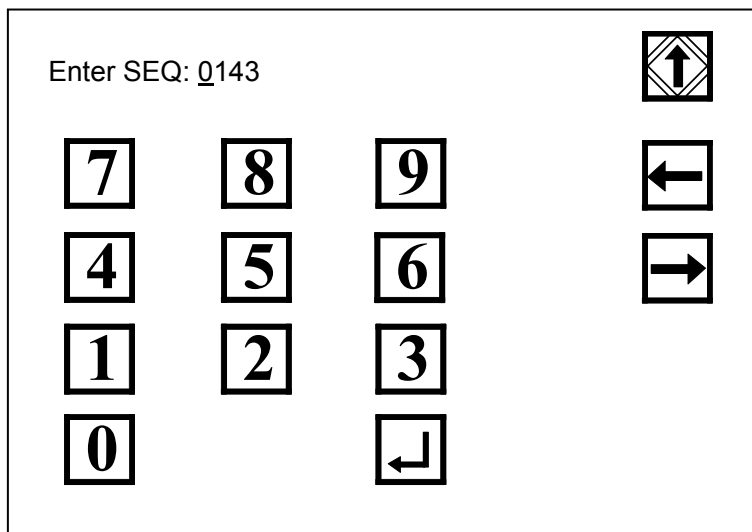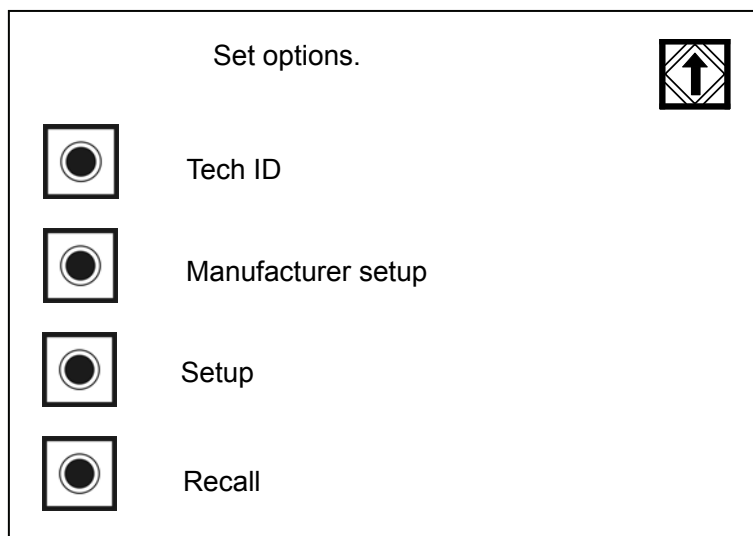
Figure 3-3-2

3.3.2.1 Tech ID

Press [◉] corresponding to "Tech ID" and the following will be displayed:

```
┌─────────────────────────────────────────┐
│                                          │
│   Enter Tech: 00000            ⬆         │
│                                          │
│      7      8      9           ←         │
│                                          │
│      4      5      6           →         │
│                                          │
│      1      2      3                     │
│                                          │
│      0             ⏎                     │
│                                          │
└─────────────────────────────────────────┘
```

Figure 3-3-3

User can input Tech ID in this interface. Press number key and input numbers to change Tech ID and then press ⏎ to confirm the change and go back to the upper menu. The newly set No. will be applied; press ⬆ to give up the change and go back to the upper menu. The original No. remains.

3.3.2.2 Manufacturer setup

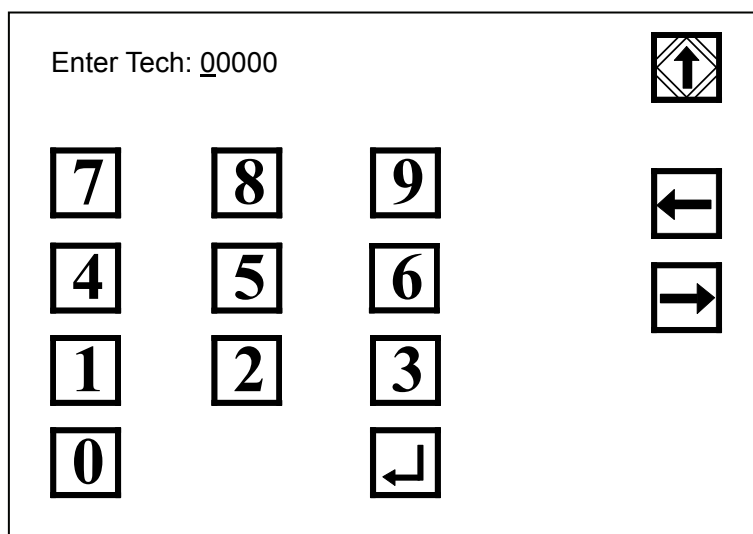"Manufacturer setup" is reserved for special use of the manufacturer and it cannot be used and changed by users. When users enter the Advanced Setting, the following will be displayed:

Figure 3-3-4

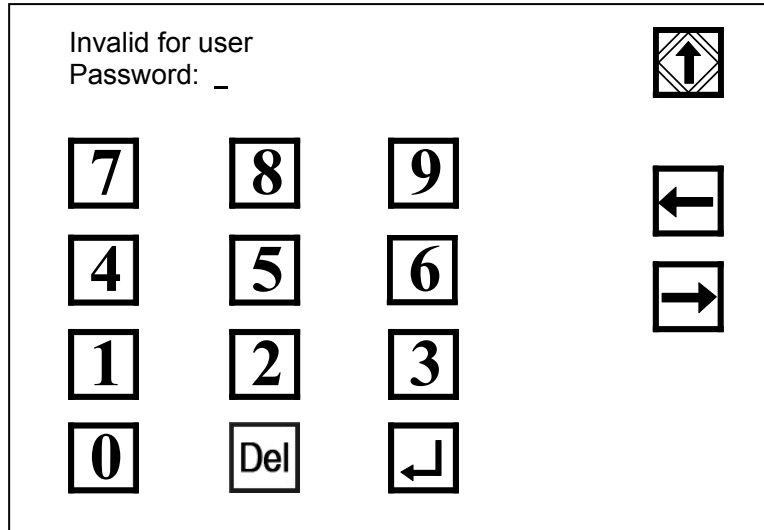Users can press the key ⬆ to exit and go back to the previous menu.

3.3.2.3 Setup

Press the key ⦿ in front of "Setting" and the screen is shown in Figure 3-3-5. Users can change the setting of date, time, computer ports, printer, work list and ID mode.
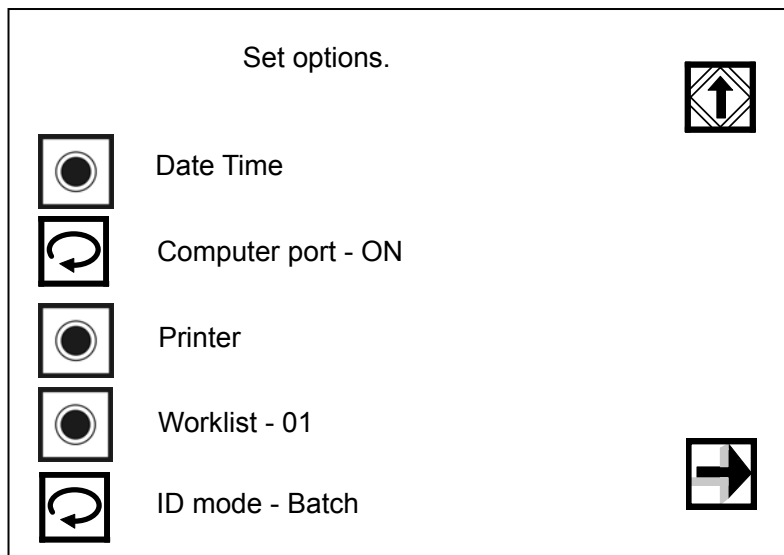

Figure 3-3-5

The user can use password protection for other options. If password setting is "ON", press the ➡ key, and Figure 3-3-6 will pop up:
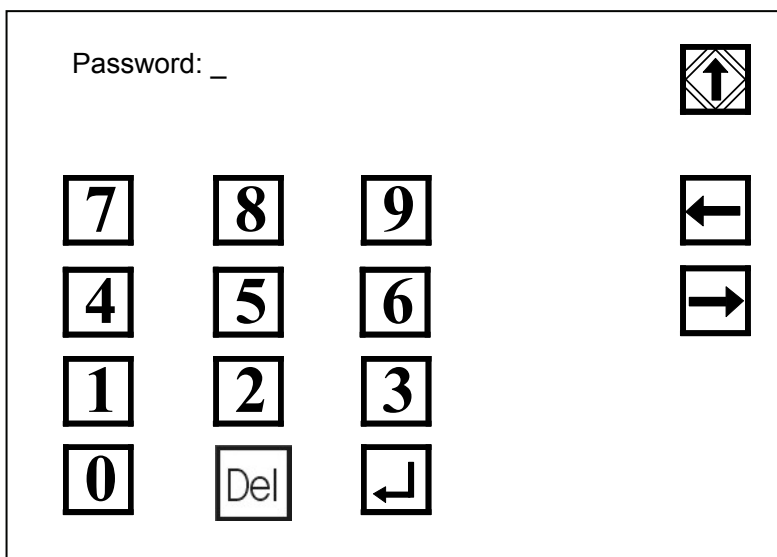
Figure 3-3-6

Display of the password input screen indicates that later option setting has password protection. Use the number keys to enter the password and press [↵] to confirm. If entering correct password, Figure 3-3-7 will show. However, if entering incorrect password or pressing [↑] after entering a password, Figure 3-3-5 will show.

The original password of the analyzer is "1234".

If password setting is "off", press the key [→] in Figure 3-3-5 and Figure 3-3-7 will pop up. The user can set a language, a result unit, plus system, and strip selection for the analyzer.
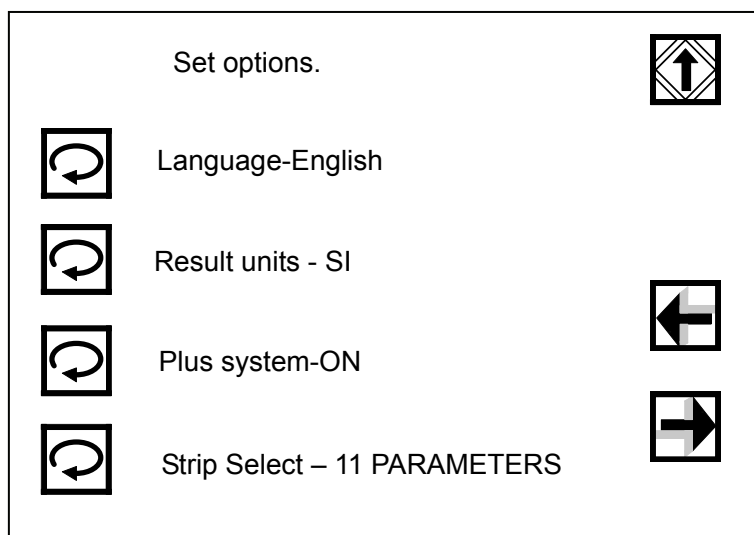
Figure 3-3-7

Press the key [→] in Figure 3-3-7 and Figure 3-3-8 will pop up. The user can set a mark for abnormal values, and the baud rate, parity bit, and data, stop bit.
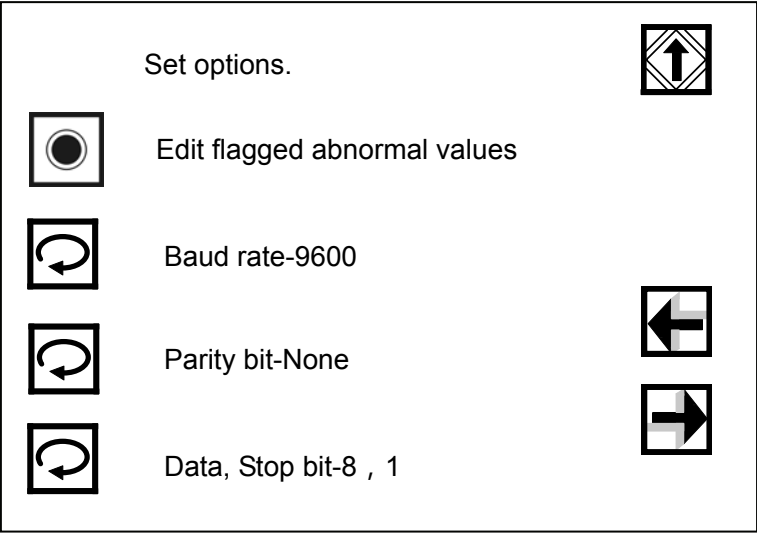
Figure 3-3-8

Press the key [→] in Figure 3-3-8 and the screen is shown in Figure 3-3-9:
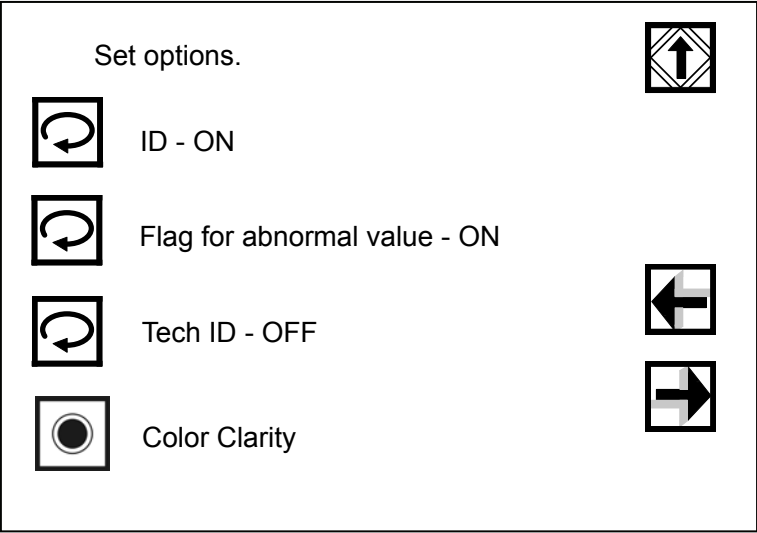
Figure 3-3-9

There are settings for ID, Flag for Abnormal Value, Tech ID, Color and Clarity on this interface. Press the key [⟳] in front of each item, the contents will be switched between "On" and "Off".

Press the key [→] in Figure 3-3-9 and the screen is shown in Figure 3-3-10:
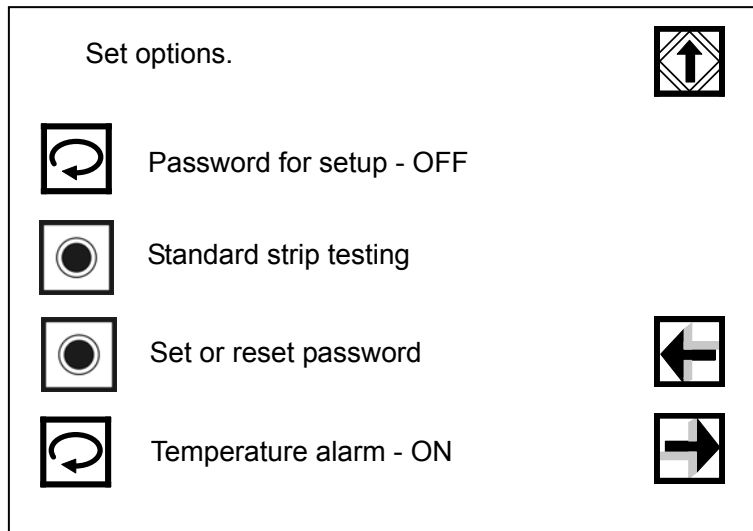
Figure 3-3-10

Users can set up password, temperature alarm etc.

Press the key in Figure 3-3-10 and the screen is shown in Figure 3-3-11:
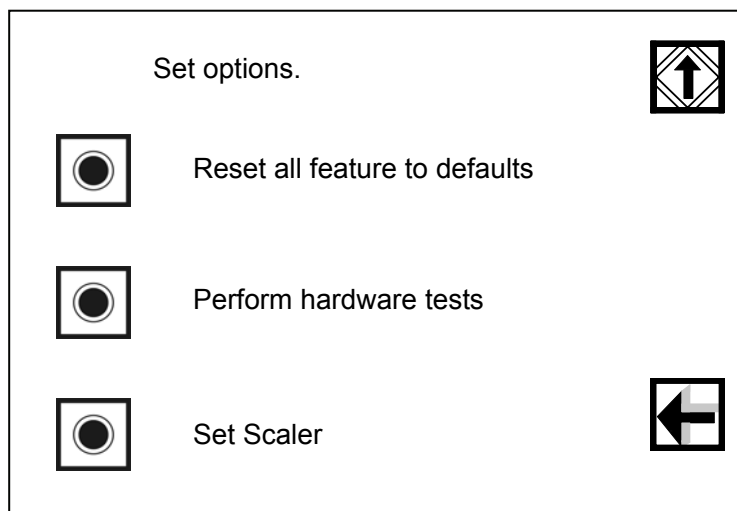
Figure 3-3-11

Users can reset all features to defaults, set the scaler and perform hardware test.

(1)Date Time

Press the sub-interface key corresponding to "Date/Time" in Figure 3-3-5 and the screen is shown in Figure 3-3-12:

3-8
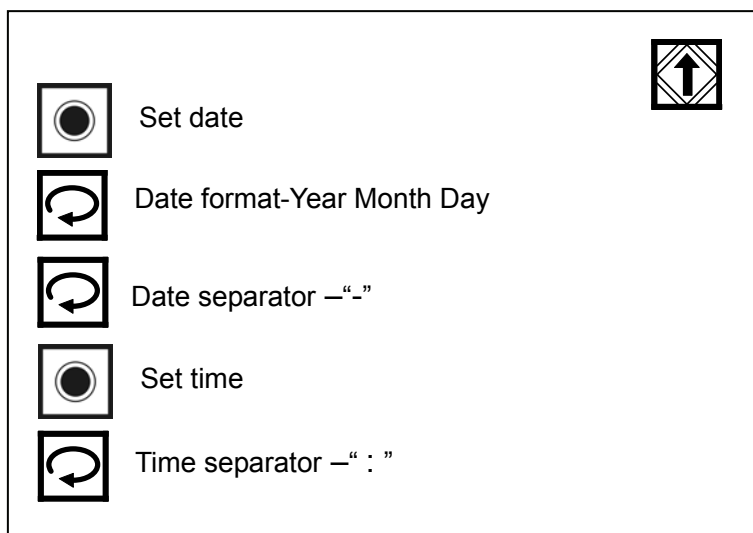
Figure 3-3-12

a)Date setting

Press the sub-interface key [icon] corresponding to "Date Setting" in Figure 3-3-12 and the screen is shown in Figure 3-3-13:
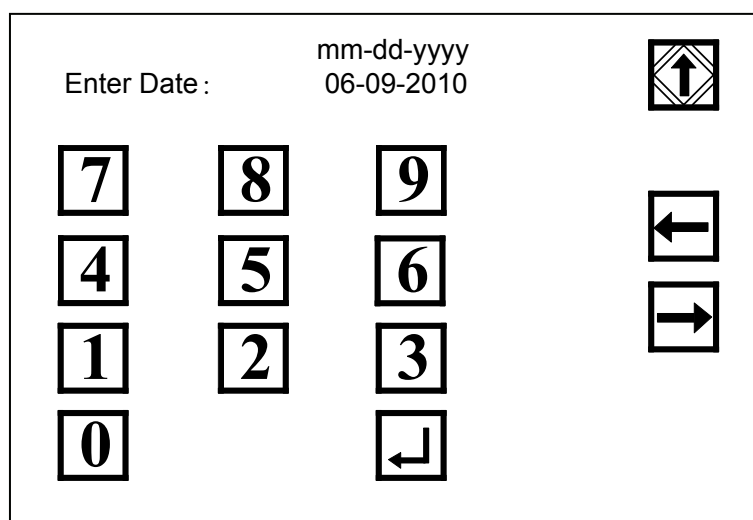
Figure 3-3-13

"06-09-2010" in Figure 3-3-13 means the current date. Users can change the date through number key by entering corresponding numbers or moving the cursor [icon] and [icon] to the place needing change to modify the date, press [icon] to confirm and return to upper menu. The system will show the new date. Press [icon] to cancel the change and return to upper menu, while the original date is still effective.

b)Date format

Press the key [icon] in front of "Date Format" in Figure 3-3-12, the contents will be switched among the options shown in the following table.

Table 3-3-1

1	Y_M_D
2	M_D_Y
3	D_M_Y

c)Date separator

Press the key [icon] in front of "Date Separator" in Figure 3-3-12, the contents will be successively switched among the options shown in the following table.

Table 3-3-2

1	-
2	/
3	.

Press the return key [icon] to go back to upper menu.

d)Time Setting: press the sub-interface key [icon] corresponding to "Time Setting" in Figure 3-3-12 and the screen is shown in Figure 3-3-14:

Figure 3-3-14

"07: 29: 15" in Figure 3-3-14 means the current time. Users can change the time through number key by

entering corresponding numbers or moving the cursor [icon] and [icon] to the place needing change to modify

the time, press [icon] to confirm and return to upper menu. The system will show the new time. Press [icon] to cancel the change and return to upper menu, while the original time is still effective.

e)Time separator

Press the key [icon] corresponding to "Time Separator" in Figure 3-3-12, the contents will be successively switched among the options shown in the following table.

Table 3-3-3

1	:
2	,
3	.

(2)Computer Port

Press the key [icon] corresponding to "Computer Port", the contents against the port will be switched between "On" and "Off".

When it is "On", the analyzer will send test data to computer through communication port; when it is "Off", the analyzer stops transmitting test data.

(3)Printer

Press the sub-interface key [icon] corresponding to "Printer" in Figure 3-3-5 and the screen is shown in Figure 3-3-15:

Report width –10

Printer--Internal
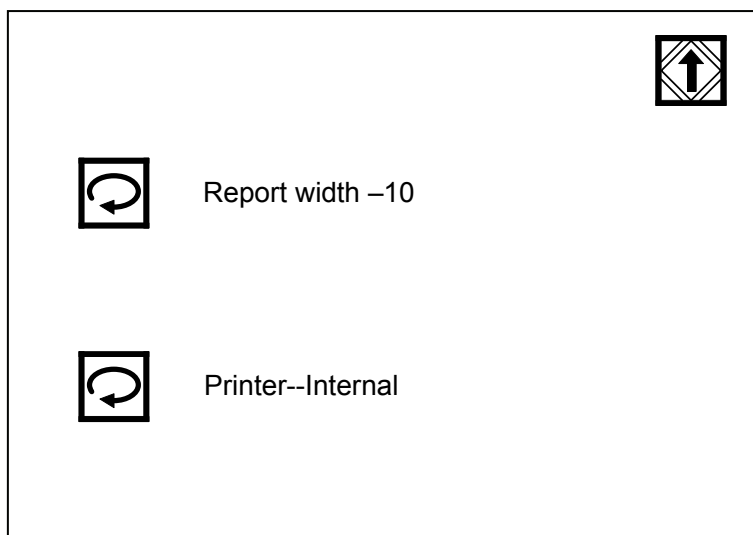
Figure 3-3-15

a)Report width

Press the key [icon] corresponding to "Report Width" in Figure 3-3-15, the contents will be successively switched among the options shown in the following table. This option is used to set up space between two records.

Table 3-3-4

1	2
2	4
3	6
4	8
5	10

b)Printer

Press the key [icon] corresponding to "Printer" in Figure 3-3-15, the contents will be switched among the options shown in the following table.

3-11

Table 3-3-5

1	Internal
2	External
3	ALL ON
4	ALL OFF

"Internal" indicates that the test result is printed out by internal thermal printer; "External" indicates test result is printed out by external printer connected with the analyzer; "ALL ON" indicates that the test result could be printed out both by internal thermal printer and external printer connected with the analyzer; "ALL OFF" indicates that the test result could not be printed out neither by internal thermal printer nor external printer connect with the analyzer.

(4) Worklist

Press the key ⊙ in front of the "Worklist" in Figure 3-3-5 and the screen is shown in Figure 3-3-16:

Enter Worklist:
01

```
7  8  9
4  5  6
1  2  3
0  Del  ↵
```

Figure 3-3-16

Users can set up and add worklist through number key by entering corresponding numbers or moving the cursor ← and → to the place needing change to modify the number, press ↵ to confirm and return to upper menu; press ⬆ to give up the change and return to upper menu, while the original worklist remain unchanged. Different worklists can be set, queried can be conducted according to worklist.

(5)ID Mode

Press the key ↻ corresponding to "ID Mode" in Figure 3-3-5, the contents will be switched among the options shown in the following table.

Table 3-3-6

1	Batch
2	One by one

(6)Language

Press the key ↻ corresponding to "Language" in Figure 3-3-7, the contents will be switched among the options shown in the following table.

Table 3-3-7

1	English	6	Turkish
2	Italian	7	Portuguese
3	Spanish	8	German
4	Russian	9	French
5	Polish	10	Hungarian

10 languages are provided for selection and can be switched.

(7)Result Unit

Press the key [icon] corresponding to "Result Unit" in Figure 3-3-7, the contents will be switched among the options shown in the following table.

Table 3-3-8

1	SI
2	General
3	+
4	CT200
5	DR200

⚠️

When the system of units are chosen as international, conventional, plus or DR200, the analyzer together with the DIRUI FUS series urine sediment analyzer an form an urine test workstation.

(8)Plus System

Press the key [icon] corresponding to "Plus System", the options against the "Plus System" will be switched between "On" and "Off".

When "Plus system" is "ON" and "Result Unit" is "Conventional", the result is shown in Figure 3-3-17; when "Result Unit" is "SI", the result is shown in Figure 3-3-18; when "Result Unit" is "Plus", the result is shown in Figure 3-3-19.

Date：2010-06-09 12：10	Date：2010-06-09 12：12	Date：2010-06-09 12：14
No.：0017	No.：0018	No.：0019
ID：----------------	ID：----------------	ID：----------------
UBG Normal 0.2mg/dL	UBG Normal 3.4µmol/L	UBG Normal
BIL Neg	BIL Neg	BIL Neg
KET Neg	KET Neg	KET Neg
CRE 50 mg/dL	CRE 4.4 mmol/L	CRE 4.4
BLD 1+ Ca25 Ery/µL	BLD Neg	BLD Neg
PRO Neg	PRO Neg	PRO Neg
MALB 10 mg/L	MALB 10 mg/L	MALB 10
NIT Pos	NIT Pos	NIT Pos
* LEU 3+>=Ca500Leu/µL	* LEU 3+>=Ca500Leu/µL	* LEU 3+
GLU Neg	GLU Neg	GLU Neg
SG >=1.030	SG >=1.030	SG >=1.030
pH <=5.0	pH <=5.0	pH <=5.0
VC 50 mg/dL	VC >=0.6 mmol/L	VC >= 0.6
A:C <30 mg/g	A:C <3.4 mg/mmol	A:C <3.4
Normal	Normal	Normal

Figure 3-3-17   Figure 3-3-18   Figure 3-3-19

When "Plus system" is "OFF" and "Result Unit" is "Conventional", the result is shown in Figure 3-3-20; when

"Result Unit" is "SI", the result is shown in Figure 3-3-21; when "Result Unit" is "Plus", the result is shown in Figure 3-3-22.

Date：2010-06-09 12：12	Date：2010-06-09 12：12	Date：2010-06-09 12：12
No.：0017	No.：0018	No.：0019
ID：----------------------	ID：----------------------	ID：----------------------
UBG Normal 0.2mg/dL	UBG Normal 3.4µmol/L	UBG Normal
BIL Neg	BIL Neg	BIL Neg
KET Neg	KET Neg	KET Neg
CRE 50 mg/dL	CRE 4.4 mmol/L	CRE 4.4
* BLD Ca10Ery/µL	* BLD Ca10Ery/µL	* BLD + -
PRO Neg	PRO Neg	PRO Neg
MALB 10mg/L	MALB 10 mg/L	MALB 10
NIT Pos	NIT Pos	NIT Pos
LEU Neg	LEU Neg	LEU Neg
GLU Neg	GLU Neg	GLU Neg
SG >=1.030	SG >=1.030	SG >=1.030
pH <=5.0	pH <=5.0	pH <=5.0
VC >=100mg/dL	VC >=5.7mmol/L	VC >=5.7
A:C <30 mg/g	A:C <3.4 mg/mmol	A:C <3.4
Normal	Normal	Normal

| Figure 3-3-20 | Figure 3-3-21 | Figure 3-3-22 |

⚠

Take H11 reagent strip for example to explain.

(9)Reagent Strip Selection

Press the key ⟳ in front of "Reagent Strip Selection" in Figure 3-3-7, the contents will be successively switched among the options shown in the following table.

Table 3-3-9

1	8 PARAMETERS
2	10 PARAMETERS
3	11 PARAMETERS
4	11-MA(N)

The contents of "Reagent Strip Selection" refer to the current reagent strip types.

⚠

Urine reagent strips applicable to H Series Urine Analyzer(Model:H-500) are DIRUIH8, H10, H11 and H11-MA (N). To ensure accurate test result, reagent strip of other types should not be applied.

(10)Setting of Flag for Abnormal Value

Press the sub-interface key ◉ corresponding to "Edit flagged abnormal values" in Figure 3-3-8 and the screen is shown in Figure 3-3-23:
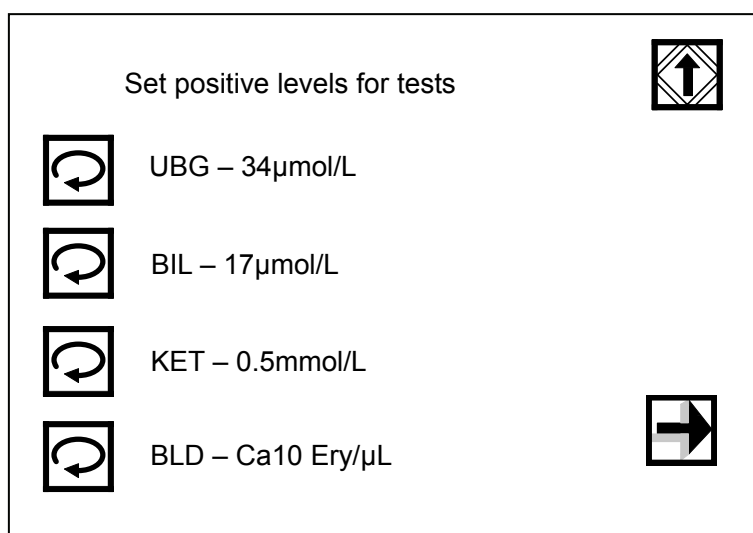
Figure 3-3-23

Users can set up PRO, NIT, LEU and GLU by pressing the key in Figure 3-3-23. Press the key corresponding to each item, the contents will be successively switched among the options shown in the following table.

Table 3-3-10

Name S/N	UBG	BIL	KET	BLD	Protein	NIT	LEU	GLU
1	17μmol/L	17μmol/L	0.5mmol/L	Ca10Ery/μL	Shadiness	Pos	Ca15Leu/μL	5.6 mmol/L
2	34μmol/L	51μmol/L	1.5mmol/L	Ca25Ery/μL	0.3g/L		Ca70Leu/μL	14 mmol/L
3	68μmol/L	>=103μmol/L	3.9mmol/L	Ca80Ery/μL	1.0g/L		Ca125Leu/μL	28 mmol/L
4	>=135μmol/L		>=7.8mmol/L	>=Ca200Ery/μL	>=3.0g/L		>=Ca500Leu/μL	>=56 mmol/L

When value of one of the test items in the test result is higher than the set abnormal value in Figure 3-3-23, "*" will appear before this item.

The result is shown in Figure 3-3-24:

```
Date: 2010-06-09 15：47
No.: 0001
ID: _ _ _ _ _ _ _ _ _ _ _ _
*UBG   1+        34μmol/L
*BIL    2+        51μmol/L
*KET    1+       1.5mmol/L
*BLD    2+       Ca80Ery/μL
PRO    Neg
NIT     Neg
LEU    Neg
GLU     Neg
SG              >=1.030
pH              <=5.0
VC              0.6 mmol/L
```

Figure 3-3-24

(11)Baud Rate, Parity Bit, Data and Stop Bit

These are used for connection between the analyzer and computer. Press the key corresponding to each

item as shown in Figure 3-3-8, the contents will be successively switched among the options shown in the following table.

Table 3-3-11

Name S/N	Baud rate	Parity bit	Data and Stop bit
1	9600	None	8, 1
2	1200	Odd	8, 2
3		Even	7, 1
4			7, 2

(12)ID Number

Press the key [icon] corresponding to "ID" as shown in Figure 3-3-9, the contents against it will be switched between "On" and "Off". When "ID" is "On", output result displays ID number; when "ID" is "Off", no ID number is displayed in the output result.

(13)Flag for Abnormal Value

Press the key [icon] corresponding to "Flag for Abnormal Value" as shown in Figure 3-3-9, the contents against it will be switched between "On" and "Off". When "Abnormal Value" is "On" and test value of one of the test items in the test result is higher than the set abnormal value, "*" will be shown in the output result; when "Abnormal Value" is "Off", there is no "*" in the output test result.

(14)Tech ID

Press the key [icon] corresponding to "Tech ID" as shown in Figure 3-3-9, the contents against it will be switched between "On" and "Off". When "Tech ID" is "Off", there is no tech ID on the test main screen (Figure 2-15); when "Tech ID" is "On", there is tech ID on the test main screen (Figure 2-15).

(15)Color and Clarity

Press the sub-interface key [icon] corresponding to "Color Clarity" in Figure 3-3-9 and the screen is shown in Figure 3-3-25:
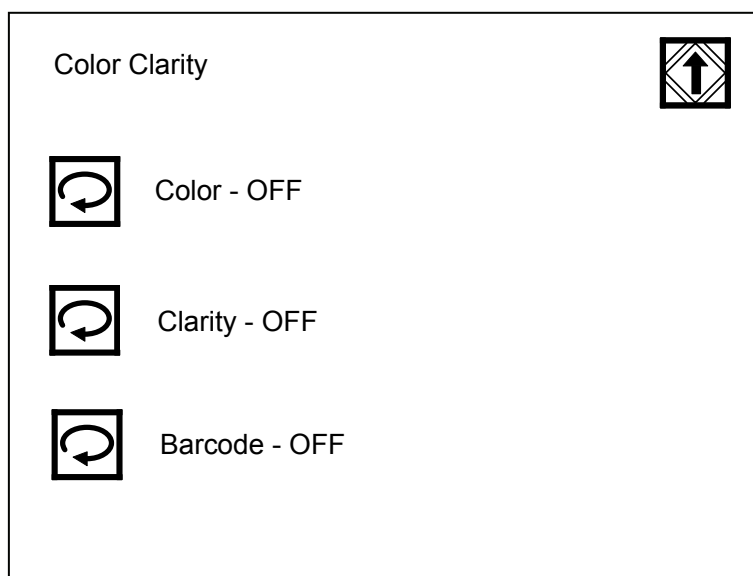
Figure 3-3-25

a)When "Color", "Clarity" and "Barcode" are all "On", press "ID" of the main menu and use external barcode

reader to scan barcodes of "Color" and "Clarity". In this case, color and clarity will be printed.

b)When "Color" and "Clarity" are "Off" while "Barcode" is all "On", press "ID" of the main men and use external barcode reader to scan barcodes of "Color" and "Clarity". In this case, color and clarity will not be printed.

c)When "Color" and "Clarity" are "On" while "Barcode" is all "Off", barcodes of "Color" and "Clarity" barcode cannot be scanned. In this case, color and clarity can be filled manually according to those of the test samples.

(16)Password Setting

Press the key [icon] corresponding to "Password Setting" as shown in Figure 3-3-10, the contents against it will be switched between "On" and "Off".

When the "Password Setting" is "Off", press the key [icon] in Figure 3-3-5 and the screen is shown in Figure 3-3-7.

When the "Password Setting" is "On", press the key [icon] in Figure 3-3-5 and the password screen is shown in Figure 3-3-6. The interface shown in Figure 3-3-7 is only available when the password entered is correct.

(17)Set or rest password

Press the sub-interface key [icon] corresponding to "Set or rest password" in Figure 3-3-10 and the screen is shown in Figure 3-3-26:

Figure 3-3-26

Screen shown in Figure 3-3-26 is for password modification. The password here is used to protect further settings shown in Figure 3-3-5. Users can use the number keys on the screen to set a new password. When the setting is completed, press [icon] to confirm and exit and new password becomes effective; press [icon] to cancel the setting and the original one remains effective.

(18)Temperature Alarm

Press the key [icon] corresponding to "Temperature Alarm" to switch between "On" and "Off". When the temperature is >37℃ or <15℃ (normal work environment temperature of the analyzer is 15℃~35℃), the analyzer will prompt an alarm.

(19)Reset all feature to defaults

Press the sub-interface key [⊙] corresponding to "Reset all feature to defaults" in Figure 3-3-11 and the screen is shown in Figure 3-3-27:

Use default value?

[Y]   [N]
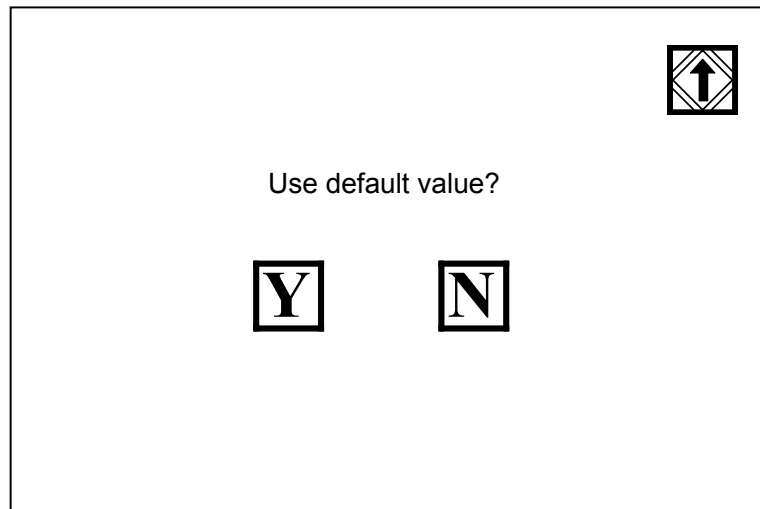
Figure 3-3-27

Press [Y] to confirm, the scaler of the analyzer will recover to original state and the screen will return to the interface shown in Figure 3-3-11.

Press [N] to cancel the setting and return to the interface shown in Figure 3-3-11.

(20)Scaler Setting

This displays scaling of value of each test item and cannot be changed randomly.

Chapter 4 Record Query and Clearing

4.1 Record Query

Press the corresponding key ⊙ for "Recall" in the screen shown in Figure 3-3-2 and the new screen is shown in Figure 4-1-1:

Recall

⊙ History record

⊙ QC record

⊙ Record Clear
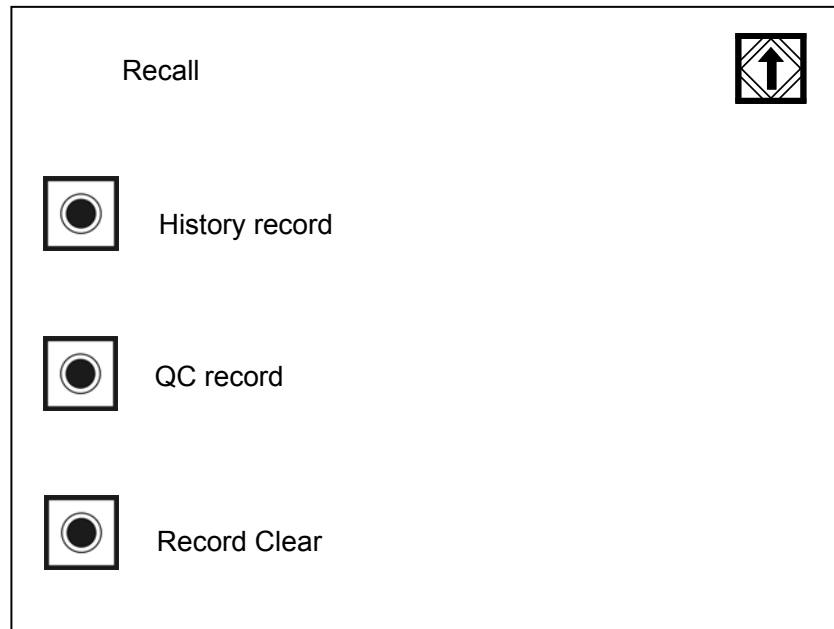
Figure 4-1-1

4.1.1 Historical Record Query

Press the corresponding key ⊙ for "Historical Record" in Figure 4-1-1 and the new screen is shown in Figure 4-1-2:

History Record

⊙ Current record

⊙ By date

⊙ By SEQ

⊙ By ID

⊙ By worklist
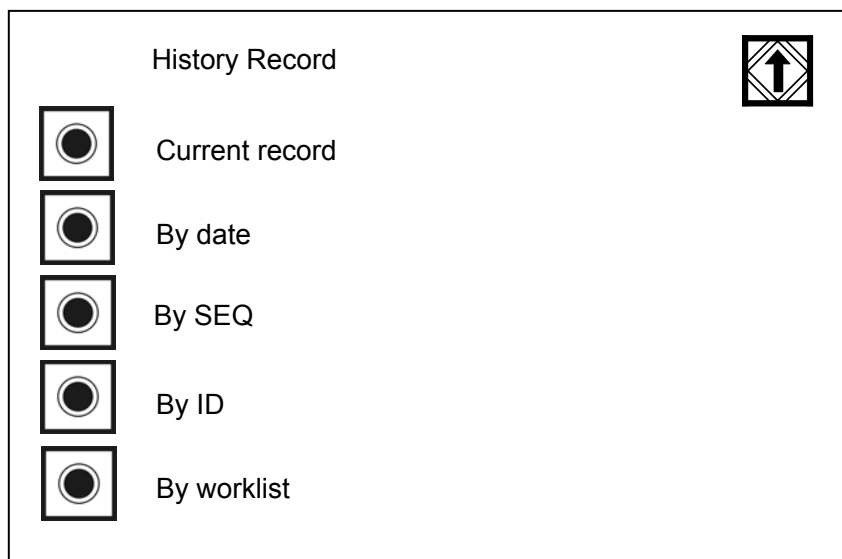
Figure 4-1-2

(1)Current Record Query

Press the key ⬤ before the "Current record" in Figure 4-1-2 and the new screen is shown in Figure 4-1-3 (take the H11 test paper for example):

```
Date： 2010-08-08  09： 13： 42        ⬆(return)
SEQ： 0001
ID：  -------------------------------
UBG            Normal   3.4µmol/L      ⬅
BIL            Neg
KET            Neg
CRE            0.9 mmol/L               ➡
* BLD          Neg
PRO            Neg
MALB           10   mg/L                ⬆
* NIT          Pos
* LEU          1+      Ca70 Leu/µL
* GLU          2+          14 mmol/L    ⬇
SG             <=1.005
pH             <= 5.0
VC             0.6 mmol/L               🖨
A： C          <3.4 mg/mmol
               Normal                   last

Color:
Clarity:
```

Figure 4-1-3

Press the return key ⬆ to return the system back to the previous menu;

Press the up-moving key ⬆ , the screen displays the former record (the sequence number is the current number minus 1);

Press the down-moving key ⬇ , the screen displays the next record (the sequence number is the current number plus 1);

Press the printing key 🖨 , print the displayed record of the screen.

(2)By date

Press the key ⬤ before the "Query Based on Date" in Figure 4-1-2 and the new screen is shown in Figure 4-1-4:

Figure 4-1-4

Press the key to cancel query and return to the upper menu.

After entering the date, press the key in Figure 4-1-4, and the new screen is shown in Figure 4-1-5 (take the H11 test paper for example):

Figure 4-1-5

Press the key to cancel query and return to the upper menu.

Press the up-moving key , the screen displays the former record (the sequence number is the current number minus 1);

Press the down-moving key , the screen displays the next record (the sequence number is the current number plus 1);

Press and to display the serial number-1 or serial number+1 of test records within the query date;

Press the printing key , print the displayed record of the screen.

(3)By number

Press the key before the "Query Based on Serial Number" in Figure 4-1-2, and the new screen is shown in Figure 4-1-6:

Figure 4-1-6

The user can enter the serial number between 0001-9999 via number key. After entering the serial number, press

 for confirmation and the record for the serial number entered will be displayed in the screen, which is

shown in Figure 4-1-5, and then press Print Key to print the record.

(4)By ID

Press the key before the "By ID" in Figure 4-1-2 and the screen is shown in Figure 4-1-7:

Figure 4-1-7

Enter the ID via number key and press [↵] for confirmation and the new screen is shown in Figure 4-1-8 (take H11 test paper for example):


```
Date: 2010-06-09 09 : 13 : 42
S/N: No. 0001
ID: --------------------------------
UBG
BIL            Normal      3.4µmol/L
KET            Neg
*BLD           Neg
PRO Neg        + -    Ca10 Ery/µL
NIT
*LEU           Neg
*GLU           + -    Ca15 Leu/µL
SG             2+     14mmol/L
pH             >=1.030
Vitamin C      5.5
               2.8 mmol/L
```

Figure 4-1-8

If the analyzer has stored the record, the record for corresponding serial number will be displayed in the screen. Otherwise, "No Record" will be displayed.

(5)By worklist

Press the key [●] before the "By worklist" in Figure 4-1-2 and the new screen is shown in Figure 4-1-9:


```
Enter Worklist:
01

  7    8    9

  4    5    6

  1    2    3

  0         ↵
```

Figure 4-1-9

The record can be queried based on the set work group. After entering the work group, press key [↵] in Figure 4-1-9 and the new screen is shown in Figure 4-1-8.

4.1.2 QC Record

The analyzer can store 200 QC records.

Press the key [◉] before the "QC Record" in Figure 4-1-1 and the screen is shown in Figure 4-1-10:

```
┌─────────────────────────────────────────────┐
│                                               │
│       QC   RECORDS                   [⬆]      │
│                                               │
│                                               │
│     [◉]    Current Record                     │
│                                               │
│                                               │
│     [◉]    By date                            │
│                                               │
│                                               │
│     [◉]    By SEQ                             │
│                                               │
└─────────────────────────────────────────────┘
```
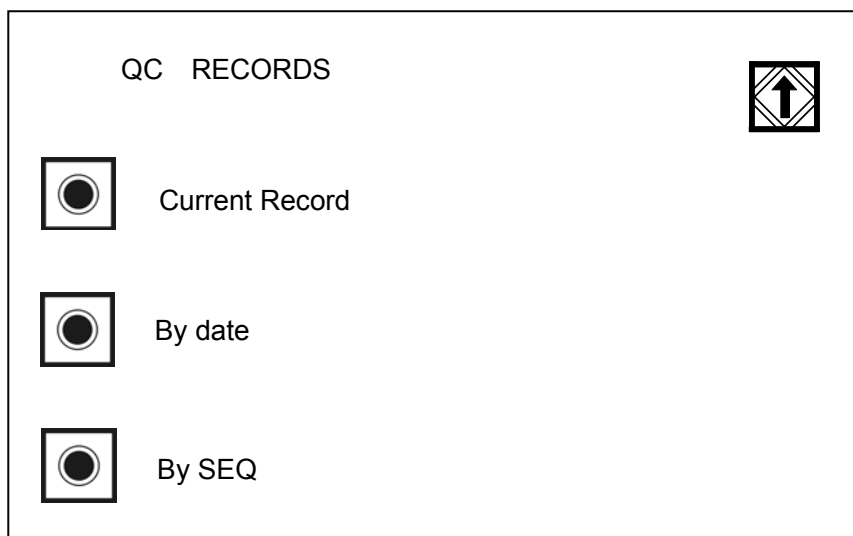
Figure 4-1-10

If the analyzer has stored the record, the record for corresponding serial number is displayed in the screen. Otherwise, "No Record" will be displayed. Press [⬆] and [⬇] to view the record; press Print Key [🖨] to print the record for serial number displayed in the screen; press [⬆] to return to the previous step.

4.2 Record Clearing

In Figure 4-1-1, press the key [◉] before "Record Clear" and the screen is shown as follows:

```
┌─────────────────────────────────────────────┐
│                                               │
│     Record                           [⬆]      │
│                                               │
│                                               │
│                                               │
│     [◉]    Clear History records              │
│                                               │
│                                               │
│                                               │
│     [◉]    Clear QC record                    │
│                                               │
└─────────────────────────────────────────────┘
```
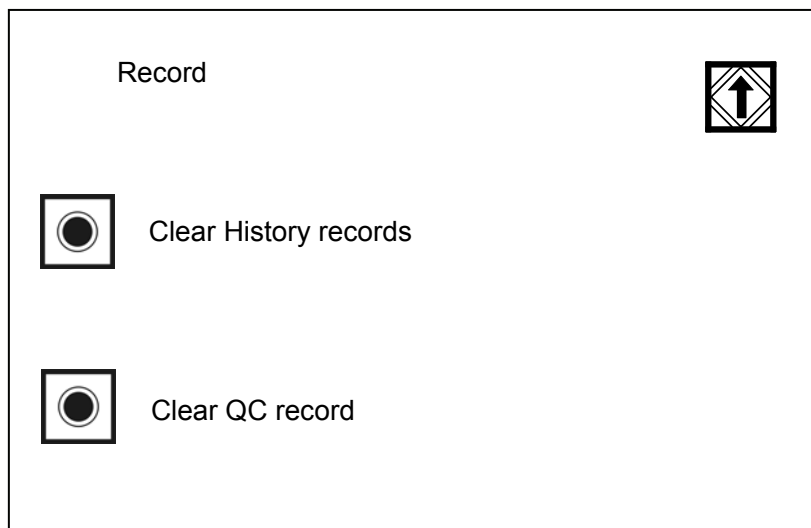
Figure 4-2-1

Press the key [◉] in front of "Clear history record" and "Clear QC record" and the screen is shown in Figure 4-2-2:
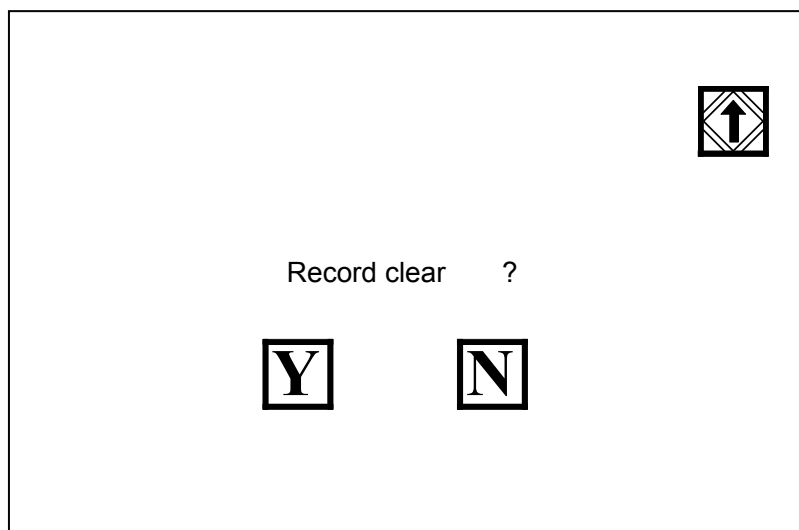
Figure 4-2-2

After pressing **Y**, the screen will display "Please wait..." and the system will clear all stored records and return to the upper menu.

4-8

Chapter 5 Quality Control and Calibration

5.1 Test on Quality Control Liquor

In order to ensure the accuracy of the test result, Dirui positive and negative urine can be used for analyzing quality control liquor for quality control monitoring under the following cases.

(1)When before daily test

(2)When replace a roll of test paper

(3)When change a new operator

(4)When the test results are questionable

Test method: in the interface of main screen shown in Figure 5-1-1, press the corresponding [image] of "Control" to enter into the screen of "Test on Quality Control Liquor", which is shown in Figure 5-1-2.
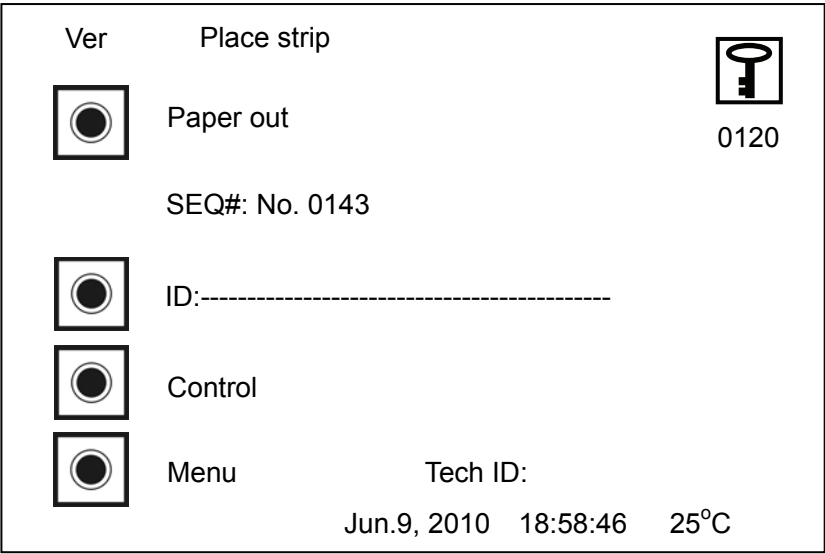
Figure 5-1-1
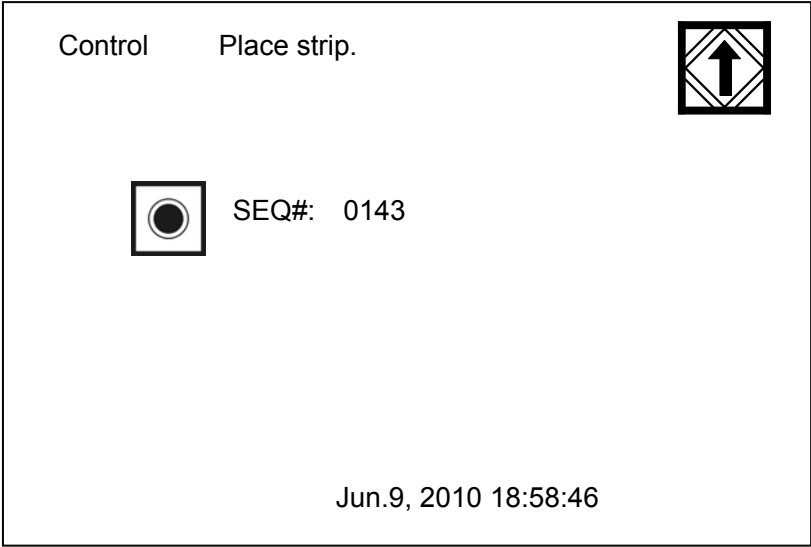
Figure 5-1-2

Put the reagent strips with urinalysis control liquor onto the strip-examining section (Figure 5-1-3), when the analyzer detects the existence of the strip, the pusher will push the reagent strip to the test section (Figure 4-1-4),

and the test result will be output after the test. Press [↑] to return to the main screen (Figure 5-1-1). Refer to the reference value in the quality control liquor instruction for whether the result is qualified.
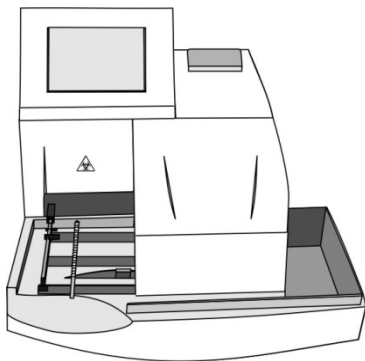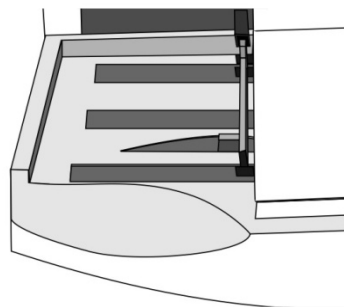
Figure 5-1-3   Figure 5-1-4

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.

5.2 Test the Calibration Strip

● **Do not dip calibration strip into water or any other liquid.**

● **There are one calibration strip equipped with the analyzer;**

● **If the calibration strip has been besmirched or damaged, please contact the supplier. Do not continue to use this calibration strip;**

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

Test method: Select "Calibration strip testing" in the screen in Figure 3-3-10 to enter the screen shown in Figure 5-2-1.

Place the calibration strip
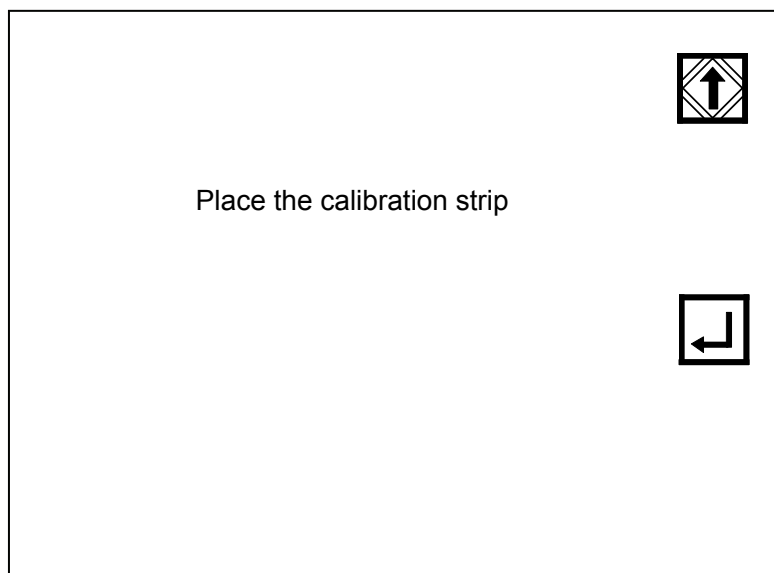
Figure 5-2-1

Put the calibration strip on the work table in strip inspection area, which is shown is Figure 5-2-2.
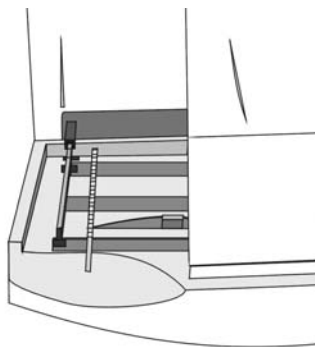
Figure 5-2-2

Press the key ![key] in Figure 5-2-1 to test the calibration strip and print the result upon completion of test.

If it can pass the calibration, test result is "Calibration OK". If it fails to pass the calibration, test 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.

Chapter 6 Conventional Urine Test

⚠

● **The urine sample may have potential infectivity; protective measures should be taken during testing, cleaning, or maintenance.**

● **Please dispose the urine sample and the waste strips according to the local regulation.**

This chapter tells the methods of conducting conventional urine test on H Series Urine Analyzer (Model: H-500). Before the test, please read "Chapter 3 Functions and Setup" for full details.

6.1 Form of Test Operation Process

```
┌─────────────────────────────┐
│ Power on the analyzer and   │
│ enter the self-testing      │
└─────────────────────────────┘
              │
              ▼
        ┌───────────┐   N    ┌───────────────────────┐
        │Self-testing├──────►│  See the Appendix D   │
        └───────────┘        └───────────────────────┘
              │ Y
              ▼
        ┌───────────────┐
        │  Main screen  │
        └───────────────┘
              │
              ▼
┌─────────────────────────────────────┐
│ Put the strip to be tested onto the │
│ strip inspection area and use pusher│
│ to move the strip to testing area to│
│ start test.                         │
└─────────────────────────────────────┘
              │
              ▼
        ┌────────────────────┐
        │ Print out the result│
        └────────────────────┘
              │
              ▼
        ┌───────────┐    Y
        │ Continue  ├────────►
        └───────────┘
              │ N
              ▼
        ┌───────────┐
        │ Power off │
        └───────────┘
              │
              ▼
        ┌────────────────┐
        │Clean the analyzer│
        └────────────────┘
```
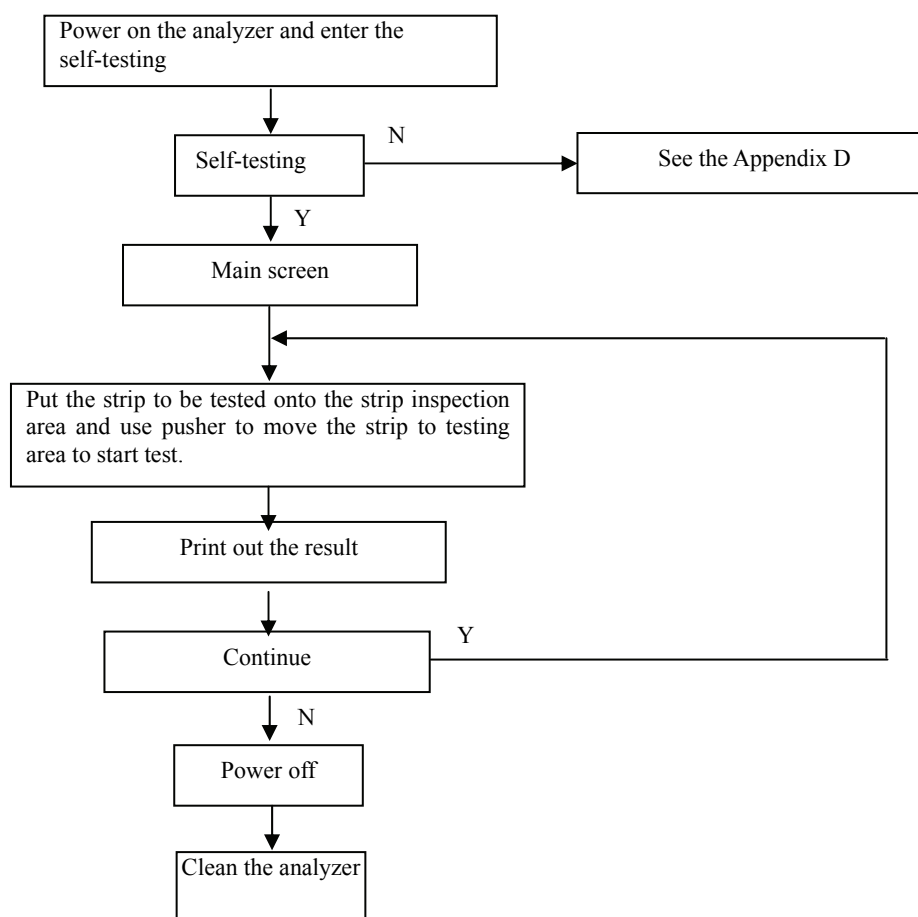
Figure 6-1-1

⚠

● **For the specific operation please read the test operation process in Section 6.2.**

● **When the self-testing doesn't pass, please refer to the malfunction information list in Appendix D.**

6.2 Test Operation Process

⚠

● **Do not place the analyzer in the area with direct sunlight for fear of affecting the precision of test.**

● **Check the type of the reagent strips before test carefully, so as to avoid the wrong test results because of the wrong type of strips used.**

● **Do not use the reagent strip that has been expired or degenerative.**

6.2.1 Check the Worktable

Before the analyzer starts, make sure that the worktable and white bench mark are clean. Clean corresponding parts according to "Chapter 6 Cleaning and Maintenance".

White bench mark
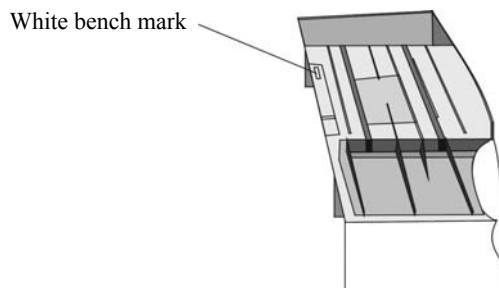
Figure 6-2-1

6.2.2 Power on the Analyzer

After finishing installing the analyzer, power on it, the system will conduct self-testing. The following figure will appear after self-testing:
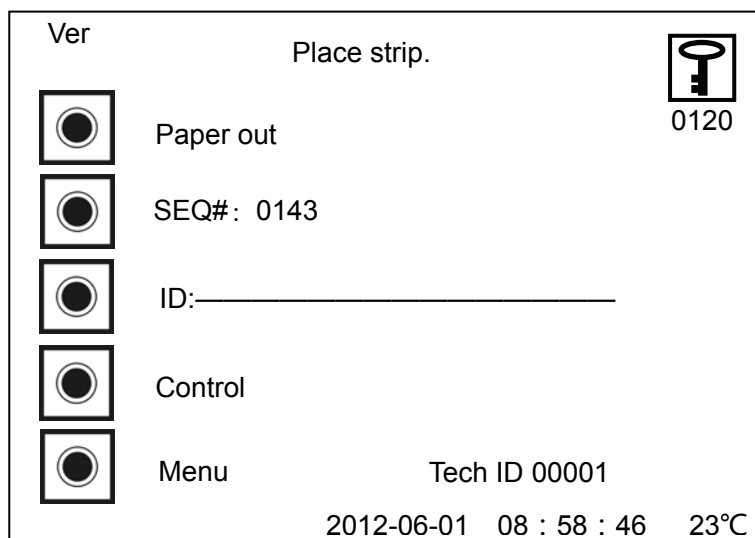
Figure 6-2-2

ID number is a sample code scanned by bar code reader. The Analyzer could connect bar cord reader through the RS-232 port. ID number will be showed in the output report. ID number can be scanned by bar code reader or input manually.

(1)Manual input: press the in front of "ID" in Figure 6-2-2 and the screen is shown as follows:

Figure 6-2-3

Press the number key to input relevant numbers. Press ⬅ and ➡ to move the cursor. Press ⬆ to set the previous ID number. If the ID number includes capital letters, please press ➡ to enter the screen shown in Figure 6-2-4.

Figure 6-2-4

Enter the ID number based on the corresponding capital letters; If the ID number involves small letter, then press ➡ on the lower right corner of the screen to enter into the small letter screen, which is shown in Figure 6-2-5:
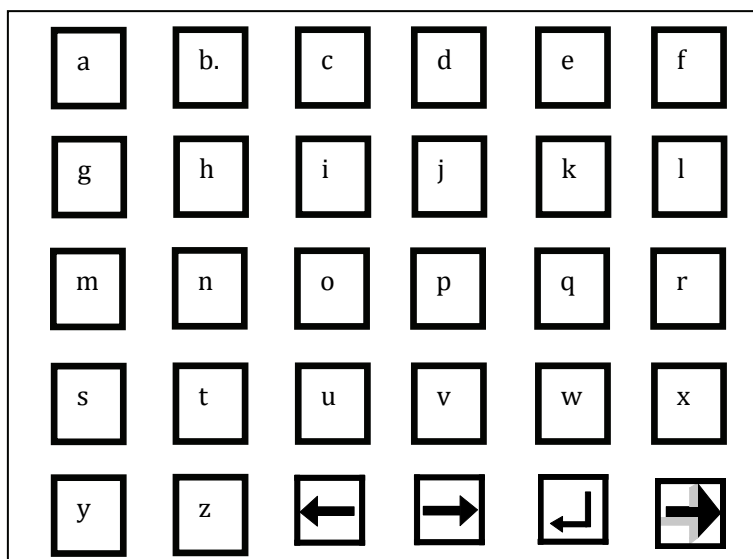
Figure 6-2-5

Enter the ID number according to corresponding small letters; Press to confirm and return to the previous menu. The cursor will stay on the next sample number. The operator can continue to enter the ID number of next sample.

Press the number key to input the corresponding letters, press and to move the cursor. Press to make confirmation.

(2)Scan the ID number entered: in the screen in Figure 6-2-3, use external barcode scanner to directly scan the input information. The barcode scanned will be displayed behind the corresponding sample number. Continuous scanning is allowed and the interface allows automatic page turning.

Upon completion of inputting ID number, press to return to the main menu and normal test can be conducted.

6.2.3 Conventional Test

Test speed for the analyzer is 514 reagent strips per hour; the test time for each reagent strip is 7 seconds. The operation method is as follows:

Step 1: Pusher is at the start location after self-testing.

Step 2: Put the reagent area of the reagent strips completely into the fresh, completely mixed, uncentrifuged urine sample and take it out immediately by moving the side of the reagent strip along the inside wall of the urine container to get rid of excessive urine.

Step 3: Place the reagent strip on the work place, and make sure that the front end of the reagent strip contacts the front wall of the work table (Figure 6-2-6). When analyzer detects the existence of the reagent strip, it will push the strip to the test section (Figure 6-2-7).

Step 4: When pusher returns to the start position (Figure 6-2-8), put another reagent strip to keep testing
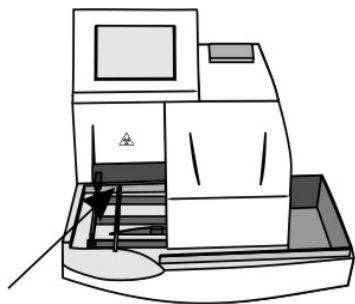
Front wall of worktable
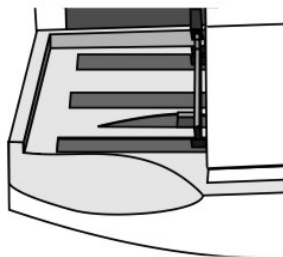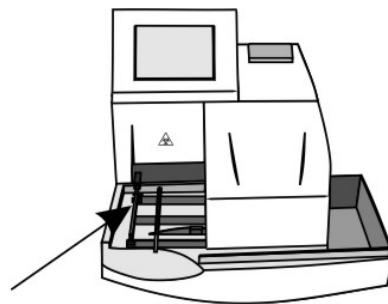
start position of pusher

Figure 6-2-6   Figure 6-2-7   Figure 6-2-8

⚠

Don't put reagent strip when the pusher is moving.

Chapter 7 Cleaning and Maintenance

⚠️

● **Do not clean the analyzer when the power is on.**

● **Do not use any organic solvent such as petrol, thinner lacquer, benzene compounds which may erode the analyzer 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 bench mark.**

● **If there is apparent scrape on white bench, please contact the supplier.**

● **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.**

7.1 Daily Cleaning

(1)The analyzer can be wiped by soft dry cloth or soft cloth with little 75% alcohol to keep it clean.

(2)LCD can be wiped by soft and no abrasion cloth.

(3)In order to make the analyzer work normally and provide correct test result, the worktable must keep clean.

(4)Draw out the pusher, worktable and step-wise board from the analyzer gently. After washing with fresh water, wipe them with soft cloth.

(5)Wipe the white bench mark clean with soft dry cloth.

(6)Install the parts well according to Chapter 2.

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

7.2 Periodical Cleaning

If there is accumulated dirt on the pusher, worktable and step-wise board, cleaning can be done according to the following procedures:

(1)Prepare a little 0.1 mol/L NaOH solution.

(2)Draw out the pusher, worktable and stepping board from the analyzer in sequence.

(3)Wipe them thoroughly by the cotton bar dipped with 0.1 mol/L NaOH solution. Clean the residual NaOH solution by fresh water.

(4)Wipe and dry those with soft cloth, install them well according to the requirements of Chapter 2.

(5)Restart the analyzer for self-testing.

⚠️

● **Do not get the white bench mark contact with NaOH solution.**

● **It is recommended that the analyzer should be cleaned based on this method every day.**

7.3 Disinfection

(1)As the pusher, worktable and step-wise board contact with the urine sample, they should be disinfected.

(2)Each of the following solutions can be used to conduct disinfections:

   ---2% glutaric dialdehyde solution

---5% sodium hypochlorite solution

(3)Pour some disinfect liquid into an appropriate container.

(4)Immerse the pusher, worktable and step-wise board into the disinfect liquid, and make sure the white bench mark does not contact the liquid.

(5)Immerse them for 10 minutes.

(6)Clean the disinfect liquid with water that remains on the above items after removing them from the disinfect liquid.

(7)Wipe and dry the pusher, worktable, step-wise board and the white benchmark with a soft cloth in turn, install them well according to the requirements of Chapter 2.

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

⚠️

● **Repeat to use glutaric dialdehyde solution for long may lead to the color change of work table, but the results will not be affected.**

● **Do not get the white bench mark contact disinfect liquid.**

7.4 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 waste groove on the right of the analyzer.

(2) Clean and sterilize the worktable, pusher, and stepping board. For detailed operation, refer to 7.2 and 7.3.

7.5 Analyzer cleaning

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.

7.6 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.

7.7 Disposal of Scraped Analyzer

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

Chapter 8 Transportation and Storage

8.1 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.

8.2 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 $-40℃ \sim 50℃$; and the relative humidity is no more than 80%.

8-2

Appendix A Manufacturer's Warranty

Dear customers:

Thank you for purchasing H-500 urine analyzer. Our company will provide 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)The warranty period for the product has been expired.

    b)Damage caused by accidental factor or improper use.

    c)Damage caused by the operation that not according to the instruction manual or without our company's permission.

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

If you need any technical support, please contact us according to 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: 4008 116 695, 400 811 6605

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

E-mail: dirui@dirui.com.cn

Telephone for complaint: +86(431)81935326   +86(431)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

A-2

Appendix B Communication with Computer

H Series Urine Analyzer (Model: H-500) links to computer through RS-232 standard serial port. The communication agreements are as follows:

Baud rate   9600bps, 1200bps (optional)

Date bit   8 bits, 7bits (optional)

Stop bit   1 bit, 2bits (optional)

Parity bit   None

Hardware handshake   None

Start symbol   02H

Single byte blank   20H

Double byte blank   40H

Line break   0DH0AH

End mark   03H

Linkage between H-500 urine analyzer and the computer:
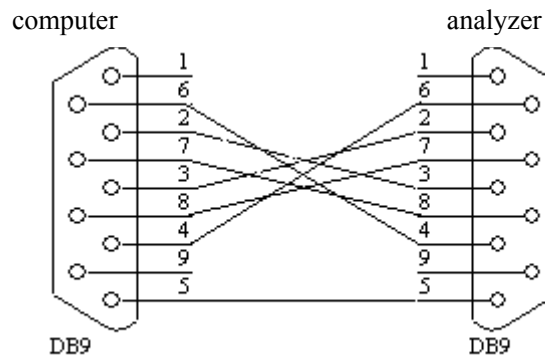
International Unit, conventional unit, Plus System Communication Format (Bar Code scanner is Off):

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(•)	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	
ETX																							

International Unit, conventional unit, Plus System Communication Format (Bar Code scanner 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	:	×	×	×	×	-	×	×	-	×	×	SP	×	×	:	×	×	CR	LF
SP	N	o	.	SP	×	×	×	×	CR	LF													
SP	I	D	:	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF			
SP(•)	U	B	G	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP(•)	B	I	L	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF	
SP(•)	K	E	T	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	
ETX																							

CT200 Output Format:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
STX	CR	LF																			
#	×	-	×	×	×	SP	SP	SP	SP	SP	SP	×	×	-	×	×	-	×	×	CR	LF
U	B	G	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
B	I	L	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
K	E	T	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
B	L	D	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
P	R	O	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
N	I	T	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
L	E	U	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
G	L	U	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
S	G	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
p	H	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
V (A)	C (L)	SP (B)	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
ETX																					

DR200 Output Format:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
STX	CR	LF																		
SP	N	O	.	×	×	×	SP	SP	×	×	-	×	×	-	×	×	×	×	CR	LF
SP	SP	SP	SP	SP	SP	SP	SP	SP	SP	SP	×	×	:	×	×	:	×	×	CR	LF
CR	LF																			
SP	p	H	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	N	I	T	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	G	L	U	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	V	C	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	S	G	SP	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	B	L	D	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	P	R	O	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	B	I	L	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	U	R	O	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	K	E	T	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	W	B	C	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
SP	(A)	(L)	(B)	SP	×	×	×	×	×	×	×	×	×	×	×	×	×	×	CR	LF
CR	LF																			
ETX																				

Note:

SP (*)--- SP or*   STX=0X02   CR=0X0D   LF=0X0A

SP=0X20   ETX=0X03   X=any ASCII character

Appendix C Analyzer Output Value

Project	Abbreviation	Conventional unit		International unit		Plus system unit
		Plus system - ON	Plus system - OFF	Plus system - ON	Plus system - OFF	
UBG (Urobilinogen)	UBG	Normal 0.2 mg/dL Normal 1 mg/dL 1+ 2 mg/dL 2+ 4 mg/dL 3+ >=8 mg/dL	0.2 mg/dL 1 mg/dL 2 mg/dL 4 mg/dL >=8 mg/dL	Normal 3.4μmol/L Normal 17 μmol/L 1+ 34 μmol/L 2+ 68 μmol/L 3+ >=135 μmol/L	3.4μmol/L 17 μmol/L 34 μmol/L 68 μmol/L >=135 μmol/L	Normal Normal 1+ 2+ 3+
BIL (Bilirubin)	BIL	Neg 1+ 1 mg/dL 2+ 3 mg/dL 3+ >=6 mg/dL	Neg 1 mg/dL 3 mg/dL >=6 mg/dL	Neg 1+ 17 μmol/L 2+ 51 μmol/L 3+ >=103 μmol/L	Neg 17 μmol/L 51 μmol/L >=103 μmol/L	Neg 1+ 2+ 3+
KET (Ketone)	KET	Neg +- 5 mg/dL 1+ 15 mg/dL 2+ 40 mg/dL 3+ >=80 mg/dL	Neg 5 mg/dL 15 mg/dL 40 mg/dL >=80 mg/dL	Neg +- 0.5 mmol/L 1+ 1.5 mmol/L 2+ 3.9 mmol/L 3+ >=7.8 mmol/L	Neg 0.5 mmol/L 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L	Neg +- 1+ 2+ 3+
BLD (Blood)	BLD	Neg Ca10 Ery/μL +- Ca25 Ery/μL 1+ Ca80 Ery/μL 2+ >= Ca200 Ery/μL 3+	Neg Ca10 Ery/μL Ca25 Ery/μL Ca80 Ery/μL >= Ca200 Ery/μL	Neg +- Ca10 Ery/μL 1+ Ca25 Ery/μL 2+ Ca80 Ery/μL 3+ >=Ca200Ery/μL	Neg Ca10 Ery/μL Ca25 Ery/μL Ca80 Ery/μL >= Ca200Ery/μL	Neg +- 1+ 2+ 3+
PRO (Protein)	PRO	Neg Trace 1+ 30 mg/dL 2+ 100 mg/dL 3+ >=300 mg/dL	Neg Trace 30 mg/dL 100 mg/dL >=300 mg/dL	Neg Trace 1+ 0.3 g/L 2+ 1.0 g/L 3+ >=3.0 g/L	Neg Trace 0.3 g/L 1.0 g/L >=3.0 g/L	Neg Trace 1+ 2+ 3+
MALB (Microalbumin)	MALB	Neg 15 mg/dL >15 mg/dL	Neg 15 mg/dL >15 mg/dL	Neg 0.15g/L >0.15g/L	Neg 0.15g/L >0.15g/L	Neg 0.15 >0.15
NIT (Nitrite)	NIT	Neg Pos	Neg Pos	Neg Pos	Neg Pos	Neg Pos
LEU (Leukocytes)	LEU	Neg Ca15 Leu/μL +- Ca70 Leu/μL 1+ Ca125 Leu/μL 2+ >=Ca500 Leu/μL 3+	Neg Ca15 Leu/μL Ca70 Leu/μL Ca125 Leu/μL >=Ca500 Leu/μL	Neg Ca15 Leu/μL +- Ca70 Leu/μL 1+ Ca125 Leu/μL 2+ >=Ca500 Leu/μL 3+	Neg Ca15 Leu/μL Ca70 Leu/μL Ca125 Leu/μL >=Ca500 Leu/μL	Neg +- 1+ 2+ 3+
GLU (Glucose)	GLU	Neg 100 mg/dL 1+ 250 mg/dL 2+ 500 mg/dL 3+ >=1000 mg/dL 4+	Neg 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL	Neg 1+ 5.6 mmol/L 2+ 14 mmol/L 3+ 28 mmol/L 4+ >=56 mmol/L	Neg 5.6 mmol/L 14 mmol/L 28 mmol/L >=56 mmol/L	Neg 1+ 2+ 3+ 4+
SG (specific gravity)	SG	1.010 1.015 1.020 1.025 >=1.030	1.010 1.015 1.020 1.025 >=1.030	1.010 1.015 1.020 1.025 >=1.030	1.010 1.015 1.020 1.025 >=1.030	<=1.005 1.010 1.015 1.020 1.025 >=1.030
PH	pH	5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	<=5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	<=5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	<=5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	<=5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Vitamin C	VC	0 mg/dL 10 mg/dL 25 mg/dL 50 mg/dL >=100 mg/dL	0 mg/dL 10 mg/dL 25 mg/dL 50 mg/dL >=100 mg/dL	0 mmol/L 0.6 mmol/L 1.4 mmol/L 2.8 mmol/L >=5.7 mmol/L	0 mmol/L 0.6 mmol/L 1.4 mmol/L 2.8 mmol/L >=5.7 mmol/L	0 0.6 1.4 2.8 >=5.7

Appendix D Malfunction Information List

No.	Message	Cause	Solution
1	Nothing was shown on the screen	It doesn't connect the power wire well	(1)Check whether the power supply is normally electrified. (2)Check whether the tube fuse is damaged. (3)Contact with the supplier if the trouble cannot be removed.
2	The printer doesn't work	Have not set the printer properly, or the paper cannot move smoothly	(1)Check whether set "int. printer" in "on" or not. (2)To see is there any paper in the printer. (3)Check if the paper goes aside to jam the printer, if yes, re-install the printer. (4)If these methods don't work, please contact the supplier.
3	The test result is wrong	The type of the strip is wrong	(1)Check whether the type of the strips is accorded with the Setup or not. (2)If this method doesn't work, please contact the supplier.
4	Screen shows "Calibration not found"	The white benchmark damaged, lost or stained. Photocoupler damaged	(1)Replace a new white benchmark. (2)Replace a new photocoupler. (3)Wipe white benchmark. (4)Restart analyzer for self-testing. (5)If these no work, please contact with supplier.
5	Screen shows "strip missing"	Strip does not conveyed to test area	(1)Restart the analyzer for self-testing. (2)Clean worktable. (3)Check up the strip type. (4)Check if there is object on the worktable or cover. (5)If these do not work, please contact with supplier.
6	Screen shows "Calibration not OK"	White benchmark dirty Radiation tube aging Calibration strip dirty	(1)Power off the analyzer and retest. (2)Clean white benchmark. (3)Replace calibration strip. (4)If these do not work, please contact with supplier.
7	Screen shows "CENTER NOT OK"	Do not find the central value	(1)Repower on the analyzer for self-testing. (2)Contact with supplier.
8	Screen shows "Stray light warning"	Ambient light abnormal Analyzer is under direct sunlight or twinkling light source	(1)Keep the analyzer away from direct sunlight. (2)Power off the twinkling light source. (3)Restart the analyzer.
9	Screen shows "Strip error"	Strip type is wrong	(1)Check if the set strip type is according with used strip type. (2)Check if the strip immerged urine sample totally. (3)If these do not work, please contact with supplier.
10	Pusher does not work	Optic detector does not work normally	(1)Check is there is direct sunlight. Keep the analyzer away from the sunlight. (2)If this does not work, please contact with supplier.
11	Screen shows "Test system error"	Test system trouble	(1)Restart analyzer for self-check. (2)Please contact with supplier.
12	Screen shows "Strip push system error"	Strip pushing system trouble	(1)Restart analyzer for self-check. (2)Please contact with supplier.
13	Screen shows "Strip moving error"	Strip conveying system trouble	(1)Restart analyzer for self-check. (2)Please contact with supplier.
14	Screen shows "Green light error"	Failure of 525nm LED	(1)Restart analyzer for self-check. (2)Please contact with supplier.
15	Screen shows "Kelly light error"	Failure of 572nm LED	(1)Restart analyzer for self-check. (2)Please contact with supplier.
16	Screen shows "Orange light error"	Failure of 610nm LED	(1)Restart analyzer for self-check. (2)Please contact with supplier.
17	Screen shows "Red light error"	Failure of 660nm LED	(1)Restart analyzer for self-check. (2)Please contact with supplier.

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
Work Table	Work Table Assembly	5 years	2.3.4	
Stepping board	Transmission Case Unit	5 years	2.3.2	
Pusher	Strip Feeding Assembly	5 years	2.3.5	
Left Support	Left/Right Support Assembly	2 years	Contact the service staff.	Inspected or replaced by the representative from the manufacturer or distributor only.
Strip	Work Table	Timely		
Thermal Printing Paper	Internal Printer	Timely	2.3.6	
Calibration Strip	Work Table	Timely		

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