MR International Healthcare Technology Co.,Ltd.

BW-300

Semi Auto Urine Analyzler
User's Manual

MR International Healthcare Technology Co.,Ltd.

CE IVD

Description

Thank you for purchasing auto urine analyzer.

Before using the product, please reading this manual carefully, and correctly use the product.

After reading, please properly save user manual, and reading it at any time.

Warning

●Don't use wet hand to pull out the power, it may get an electric shock.

●Don’t use damaged wires and connecting cables. Don’t trample, twist or pull the wires and cables. If the wires and cables are broken, it may cause a fire.

●The analyzer must be used under good earthing.

●Confirm that the input voltage meets the requirements of the instrument, using the specified specifications fuse.

●Before connect the power cable, please confirm analyzer switch is in a state of [0].

●Do not be used in inflammable and explosive environment.

●During the instrument running, please do not contact with moving parts to avoid accidents.

Attention

●The instrument must be used by medical laboratory professionals or trained doctors, nurses or or laboratory technicians.

●The hospitals or inspection organizations should prepare a maintenance plan, and in strict accordance with the it to maintenance, otherwise it may result in equipment failure.

●Please use and save the test strips refer to the user manual, and ensure to use them in the period of validity.

●Don't use the test strips that exceed of period of validity.

●Don't use turpentine oil, benzene to clean the external of instrument, because it may cause the change of the color and shape. Scrub with a soft cloth or wet cloth. For serious besmirch, clean with diluted detergent or alcohol.

●Winter outdoor temperature is lower, the instrument should be save at room temperature for 24 hours , then use it to test.

Biological hazard mark.

● Operators have an obligation to abide the region/ country rules for reagents, consumables and other emissions, waste liquid and waste sample processing.

●Sample has potential biological risk of infectious, may irritate eyes, skin and mucous membrane. Operators should comply with the requirements of the laboratory safety operation, and dressed in personal equipment (e.g., gloves) when contact related items in the laboratory.

●Correctly handling equipment consumables.

●Don't reuse of disposable product

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Chapter 1 Introduction to urine analyzer

【**Product name**】Urine Analyzer

【**Model**】BW-300

【**Company name**】MR International Healthcare Technology Co.,Ltd.

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【**Product specification NO.**】YZB/Lu 0439-2014

【**Date of manufacture**】See the main engine nameplate

【**Service life** 】8 years

【**Structural composition**】Sample introduction, photo processing system, control system, analysis and processing software, display system, printing system, waste liquid waste collection device.

【**Range of application**】Routine urine dry chemical analysis, and the urine analysis strip, according to the dipsticks reagent area produced by reaction with biochemical components in urine samples, the color change of the detection of urine samples in urine bravery former, bilirubin, ketone body, blood, protein, nitrite, white blood cells, glucose, PH, specific gravity, creatinine, calcium ion, trace albumin.

【**Notes, warnings and suggestive statements**】

1. Do not place the analyzer in direct sunlight during the test to avoid the failure of the bar device or abnormal data output.

2. Do not touch the two belts, the display screen and the shell with any sharp tools to avoid damage;Do not use gasoline, paint thinner and other organic solvents to wipe the belt, the shell, these solvents will make the analyzer parts deformation or life shorter, affect the work of the instrument, only can use the manufacturer designated clean cotton clean belt, with a clean cloth dipped in water or diluted cleaning agent to scrub the instrument shell.

3. After the instrument is shut down, it must wait 1 minute before starting up to avoid damaging the instrument circuit.

4. Perform quality control on the urine analyzer with the standard bar every day, and the test results shall be consistent with the test values in the standard bar; otherwise, the equipment shall be stopped and the manufacturer or supplier shall be notified for maintenance.

5. The test paper type specified by the manufacturer must be used as required, otherwise the accuracy of the test results cannot be guaranteed.

6. When placing the equipment, please do not block the power plug and socket of the equipment to ensure that in case of emergency, the plug can be disconnected in time to cut off the power supply of the equipment.

【Software version】BW-300.1

【Function】

a) Should be able to boot self - check, identify and report errors;

b) The resulting units shall have at least the international system of units;

c) Should have output port;

d) Should be able to store test data;

e) The instrument shall have a calibration function.

【Performance】

1、Repeatability

The CV of the analyzer image recognition test results is less than 1%.

The variation coefficient (CV) of each color block on the strip was less than 1% after 20 tests of the same strip.

2. Accuracy

The difference between the test result of the adaptive urine analysis strip and the marked value of the corresponding reference solution shall not be more than one order of magnitude in the same direction, and the reverse difference shall not occur.The positive reference solution shall not have a negative result, and the negative reference solution shall not have a positive result.

3. Stability

Within 8h after the analyzer was started, the CV of the image recognition test results did not exceed 1%.

4. Test speed

The analyzer shall test samples at a speed of not less than 500 pieces per hour.

5. Carrying pollution

Test the positive samples with the highest concentration results of all test items except specific gravity and PH, then test the negative samples, and the negative samples shall not be positive.

6, Safety

Comply with appendix 1.Safety requirements, test methods and inspection rules and appendix 2. Safety requirements and test methods.

7. Environmental experiment

Comply with GB/ t14710-2009 requirements.

8. Electromagnetic compatibility

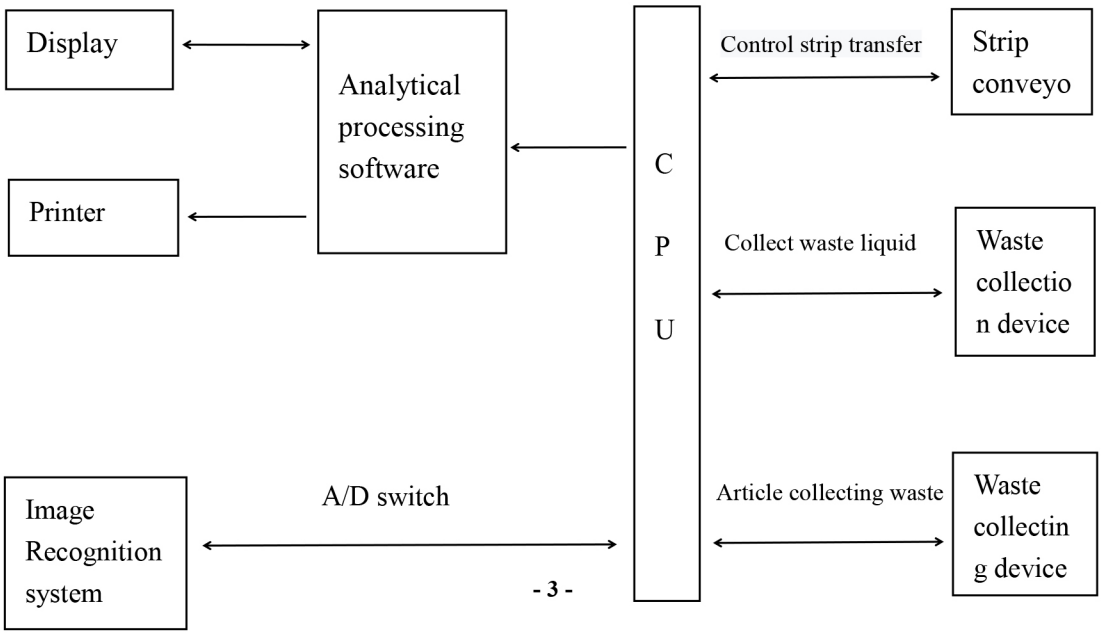
Comply with GB/ t18268.1-2010 and GB/ t18268.26-2010.

1.2 Introduction

The urine analyzer adopts the dry chemical method, and the color change occurs in the chemical reaction between the color block on the paper strip and the different component indicators in the urine (the concentration of individual components in the urine corresponds to the color change of the color block).On the principle of analysis, the paper strip soaked in urine was captured by the camera to form an image, and the position of the color block of the paper strip was automatically identified. Then the color of the color block was corrected and restored, and then the color gradient of the color block was compared with the standard color block for analysis, so as to obtain the index data of each component in the urine.

When steeped the urine samples of the strip are placed in the article into the system (belt), the instrument of transfer units in accordance with the procedures set transfer dipsticks, transferred to the set position, the image recognition system of the current strip Figures, identification and correction of various pieces of color, and compared with the standard color of the system, it is concluded that the current of each component content in urine samples.Compared with the traditional color recognition testing method, this method is simple, intuitive and accurate.

The principle block diagram of the urine analyzer is shown as follows:



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1.3 technical index

Test item	Urinogen (URO) Bilirubin (BIL) Ketone body (KET) Blood (BLD) Protein (PRO) Nitrite (NIT) Leukocyte(LEU) Glucose (GLU) Specific gravity(SG) Calciumion (Ca) Microalbumin (MAL) Creatinine (CRE) Power of hydrogen(PH)
Test principle	color changes occur in chemical reactions between the color blocks on the test strip and different components in the urine (the concentration of individual components in the urine corresponds to the color changes of the color blocks), and the data of each component in the urine can be obtained through image recognition and comparative analysis
Data storage	Routine records 20000,Emergency records 10000, Quality control records 1000
External output	Serial rs-232 interface, network interface, USB interface
Language	Chinese, English, etc
Power	220V, 50Hz
Power	50 VA
Fuse wire specification	250V 2A
External size	342mm x 300 x 248mm(length x width x height)
Weight	3 kg
Printer	Thermal printer built in
Transmission	Two-way transmission
Transfer rate	9600 BPS

Note: the urine analyzer can be connected to the bar Code reader, and can recognize EAN-13,EAN-8,Code-39,Code- 128 Code.

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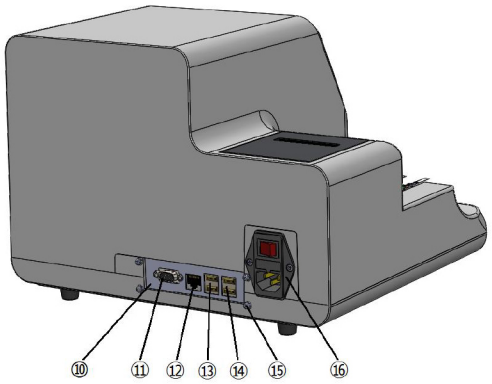
1.4 Primary structure

1-1



1-2

1 upper shell	2 lower shell	3 waste boxes
4 waste liquid box	5 feet	6 test strips
7 printer cover (built-in printer)	8 display panel decorative frame	
9 display panel	10 interface baffle	11 computer serial interface
12 network interface	13 USB interface	14USB interface
15 M3*8 pan head combination screw	16Power cord socket	

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1.5 Identification

symbol	significance
	Prompt the operator attention, otherwise may cause personal injury.
	Prompt the operator to pay attention to, emphasize the important information in the operation steps or the user needs to pay special attention to the content。
	Biological contamination symbol, indicates operator's attention, otherwise there is potential risk of biological infection.
~	Ac symbol
IVD	For in vitro diagnostic use only
SN	Serial number
	Grounding mark
	Disconnect power supply
	Plug in supply

 means “upward”

 means “handle with care”

 means “damp proof”

 means“Avoid the sun”

The above symbol information is included in the analyzer, test strip box

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Chapter 2 Installation of urine analyzer

2.1Environmental conditions for instrument installation

- It is recommended to install the instrument by professionals;
- If self-installation, please read this instruction carefully and choose the appropriate wording;
- Please place the instrument on a stable, flat surface, not with the centrifuge and other vibration sources;
- Do not put the instrument in places that can be affected by chemicals, corrosive gases or strong electromagnetic interference;
- Do not place the instrument in direct sunlight, humidity or high temperature;
- The equipment shall be placed with enough space for ventilation and maintenance by operators, and be able to operate the device switch and power plug;
- Do not disassemble or modify the instrument;
- Do not place any liquid bottle on the instrument to prevent the bottle from spilling into the inside of the analyzer;
- Instrument working environment temperature range of 15 ℃ ~ 35 ℃, the best temperature 20 ℃ to 25 ℃, relative humidity 75% or less.

2.2 Devanning

After receiving the goods, check whether the outer packing is obviously damaged. Take out the urine analyzer and accessories from the packing box and check with the packing list. If the outer packing or parts are damaged, please contact the manufacturer or supplier.

2.3 Instrument installation

2.3.1 installation of printing paper

(1) choose the width of 57 mm, less than 45 mm in diameter of the thermal printer paper roll;

(2) open the installation arrow of the printer box cover indicating the direction;

(3) put the printing paper into the printer box;Run the paper under the pulley and roll the knob at the same time to draw out the printing paper and cover the box.(the printer can automatically draw out the printed paper when the instrument is working on power.)

2.3.2 power line connection

Connect one end of the power cord to the power interface of the equipment and the other end to the special power supply of the hospital to ensure reliable grounding of the power supply.

 Note that the socket connected to the power cord must be reliably grounded.

2.3.3 connect the computer

The instrument can be connected to the computer through a communication cable to transmit data to the computer.Plug one end of the communication cable into the communication interface on the back of the instrument and the other end into the serial interface of the host computer.

2.4 start-up of the instrument

2.4.1 first boot check

After the installation of the instrument, the machine should be started for the first time. Firstly, check whether the fuse in the safety socket behind the instrument is installed in place, plug in the power cord, and turn on the power switch. If any problem or display error is found in the process, please contact the manufacturer or supplier.

2.4.2 Instrument initialization

After turning on the power switch, the display says "the device is initializing...", the instrument is initialized（Figure 2-1）

Figure 2-1

2.4.3 After passing the self-test, the main menu will be displayed on the display screen：（Figure 2-2）

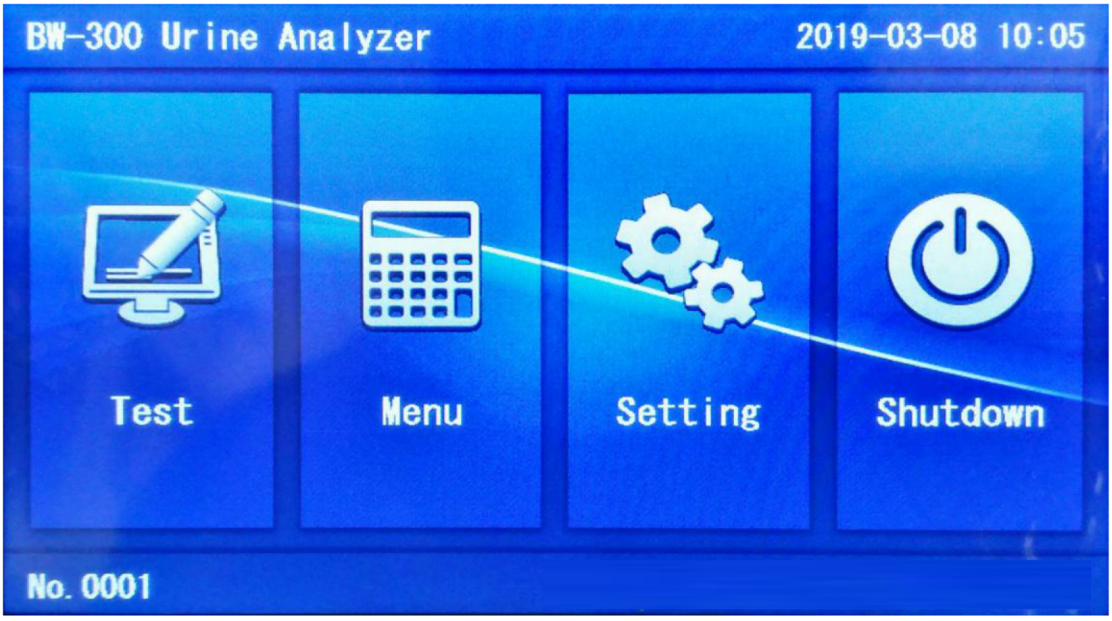

Figure 2-2

2.4.4 Use of the shutdown key：

After the completion of daily test work, you can click the 

on the right side in FIG. 2-2. There is a prompt as shown in FIG. 2-3 on the screen."As shown in Figure 2-4, a few seconds later, the prompt" the system has been shut down, please cut off the power!As shown in figure 2-5, the power can be turned off.

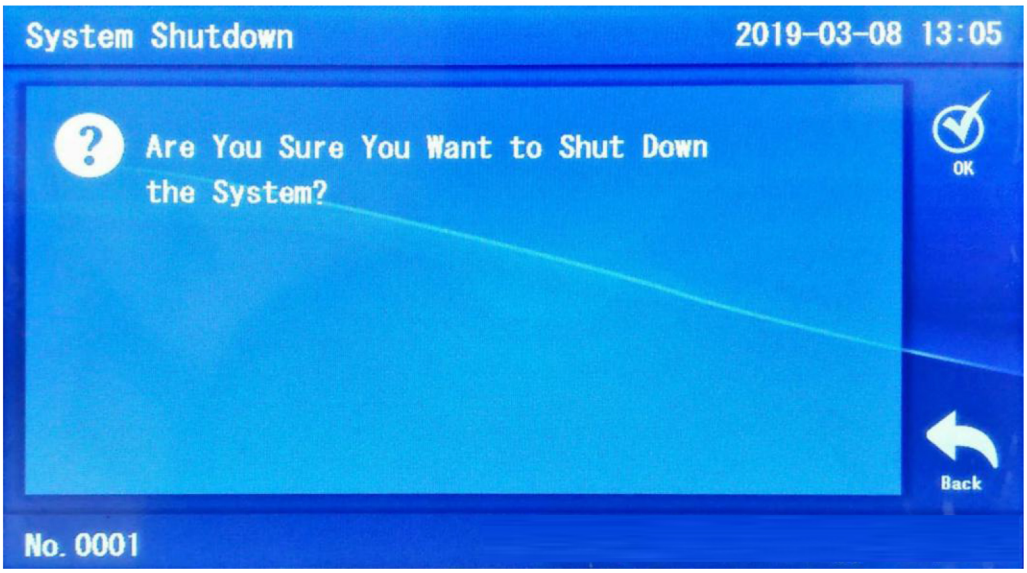

Figure 2-3

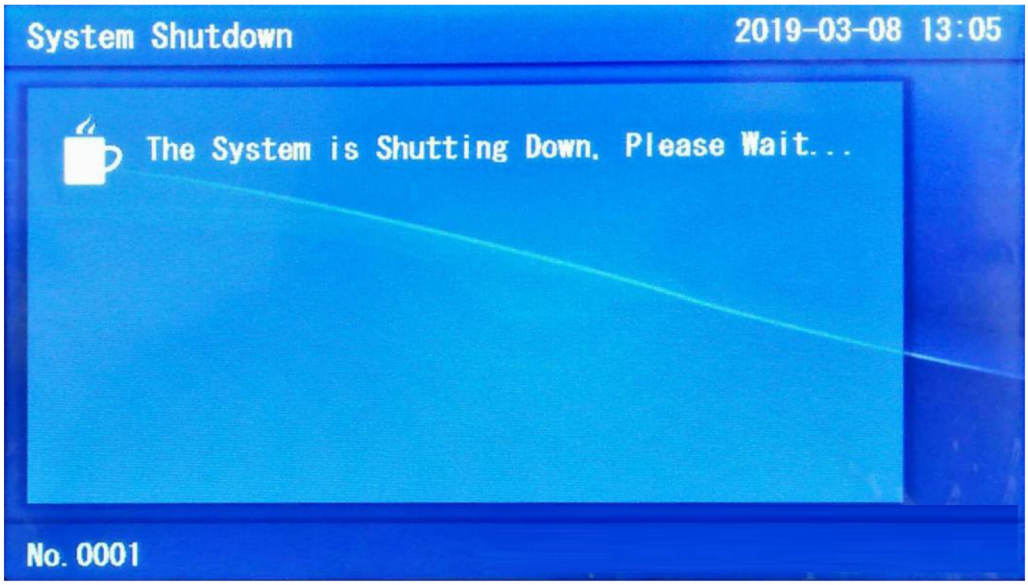

Figure 2-4

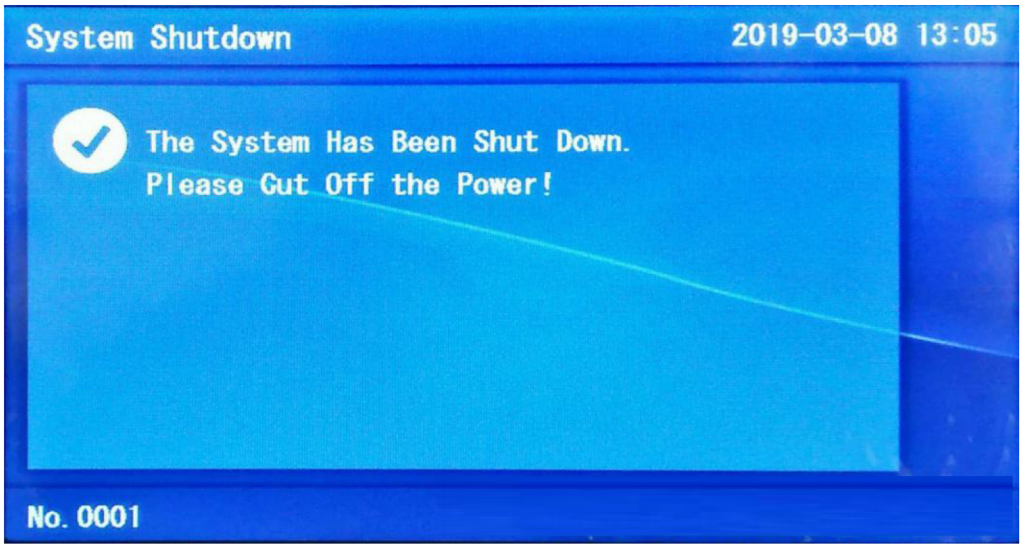

Figure2-5

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Chapter 3 Functions and Settings of the urine analyzer

3.1 Summarize

The urine analyzer realizes man-machine dialogue through the touch screen, which displays the relevant setting options and setting values. The user only needs to click the corresponding touch button to complete the setting operation.Do not damage the touch screen by using hard or sharp objects.

3.2 Button instruction

3.2.1 Home page

(1) Name: detection key

Function: start testing.

Location: the first shortcut key on the home page.

(2) Name: function key

Function: enter the menu page, can query results, set the number, system upgrade and other operations.

Location: the second shortcut key on the home page.

(3) Name: setting key

Function: enter the control panel page, you can set the time, language, test paper and other operations.

Location: the third shortcut key on the home page.

（4）Name: shutdown key

Function: turn off the instrument.

Location: the fourth shortcut key on the home page.

3.2.2 Function button

(1) Name: history

Functionality: detailed record of previous tests

Location: function page.

(2) Name: query record

Function: query records by code

Location: function page.

(3) Name: filter records

Function: filter records by date

Location: function page

（4）Name: clear the record

Function: it can clear all the records of the machine and operate carefully

Location: function page.

（5）Name: device debugging

Function: set value test and aging test (developer option)

Location: function page

（6）Name: system Settings

Function: enter the control panel page, you can set the time, language, test paper and other operations

Location: function page

（7) Name: system upgrade

Function: upgrade the system

Location: function page

(8)Name: system restart

Function: restart the system

Location: function page

(8)Name: system shutdown

Function: the same as the main interface of the "shutdown" key

Location: function page

3.2.3Functional details

（1）History

Click "history" in the "function" key, and figure 3-1 will pop up, in which there are detailed test records.

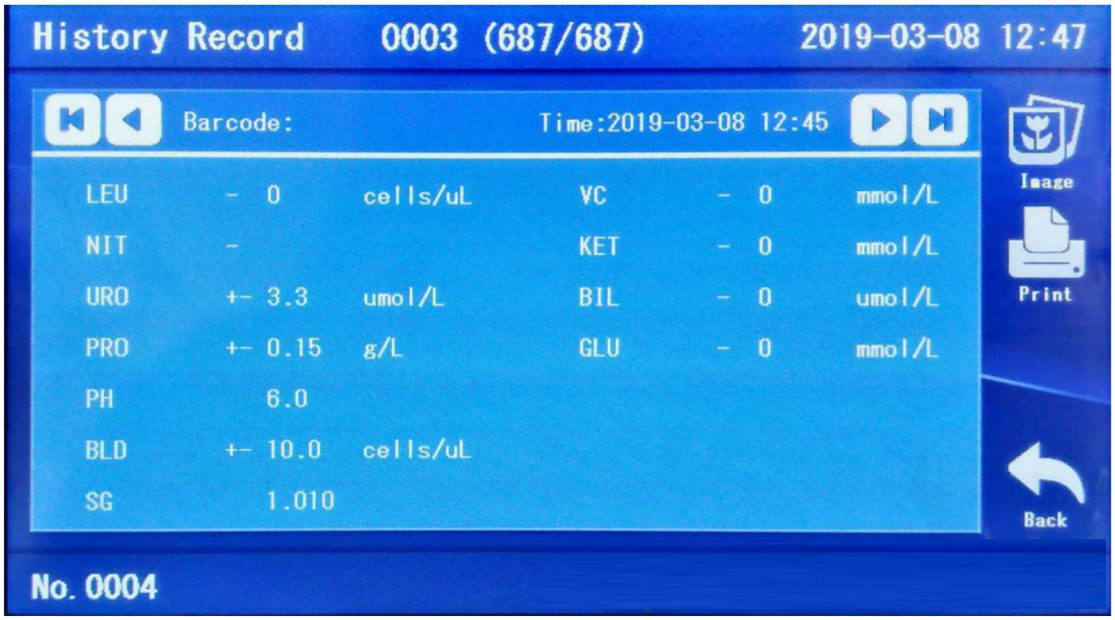


Figure 3-1

Click the button 

on the top right corner of Figure 3-1,it will pop up Figure 3-2,which shows the pictorial diagram of the test result of current sample.

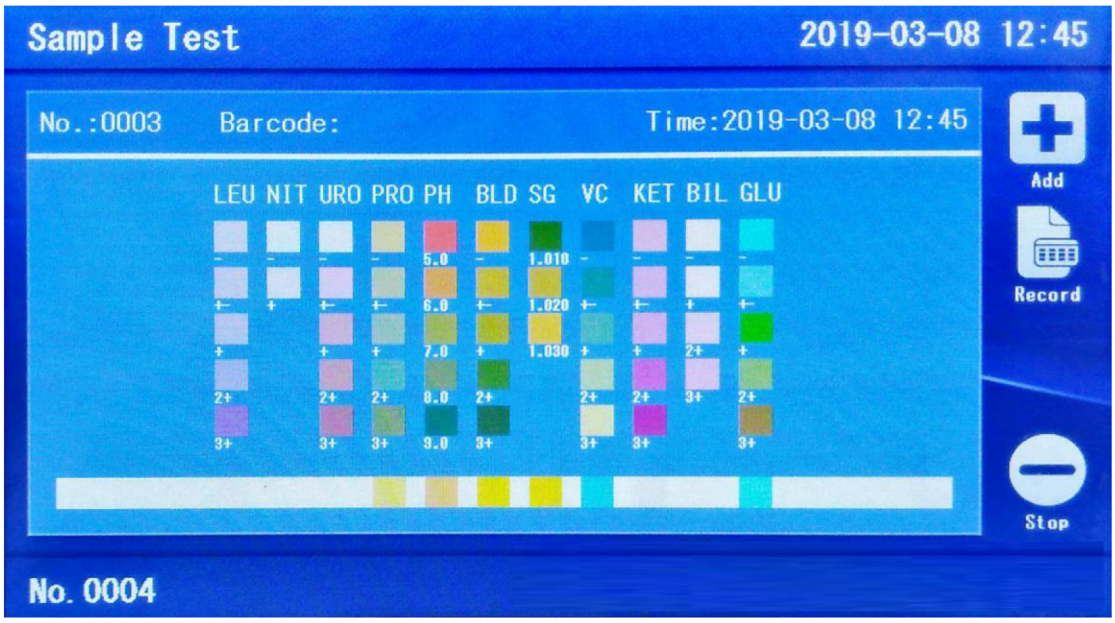


Figure 3-2

Click 

to return to Figure 3-1,click 

in Figure 3-1 to print current result,click 

to discard changes and return to the previous menu.

（2）Query record

Click“Query record”in“Function”menu can query the test result according to serial number, input the serial number need to be queried and click 

， click 

（Figure3-3）, it will pop up the test record of corresponding number（Figure 3-4）， click 

to discard changes and return to the previous menu.

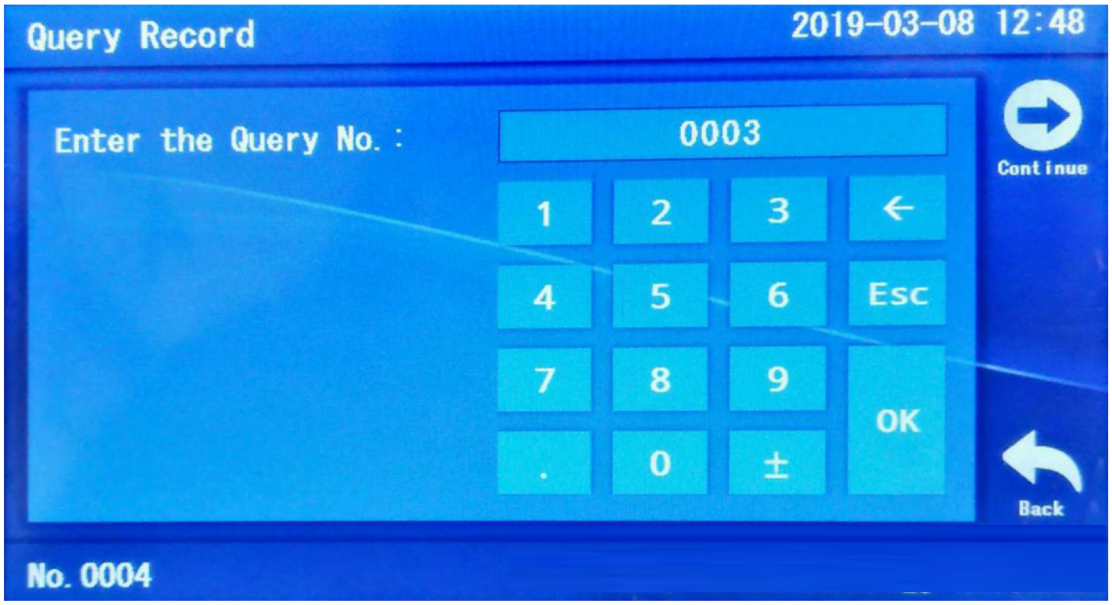


Figure 3-3

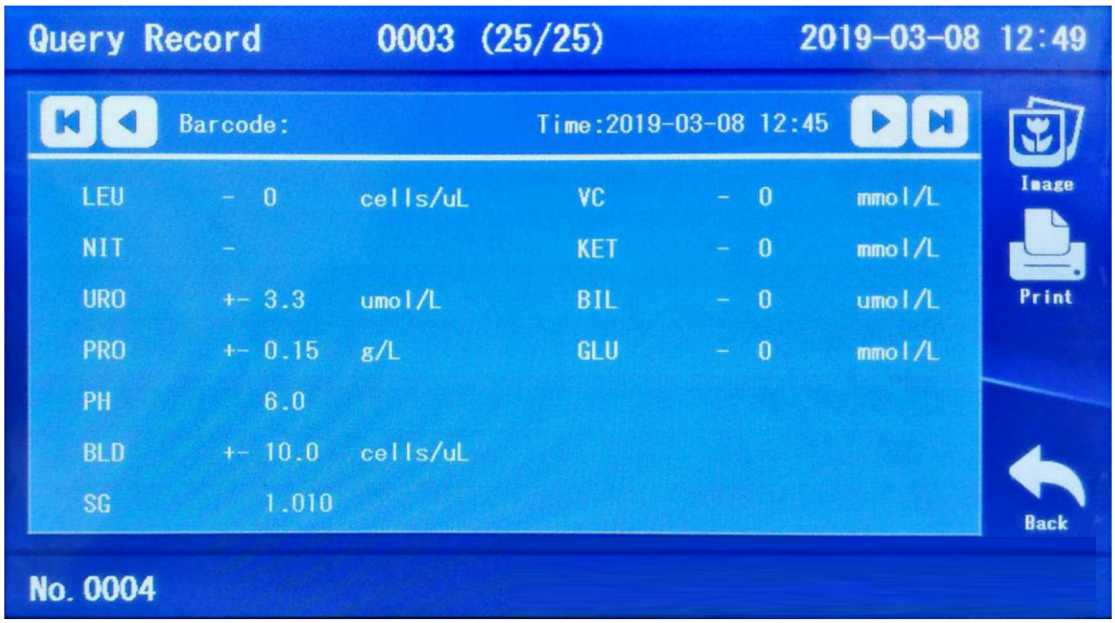


Figure 3-4

（3）Filter record

Click“Fliter record”in“Function”menu can query the test result according to the date， input the date need to be queried （Figure 3-5），click 

, it will pop up all the test record of corresponding date（Figure3-6），click 

to discard changes and return to the previous menu.

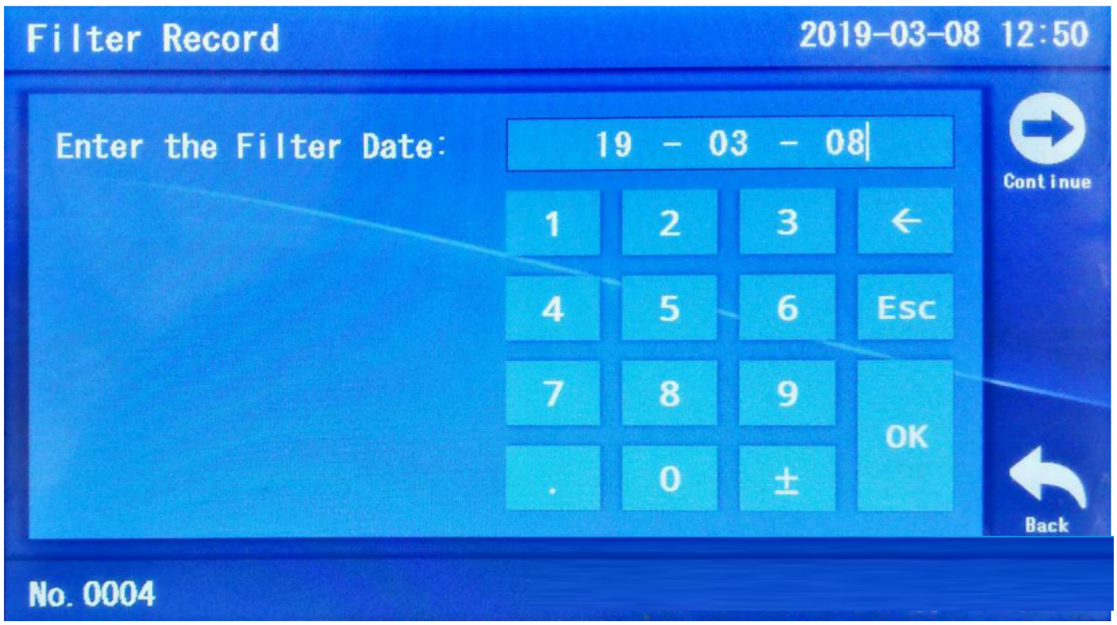


Figure 3-5

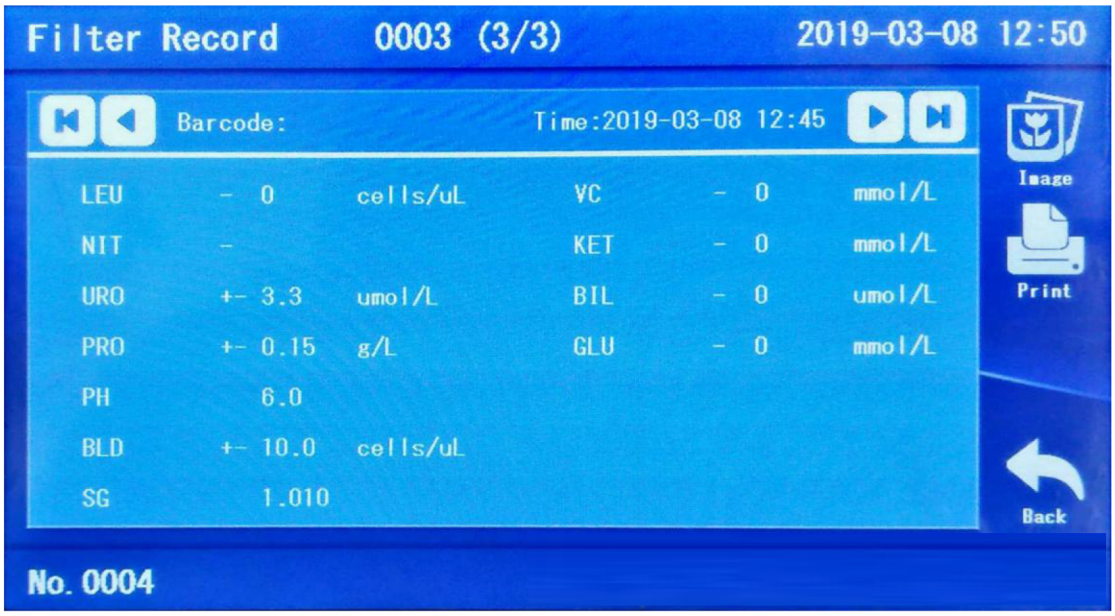


Figure 3-6

（4）Clear record

Click“Clear record”in“Function”menu to clear all the record in the machine, （be careful to operate）,after click, it will pop up Figure3-7， click 

,the system will delete all the record, click 

to discard changes and return to the previous menu.

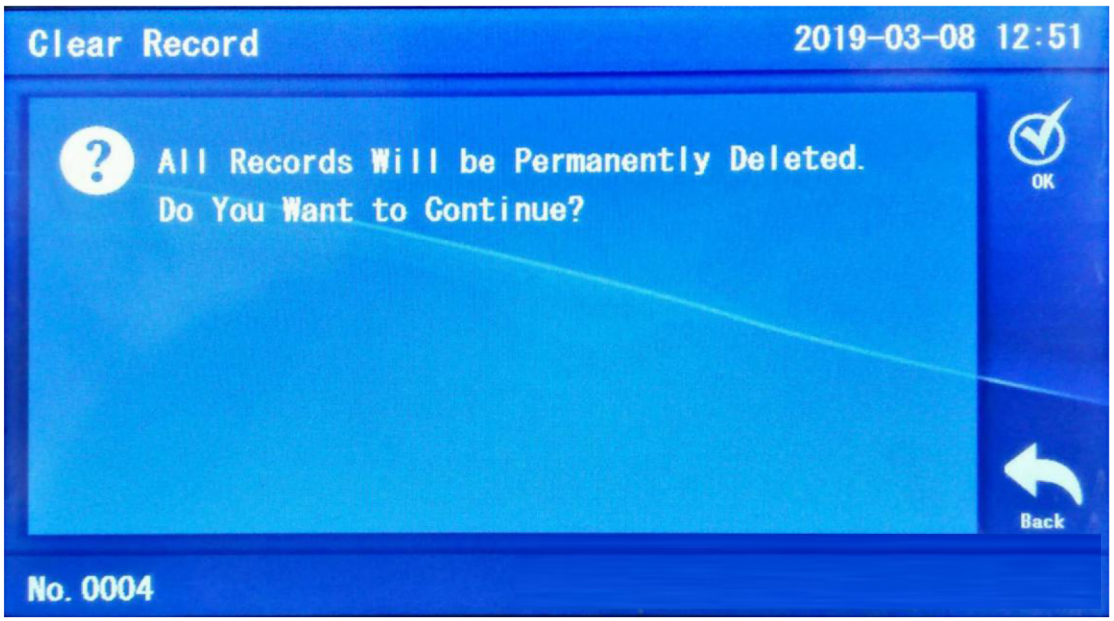


Figure 3-7

（5）Device debug

"Device debug"in"Function"menu is developer option,after click, it will pop up Figure 3-8，please select carefully.

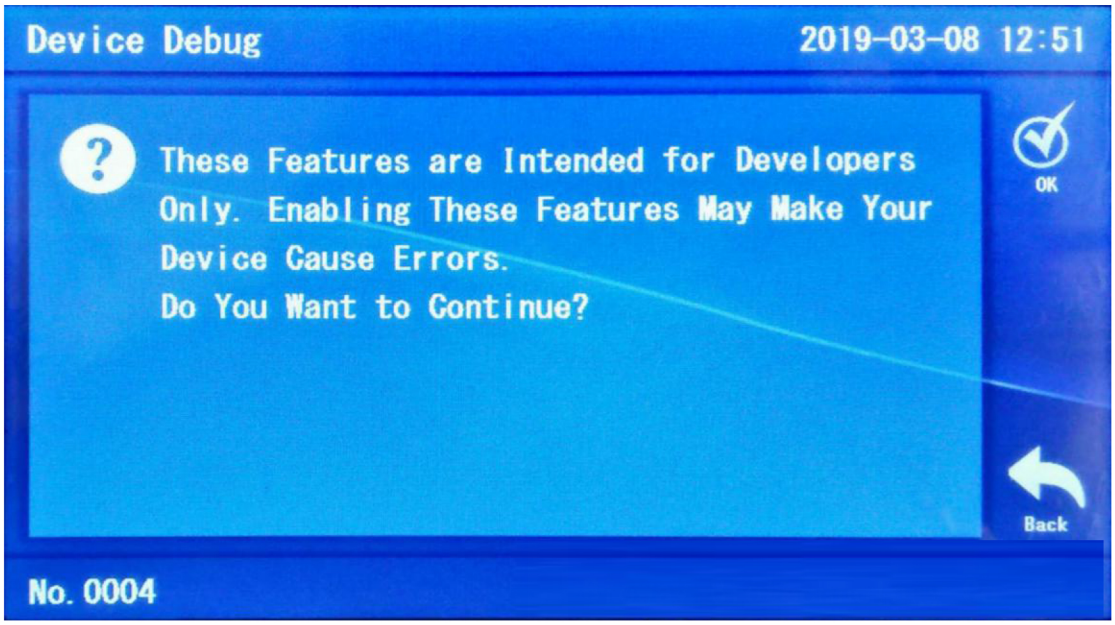


Figure 3-8

Click 

, it will pop up Figure 3-9， you can set the value test and the aging test. Click 

to discard changes and return to the previous menu.

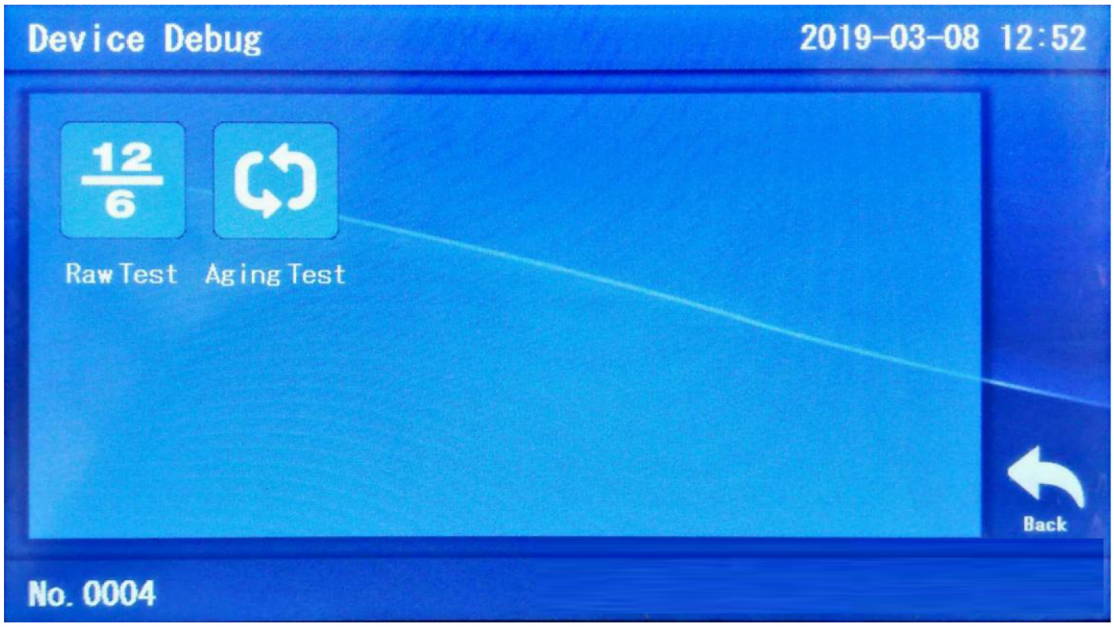


Figure 3-9

（6）System setting

The“System setting”in“Function”menu is same as the “Setting”under main interface， will clarify later.

（7）System upgrading

The“System upgrading”in“Function”menu can upgrade the software, this function can only operated by professionals.

（8）System restarting

The“System restarting”in“Function”menu can restart the machine， after click, it will pop up Figure 3-10，click 

then the machine will restart，click 

to discard changes and return to the previous menu.

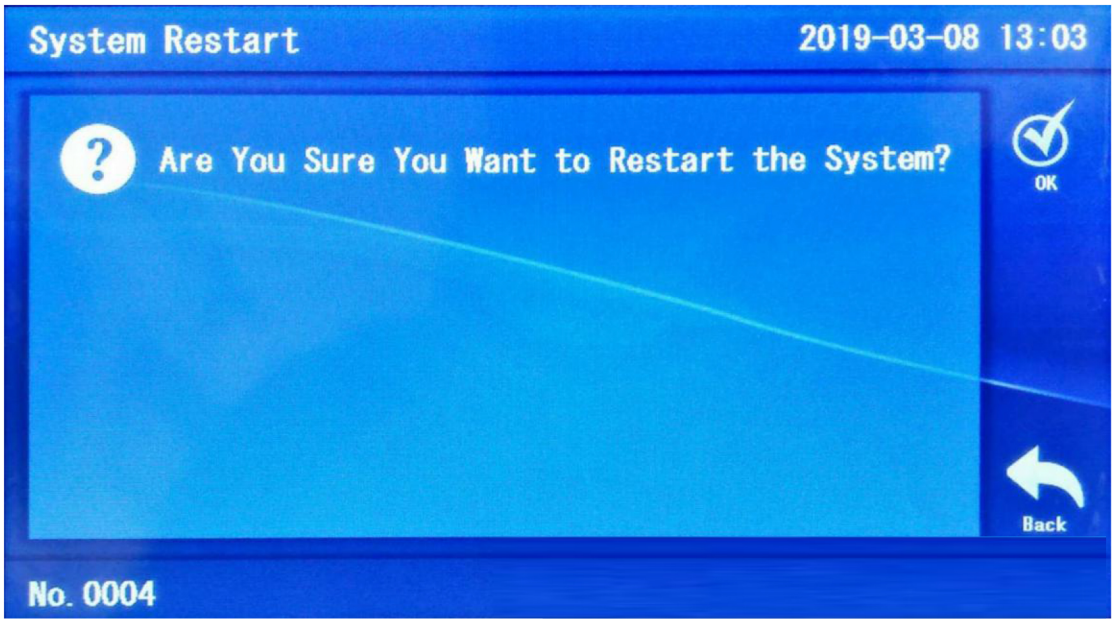


Figure 3-10

（9）System shutdown

The“System shutdown”in“Function”menu is same asthe “Shutdown”under main interface,after click, it will pop up Figure 3-11，click 

then it will shutdown，wait a few seconds and shut off when it hints“System shutdwon， please cut power”.

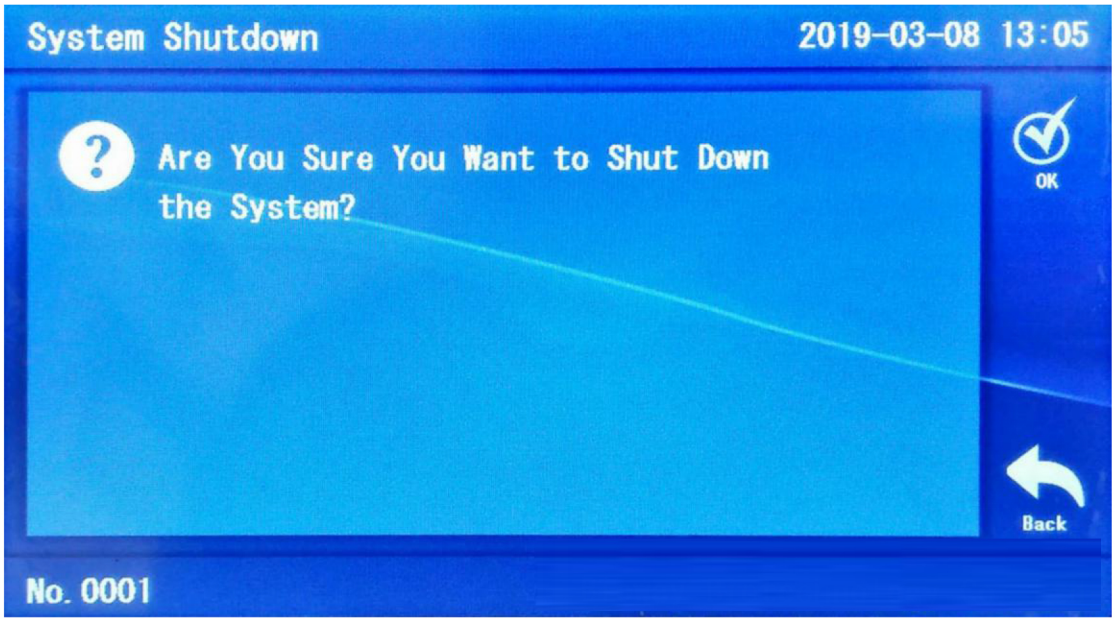


Figure 3-11

3.2.4Setting details

（1）Sample number

Click 

in“Setting”menu to input number

（2）System time

Click 

in“Setting”menu to set system time.

（3）System date

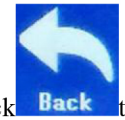
Click 

in“Setting”menu to set system date.

（4）Date format

Click 

in“Setting”menu, it will pop up Figure 3-12，choose corresponding format and click 

to modify date format and reture to the previous menu, click 

to discard changes and return to the previous menu.

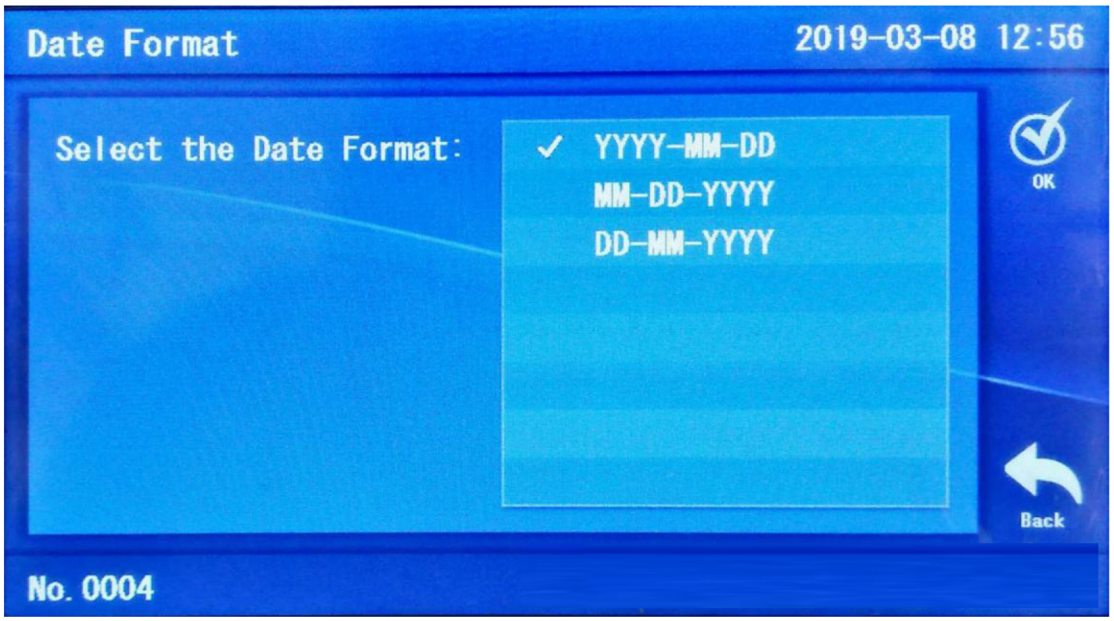


Figure 3-12

（5）Print option

Click 

in“Setting”menu, it will pop up Figure 3-13,choose whether to print or not.

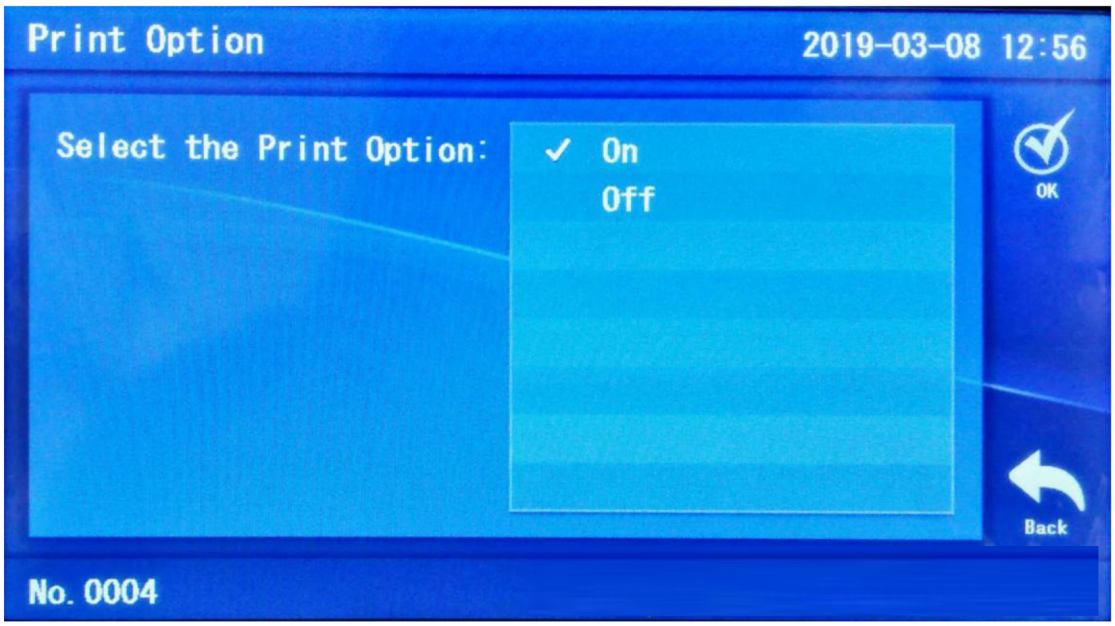


Figure 3-13

（6）Test strip

Click 

in“Setting”menu, it will pop up Figure 3-14,choose test strip model.

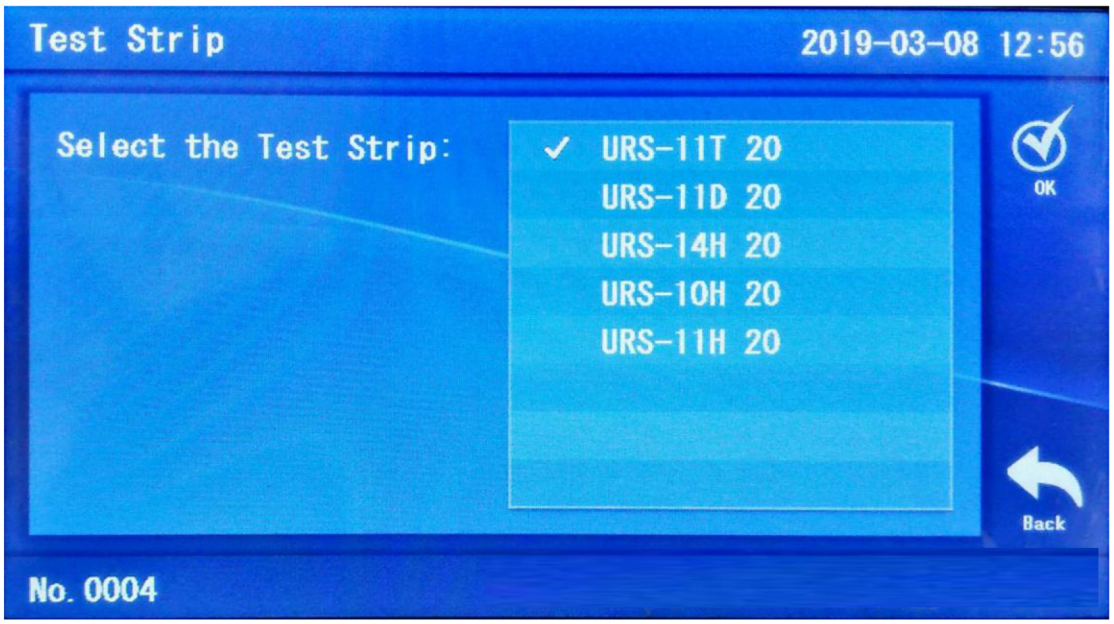


Figure 3-14

（7）Report unit

Click 

in“Setting”menu, it will pop up Figure 3-15,choose international, standard or symbol.

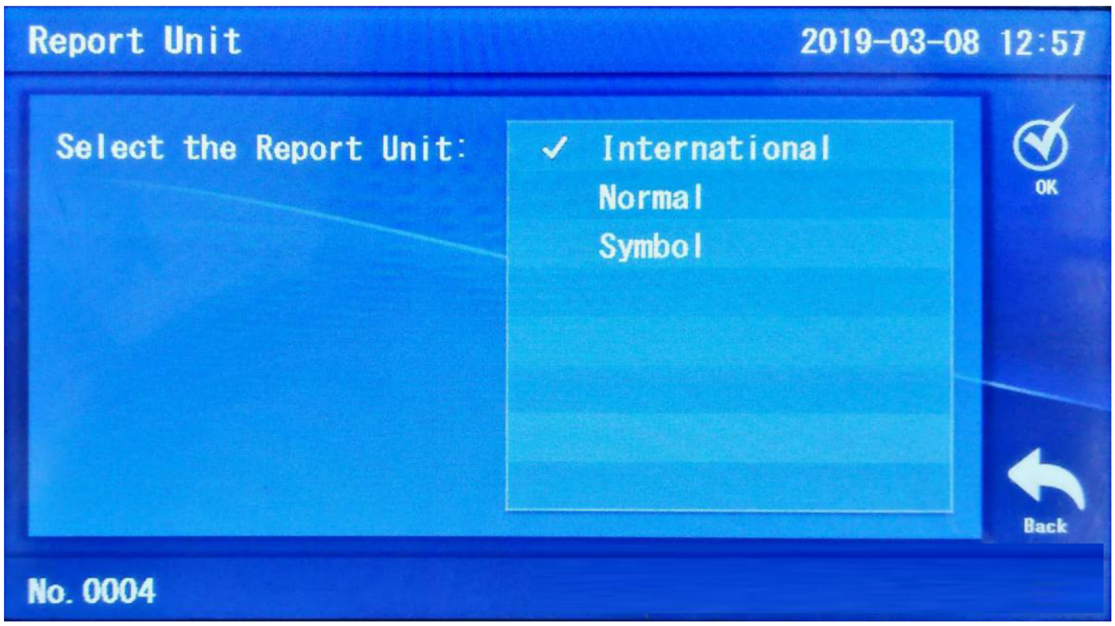


Figure 3-15

（8）Symbol option

Click 

in“Setting”menu to choose whether to open symbol or not, you can choose whether to open symbol ot not,when “Symbol system” is “Open”:

When "Unit system setting" is "conventional", the print result is shown in Figure 3-16；

When "Unit system setting" is "international", the print result is shown in Figure 3-17；

When "Unit system setting" is "symbol", the print result is shown in Figure 3-18.

2010-01-01 11：40　26℃
Sample No.：0011
ID
Rack No.：
*URO 3+　>=8mg/dL
*BIL 3+　>=6mg/dL
*KET 3+　5mg/dL
*BLD 2+　Ca80Ery/uL
*PRO 3+　>=300mg/dL
*NIT Pos
*LEU 3+　>=Ca500Leu/uL
*GLU 1+　100mg/dL
SG　>=1.030
PH　<=5.0

Figure 3-16

2010-01-01 11：40　26℃
Sample No.：0011
ID
Rack No.:
*URO 3+　>=135umol/L
*BIL 3+　>=1.3umol/L
*KET +-　0.5mmol/L
*BLD 2+　Ca80Ery/uL
*PRO 3+　>=3.0g/L
*NIT Pos
*LEU 3+　>=Ca500Leu/uL
*GLU 1+　5.69mmol/L
SG　>=1.030
PH　<=5.0

Figure 3-17

2010-01-01 11：40　26℃
Sample No.：0011
ID
Rack No.：
*URO　3+
*BIL　3+
*KET　+-
*BLD　2+
*PRO　3+
*NIT　Pos
*LEU　3+
*GLU　1+
SG　>=1.030
PH　<=5.0

Figure 3-18

When“symbol system”is“Open”:

When "Unit system setting" is "conventional", the print result is shown in Figure 3-19；

When "Unit system setting" is "international", the print result is shown in Figure 3-20；

When "Unit system setting" is "symbol", the print result is shown in Figure 3-21.

2010-01-01 11：40 26℃
Sample No.：0011
ID
Rack No.：
*URO >=8mg/dL
*BIL >=6mg/dL
*KET 5mg/dL
*BKD Ca80Ery/uL
*PRO >=300mg/dL
*NIT Pos
*LEU >=Ca500Leu/uL
*GLU 100mg/dL
SG >=1.030
PH <=5.0

Figure 3-19

2010-01-01 11：40 26℃
Sample No.：0011
ID
Rack No.:
*URO >=135umol/L
*BIL >=1.3umol/L
*KET 0.5mmol/L
*BLD Ca80Ery/uL
*PRO >=3.0g/L
*NIT Pos
*LEU >=Ca500Leu/uL
*GLU 5.69mmol/L
SG >=1.030
PH <=5.0

Figure 3-20

2010-01-01 11：40 26℃
Sample No.：0011
ID
Rack No.：
URO 3+
BIL 3+
KET +-
BLD 2+
PRO 3+
NIT Pos
LEU 3+
GLU 1+
SG >=1.030
PH <=5.0

Figure 3-21

（9）Abnormal mark

Click 

in“Setting”menu to choose whether to add abnormal mark*.

（10）URO first value

Click 

in“Setting”menu, it will pop up Figure 3-22 , press“+-3.3/-0/-3.3”button 

to modify and return to the previous menu, click 

to discard changes and return to the previous menu.

Figure 3-22

（11）Brightness level

Click 

in“Setting”menu, it will pop u Figure 3-23，can choose corresponding option according to the brightness.

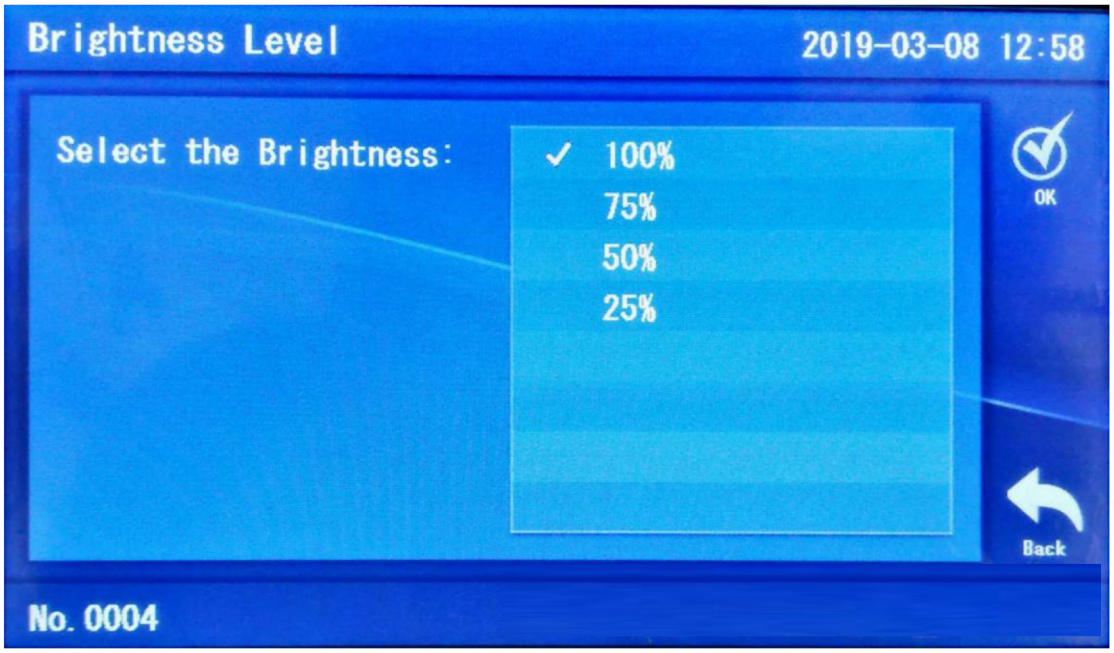


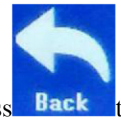
Figure 3-23

（12）System language

Click 

in“Setting”menu to choose Chinese,English etc as Figure 3-24，press“Chinese/English” 

to modify as Chinese/English

and return to the previous menu， press 

to discard changes and return to the previous menu.

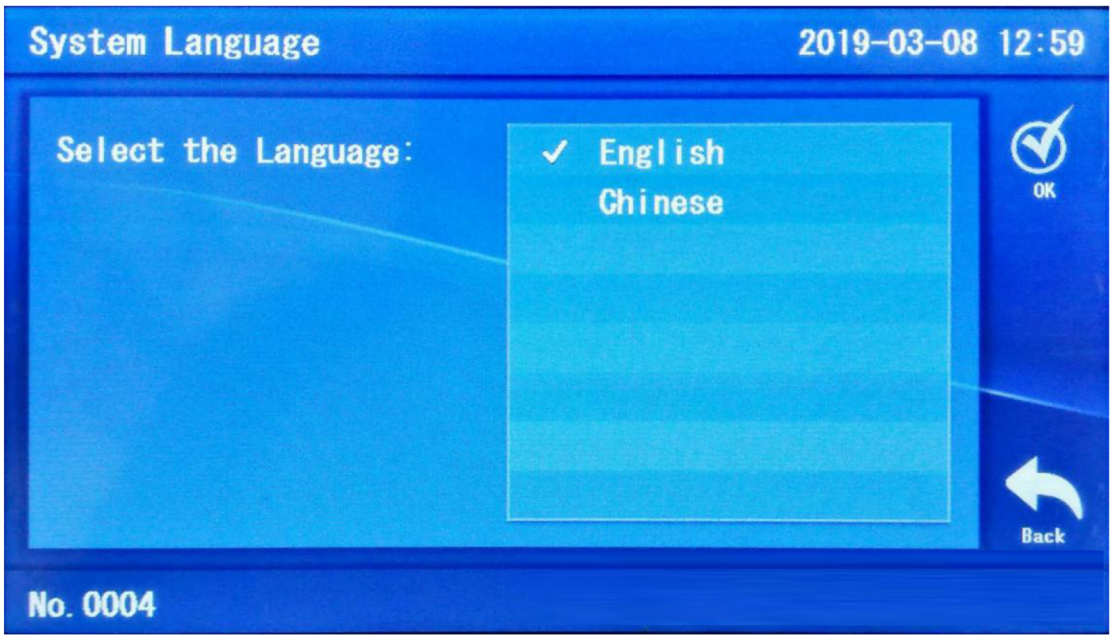


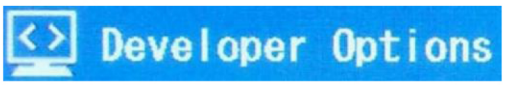
Figure 3-24

（13）System information

Click 

in“Setting”menu, it will show software version and other information of each unit.

（14）Developer options

Click 

in“Setting”menu, can set,import, export setting of test strips and test item gradient as shown in Figure 3-25，click 

, it will pop up Figure 3-26.

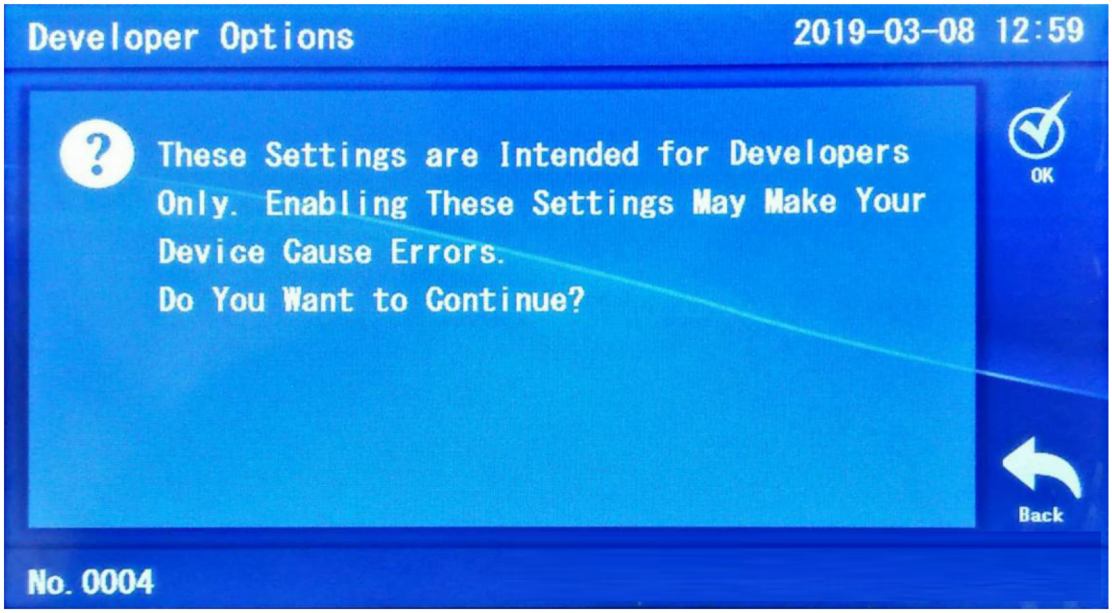


Figure 3-25

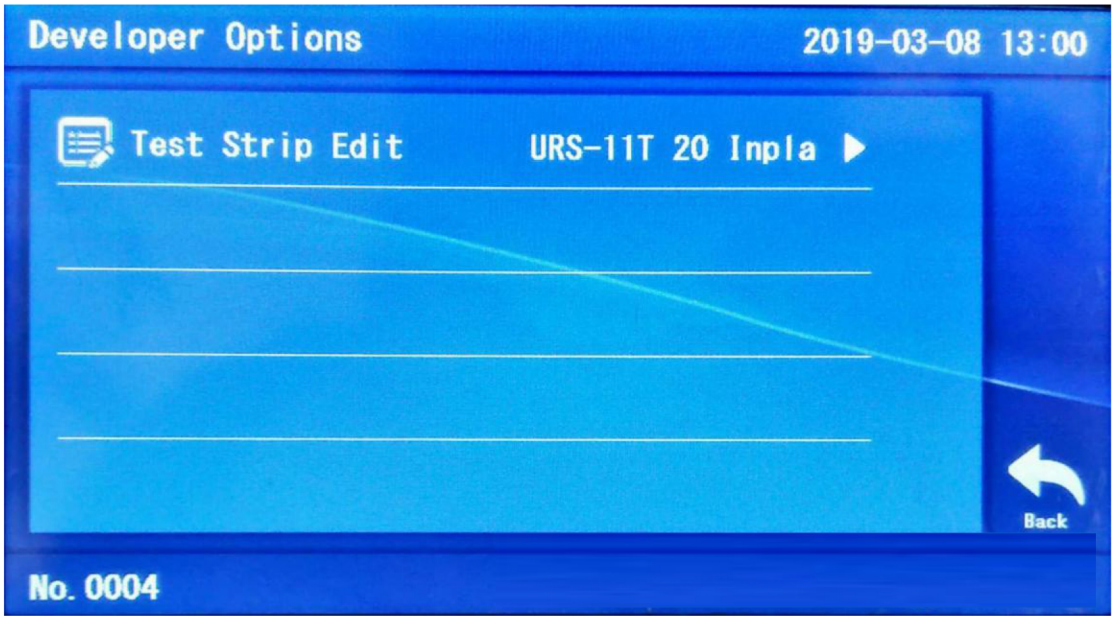


Figure 3-26

Click 

, it will pop up Figure 3-27.

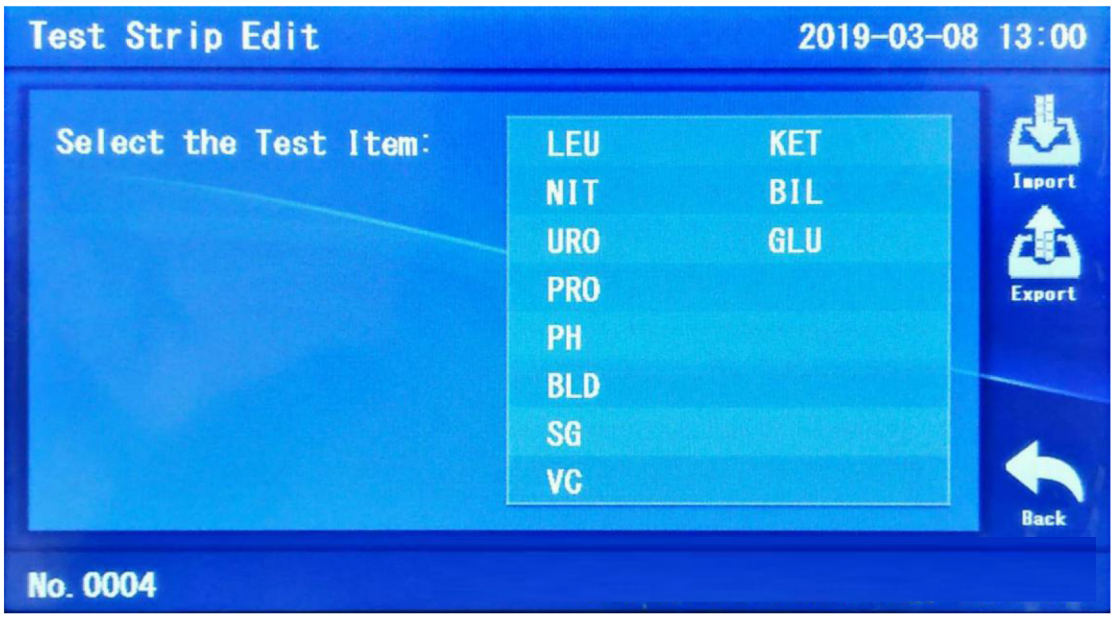


Figure 3-27

Click each item it will pop up corresponding test item gradient setting interface,shown as Figure 3-28.

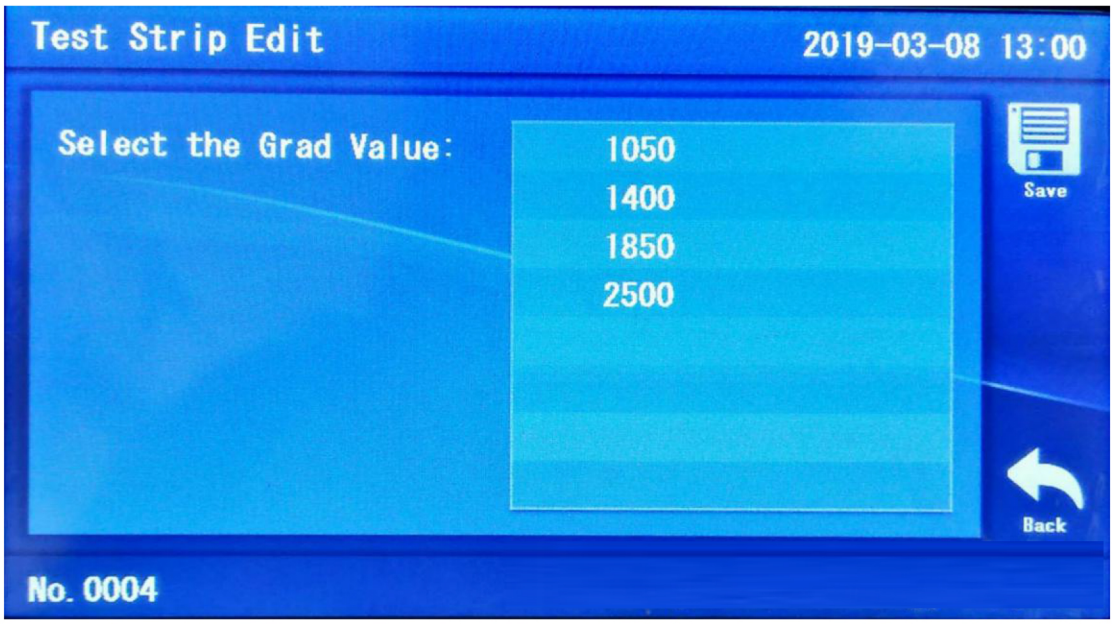


Figure 3-28

Click the gradient value and then click 

to finish setting and return to the previous menu.

Can import and export each parameter according to Figure 3-27.

（15）Factory data reset

Press 

in“Setting”menu, it will delete all the record and

configuration data of the machine, please operate carefully, shown as Figure 3-29, click 

, the machine will delete the data permanently and automatically restart the device.

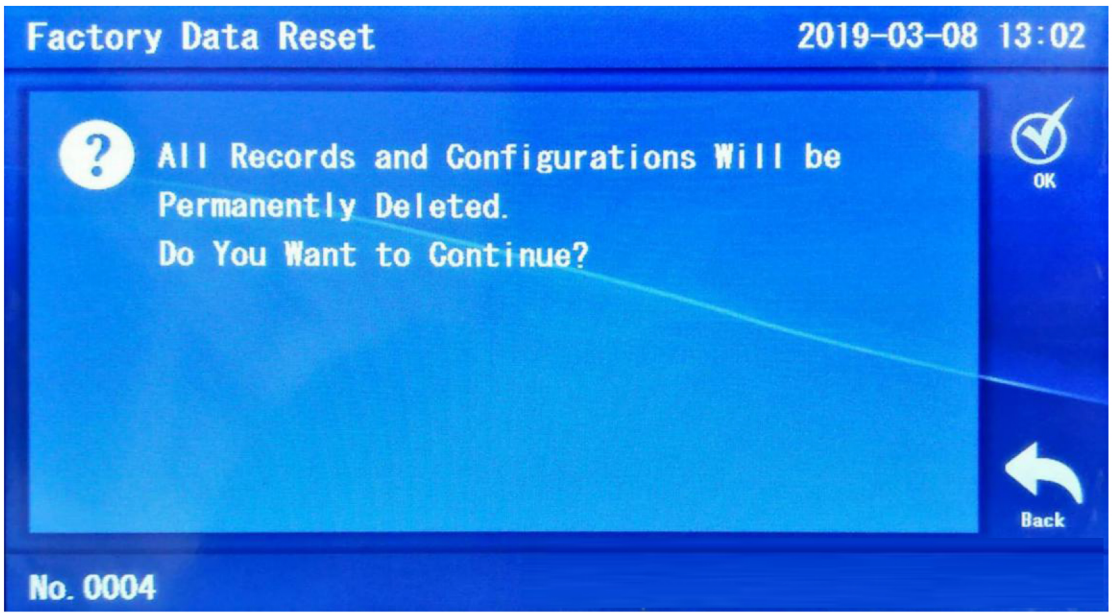


Figure 3-29

CE IVD

Chapter 4 Basic Operation

Declaration： Please use the machine strictly according to the above user manual, or the stability of the machine and safety protection provided by the machine will be damage!

4.1 Preparation

Caution

● The operator should be trained for the operation and read the user manual and cautions.

● Safety protection unit is required before operation in case of physical injury.

Caution: please make sure the strip model before the start to make sure the reliability of the test result.

● The user need to make sure the strip model to match the machine and prepare correct strips。

● open the printer to check there are papers or not. If the color of the papers changed to pink, it means that the papers are going to run out. Please place more papers.

4.1.1 Barcode Using Requirements ★

a) Model：CODE128、CODE39.

b) Barcode Label Size： the print width of the strips should not be less than 12mm（In order to avoid the machine cannot read the barcode when the tube is rotating）.The numbers of figure for the barcode should be in the range of 4 to 15.

c) Both of the blank area at the top and bottom should not be less than 3mm for each barcode label.

d) Requirements of Barcode Label Stickup：

- Barcode label should be stick smoothly without wrinkle ；
- The barcode label should be stick in the correct position (the lower edge including the top blank area could not be lower than scale line of the tube) in order to insure to read the barcode correctly (Figure 6-4). Be sure that all of the barcode labels can be watched from the lengthways rabbets when put the tubes into the tube-racks；
- When the barcode is a lowercase letter of CODE39 code, after scanned, the ID number on the screen displayed and on the printed report sheet should plus “+” before the corresponding uppercase letter; when query the record, since “+” cannot be input, the record can only be

queried according the sample No., not by ID number.

-

For example： If the ID number is 36Fa, the result is showed 36F+A.“+”takes up a character bit also。

4.1.2 Urine Specimen★

a) The quantity of the urine： the strips should be completely dipped into the urine specimen。

Attentions：

- Please completely shake well the urine specimen(Don not centrifuge the urine or the sensitivity of the test result will be influenced)。
- Use fresh urine specimen。 If the urine specimen is not used in 1 hour after collected, please store the specimen in cold storage; restore the specimen to room temperature。
- Do not add corrosion remover, disinfector and detergent into the urine specimen。
- Urine specimen must avoid the sunshine。
- If the urine contains Ascorbic Acid, the test result of Glucose maybe lower the real value。

4.2 Normal Test★

（1）After the self-detection, the display shows this（Figure4-1）：

Figure 4-1

Figure 4-1：“No.0016” means present ID; the system date and time show in top right corner.

(2)Click 

, you will see figure 4-2.

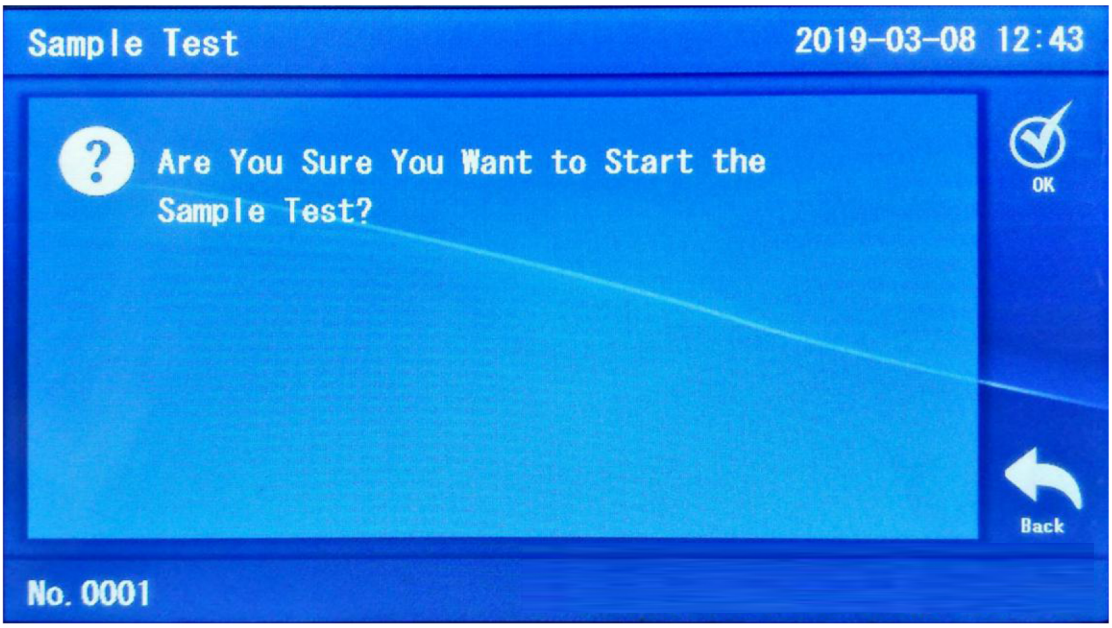


Figure 4-2

Put the strips covered with urine in the corresponding place; Click the button 

.

The belt of the machine starts to work. The strips will be taken to the camera automatically.

After photograph and analysis, you can get the test report（Figure 4-3），Click button 

to go back to upper menu：

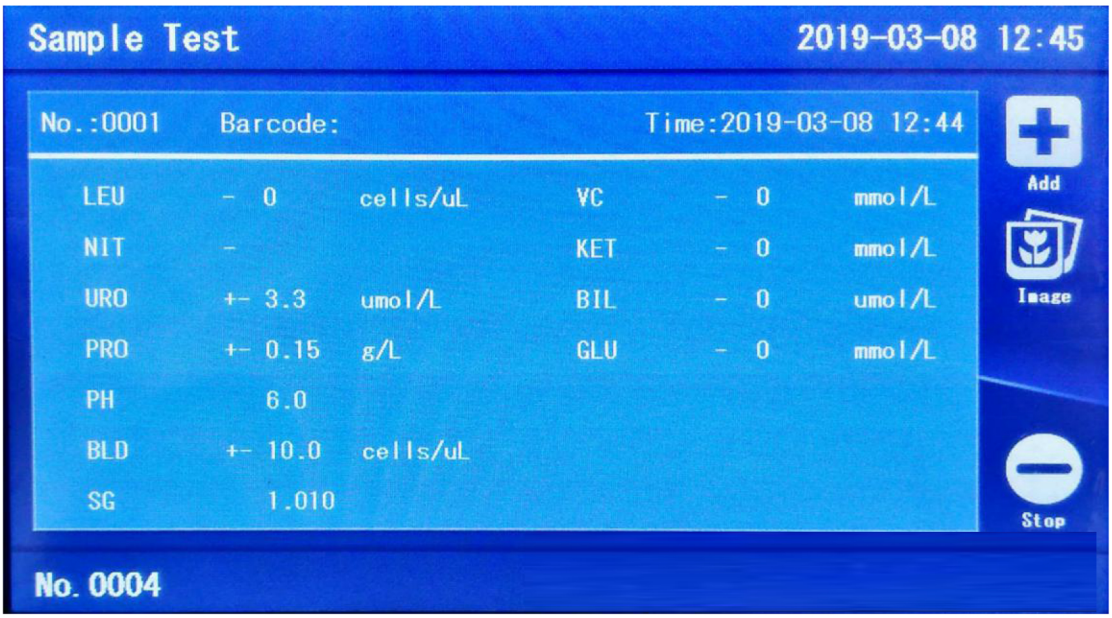


Figure 4-3

Click the button 

, in top right corner of figure4-3. The figure 4-4 will pop up, there are test result in the picture 4-4.

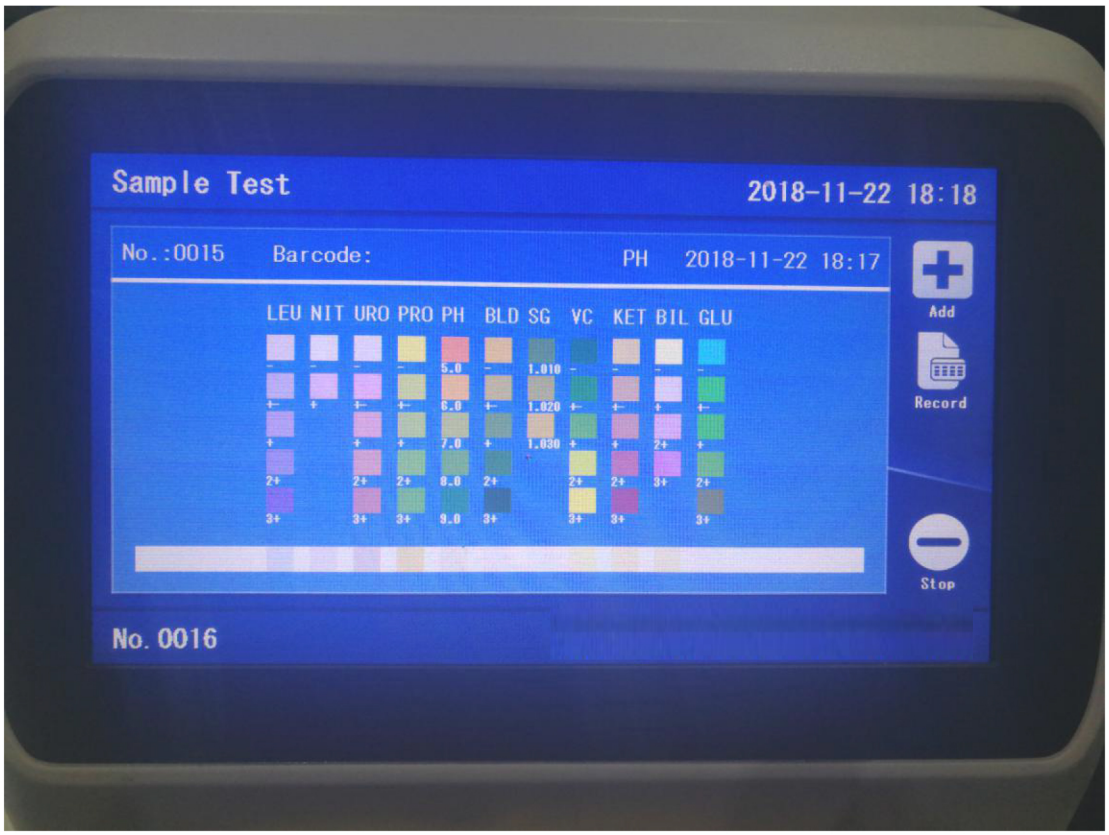


Figure 4-4

Click the button 

in the top right corner in figure 4-4，the screen will go back to figure 4-3，click button 

to go back to upper menu.

4.3 Testing Sample★

If the machine is in the testing module, what the screen shows like the figure 4-5：

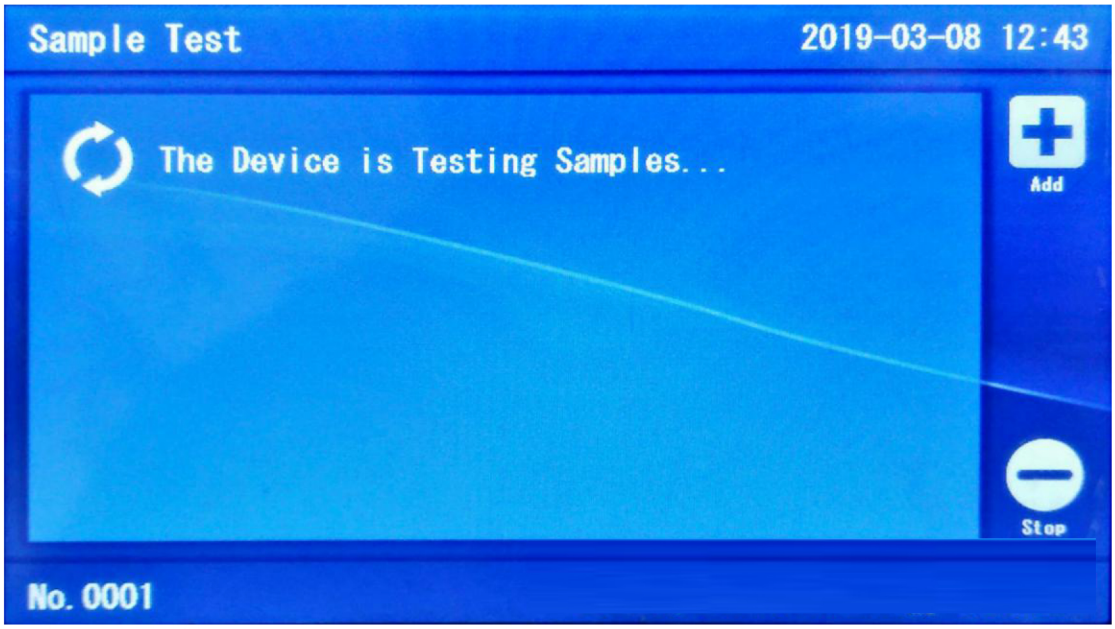


Figure 4-5

Click button 

, the figure 4-6 will pop up. Click button 

to add specimen number.

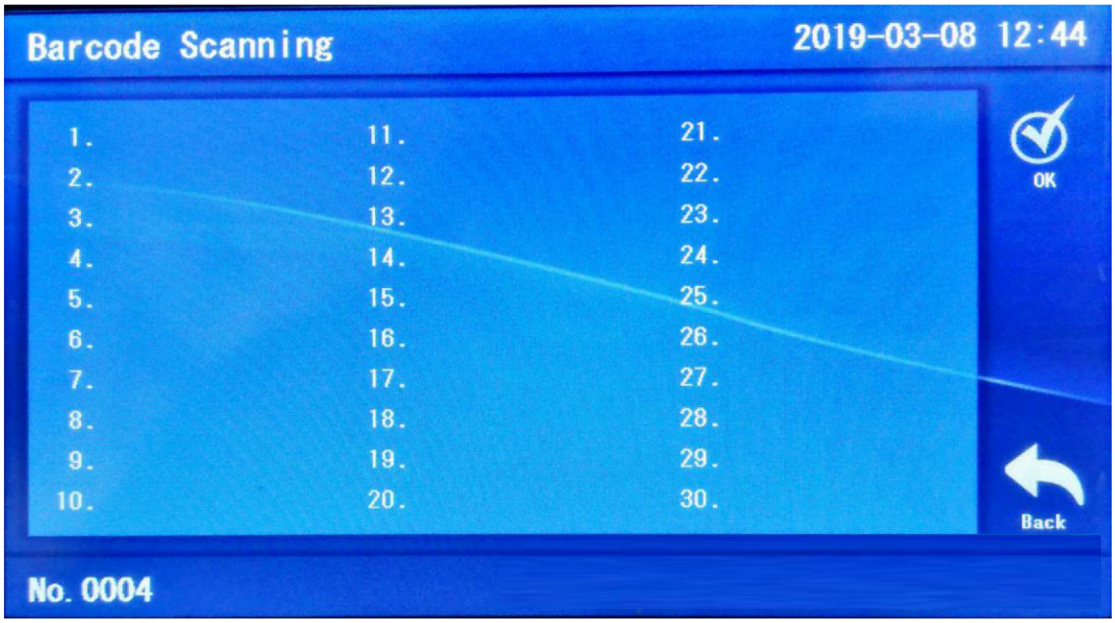


Figure 4-6

4.4 Cancel the Test★

Click button 

in the figure 4-5, figure 4-7 will pop up.

Click button 

to stop he current test to back to the main menu.

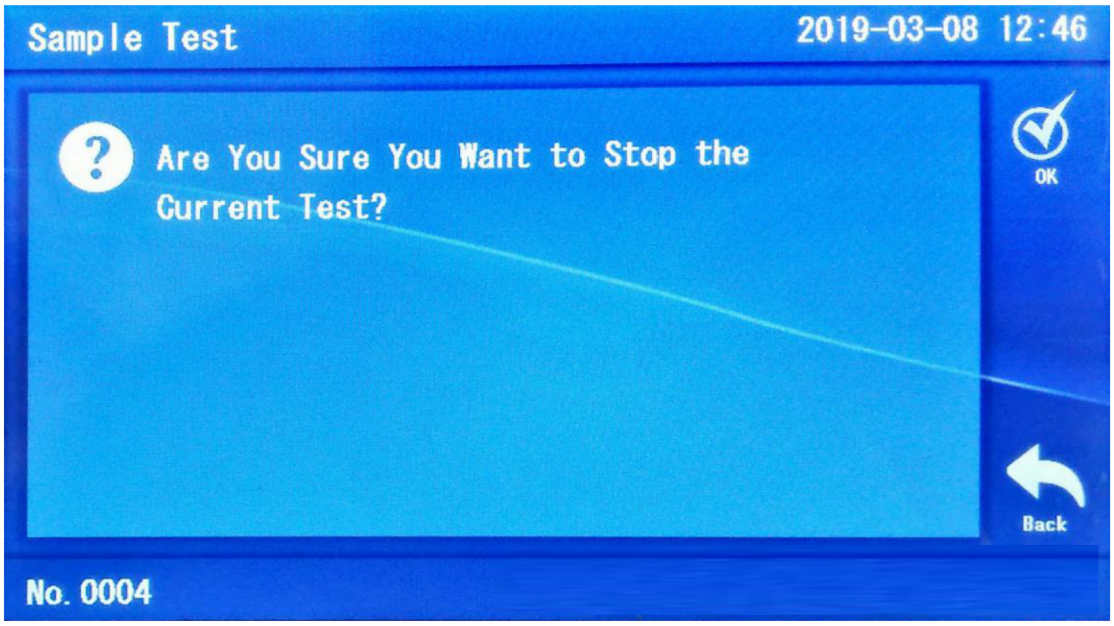


Figure 4-7

The machine will be initialized after the cancel operation. The screen will be back to the main

menu after the initialization.

4.5 Attentions in the testing★

- It is recommended that completely shake well the urine specimen manually when there is solid precipitation in the urine specimen.
- Dip the test area of strip into the fresh, fully shake and uncentrifuged specimen completely. Then take out it immediately and lean the strip on the edge of the tube to scrap excrescent urine.
- The strips should be placed in the right place.
- Please discreetly click button 

in the testing in case of the unrecovered mistaken.

Chapter 5 Maintenance

Required tools：tweezers、dedicated cleaning cotton balls, protection gloves, stilled water.

The maintenance and detection should hand over to the trained person. The items consist of ventilation installation, disposing the garbage comply with relevant regulation, for example < Clinical waste management ordinance > etc.

Declaration: Please use the machine strictly according to the above user manual, or the stability of the machine and safety protection provided by the machine will be damage!

5.1 Attentions for daily maintenance

5.1.1 Use soft dry cloth to clean the machine to keep it clean. If the surface of the machine is dirty, please use clean water. The organic solvent like gas, paint thinner and benzene compounds are forbidden. This kind of organic solvent will deform the analyzer and affect its operation.

5.1.2 Using water to clean the LCD is forbidden. Clean it using clean & soft dry cloth or tissue is allowed.

5.2 Cleaning the belt

5.2.1 Daily Clean

1）Take out the waste materials box and put specified common cotton balls into both of the dedicated grooves.

2）Finish the clean work during the instruction self-test process and then take out the cotton balls.

NOTE: Do not use any material which can damage the belt to clean it. Do not use any solvent to clean the belt.

5.2.2 Regular cleaning

If there are urine alkali ion the belt, please clean the belt as following steps:

1）Take out the waste materials box and put specified common cotton balls into both of the dedicated grooves.

2）Finish the clean work during the instruction self-test process and then take out the cotton balls.

5.2.3 Disinfection treatment

It is recommended that clean the belt, waste liquid box and waste materials every week.

Please operate as following steps:

1） Take out the waste liquid box and waste materials and throw waste liquid and waste materials away.

2）Take daily decolorizer(5%sodium hypochlorite) to use directly or attenuate the decolorizer to be 1/20 solution(add 5ml of decolorizer into 95ml of water).

3） Put the waste materials into the solution completely for 10 minutes and then clean it with fresh water. If there are logos in the surface of the waste box, please put the waste box into the solution except the logo surface.

4）Clean every accessory with soft tissue or cloth.

5）Install all of the accessories.

6）Execute the “5.2.2 Regular cleaning” to clean the belt.

5.3 Spare Parts List★

1、Standard Parts

1.1 User Manual	1unit
1.2 Warranty card	1unit
1.3 Certification of quality	1unit
1.4 Standard test strip	1piece
1.5 Standard test value	1unit
1.6 Printer paper	1roll
1.7 Power line	1piece

Attention：Please check the above spare parts when unpacking the case. If there is any defect, please contact the sales staff. If damaged, lost or consumed in the process of use, please use the spare parts supplied by the manufacturer, otherwise it will affect the stability of the instrument test and the safety protection provided by the instrument.

5.4 Accessories replacement

a. Fuse replacementdis

Unplug the host power cord and remove the fuse holder on the power socket with a flat blade screwdriver. Then put the fuse in the clip of the fuse holder.

b. Printing paper replacement

① Open the box of the printer following the direction of the sorrow and take out the used up paper tube.

② Open the compaction handle and place the new-opened printing paper down to the compaction roller.

③ Turn the compaction roller manually for about 50mm and then lock the compaction handle tightly.

④ Thread the printing paper through the gap of the printer cover. Close the printer cover.

Chapter 6 Transportation and Storage Conditions

6.1 Transportation

The instrument should be moisture-proof and waterproof during transportation to prevent severe vibration and extrusion. Loading and unloading should be handled gently。

6.2 Storage

The instrument should be stored in the room of absence of chemicals, corrosive gas, good ventilation, clean. The room temperature should be kept in 15℃-35℃.

Chapter 7 Electromagnetic Compatibility

According to the regulation of GB4824, our company product urine sediment analyzer belong to group 1 class A nonliving support equipment, when using this equipment, it should be far away from the strong power, high frequency radio transmitters, radar station big current, etc.

The Statement

a)The equipment meets the emission and immunity requirements specified in GB/T18268.26.。

b) The equipment is designed and tested according to class A equipment in GB4824. In the home environment, the equipment may cause radio interference and need to take protective measures.

c) It is recommended to assess the electromagnetic environment before using the equipment

Caution: It is forbidden to use this equipment next to a strong source of radiation, such as an Unshielded rf source, otherwise it may interfere with the normal operation of the equipment.

The power cord：1.5m

Basic performance claimed by electromagnetic compatibility

Accuracy：All of the test results about the standard strip must be in accord with the test value of standard strip.

CE IVD

Appendix A

Guarantee

Dear users：

Thanks for using our urine analyzer, our company will provide you with the following service:

一 Provide technical service at any time.

二 The warranty period is 1 year since the purchase.

三 we will provide you paid service for the following situation:

1) Products beyond the warranty period；
2) Damage caused by accident and improper use；
3) Damage cause the instruction is not used according to specification and seif-repair.

Our company will provide you with you upgrade service with the improvement of technology.

For technical support，please contact us：

MR International Healthcare Technology Co.,Ltd.
ADD:Unit 83 on 3rd Floor,Yau Lee Center No.45,Hoi Yuen Road,Kwun Tong Kowloon,HK
Tel: +86-431-81317781 / +86-431-81317079
E-mail:sales@mr-healthcare.com
Website:http://www.mr-healthcare.com

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Appendix B

Interface connecting urine analyzer and computer

The urine analyzer is connected to the computer via RS-232 standard interface. The communication protocol is as follows:

Baud rate:	9600,4800,1200,19200(optional)
Data bits:	8 bits
Stop bits:	1 bit
Check:	none
Hardware handshake	none
First symbol	02H
Single-byte space	20H
Double-byte space	40H
Line break	0DH0AH
End mark	03H

The urine analyzer is connected with the computer:

Appendix C : Data communication format when the ID number is set to be open. (international unit, regular unit, plus unit)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
STX	CR	LF																							
SP	x	x	x	x	-	x	x	-	x	x	SP	x	x	:	x	x				x	x	x	x	CR	LF
SP	M	E	A	S	SP	SP	N	O	.	SP	x	x	x	x	CR	LF									
SP	I	D	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF			
SP	P	O	R	T	SP	N	O	.	x	x	x	x	x	x	CR	LF									
SP (*)	U	B	G	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	B	I	L	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	K	E	T	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	B	L	D	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	P	R	O	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	N	I	T	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	L	E	U	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	G	L	U	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (!)	S	G	SP	SP	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	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	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	M	A	L	B	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
ETX																									

Data communication format when the ID number is set to be closed. (international unit, regular unit, plus unit)

CE IVD

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
STX	CR	LF																							
SP	x	x	x	x	-	x	x	-	x	x	SP	x	x	:	x	x				x	x	x	x	CR	LF
SP	M	E	A	S	SP	SP	N	O	.	SP	x	x	x	x	CR	LF									
SP	P	O	R	T	SP	N	O	.		x	x	-	x	x	CR	LF									
SP (*)	U	B	G	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	B	I	L	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	K	E	T	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	B	L	D	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	P	R	O	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	N	I	T	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	L	E	U	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (*)	G	L	U	SP	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP (!)	S	G	SP	SP	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	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	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
SP	M	A	L	B	SP	SP	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	CR	LF	
ETX																									

Annotation：

SP(*)---SP OR*

STX=0X02 CR=0X0D LF=0X0A

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

CE IVD

Appendix D

Test Value of Urine Analyzer

Item	Abbreviation	Conventional Unit		International Unit		Symbol system
		plus sign system open	plus sign system closed	plus sign system open	plus sign system closed	
Urobilinogen	UBG	Normal 0.2mg/dL Normal 1mg/dL 1+ 2mg/dL 2+ 4mg/dL 3+ >=8mg/dL	0.2mg/dL 1mg/dL 2mg/dL 4mg/dl >=8mg/dL	Normal 3.4umol/L Normal 17umol/L 1+ 34umol/L 2+ 68umol/L 3+ >=135umol/L	3.4umol/L 17umol/L 34umol/L 68umol/L >=135umol/L	Normal Normal 1+ 2+ 3+
Bilirubin	BIL	Neg 1+ 1mg/dL 2+ 3mg/dL 3+ >=6mg/dL	Neg 1mg/dL 3mg/dL >=6mg/dL	Neg 1+ 17umol/L 2+ 51umol/L 3+ >=103umol/L	Neg 17umol/L 51umol/L >=103umol/L	Neg 1+ 2+ 3+
Ketone	KET	Neg +- 5mg/dL 1+ 15mg/dL 2+ 40mg/dL 3+ >=80mg/dL	Neg 5mg/dL 15mg/dL 40mg/dL >=80mg/dL	Neg +- 0.5mmol/L 1+ 1.5mmol/L 2+ 3.9mmol/L 3+ >=7.8mmol/L	Neg 0.5mmol/L 1.5mmol/L 3.9mmol/L >=7.8mmol/L	Neg +- 1+ 2+ 3+
Blood	BLD	Neg +- Ca10 Ery/UL 1+ Ca25 Ery/Ul 2+ Ca80 Ery/uL 3+ > =Ca200 Ery/uL	Neg Ca10 Ery/UL Ca25 Ery/Ul Ca80 Ery/Ul > =Ca200 Ery/uL	Neg +- Ca10 Ery/UL 1+ Ca25 Ery/Ul 2+ Ca80 Ery/uL 3+ > =Ca200 Ery/uL	Neg Ca10 Ery/UL Ca25 Ery/Ul Ca80 Ery/uL > =Ca200 Ery/uL	Neg +- 1+ 2+ 3+
Protein	PRO	Neg Trace Trace 1+ 30mg/dL 2+ 100mg/dL 3+ > =300mg/dL	Neg Trace 30mg/dL 100mg/dL >=300mg/dL	Neg Trace Trace 1+ 0.3g/L 2+ 1.0g/L 3+ > =3.0g/L	Neg Trace 0.3g/L 1.0g/L >=3.0g/L	Neg Trace 1+ 2+ 3+
Nitrite	NIT	Neg Pos	Neg Pos	Neg Pos	Neg Pos	Neg Pos
Leukocytes	LEU	Neg +- Ca15 Leu/uL 1+ Ca70 Leu/uL 2+ Ca125 Leu/uL 3+ > =	Neg Ca15 Leu/uL Ca70 Leu/uL Ca125 Leu/uL > = Ca500Leu/uL	Neg +- Ca15 Leu/uL 1+ Ca70 Leu/uL 2+ Ca125 Leu/uL 3+ > =	Neg Ca15 Leu/uL Ca70 Leu/uL Ca125 Leu/uL > = Ca500Leu/uL	Neg +- 1+ 2+ 3+

CE IVD

		Ca500Leu/uL		Ca500Leu/uL		
Glucose	GLU	Neg 1+ 100mg/dL 2+ 250mg/dL 3+ 500mg/dL 4+ ＞=1000mg/dL	Neg 100mg/dL 250mg/dL 500mg/dL ＞=1000mg/dL	Neg 1+ 5.6mmol/L 2+ 14mmol/L 3+ 28mmol/L 4+ ＞=56mmol/L	Neg 5.6mmol/L 14mmol/L 28mmol/L ＞=56mmol/L	Neg 1+ 2+ 3+ 4+
PH	PH	< =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	< =5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 > =9.0

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Appendix E

Malfunction Guidance

Number Serial	Malfunction Hint/Possible Malfunction	Solutions
1	Serial port opening failure	Please contact with the manufacturer
2	Camera opening failure	Please detect the cables of the camera are fastening or not
3	Please clean the bottom board	Cleaning the bottom board using washing liquid after taking out it
4	Barcode scanner opening failure	Please check out the barcode scanner is connected or not
5	The angle of inclination of the strips is excessive	Please replace the strips
6	No marks of BIOWAY	Please use the specified strips
7	Test unit communication failure	Please detect the communication cables and ports
8	Printer out of papers	Please supplement papers
9	No detecting of scrap strips box	Please replace the scrap strips box
10	Scrap strips box is full	Please cleaning the scrap strips box

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