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Product Standard No.：YZB/YUE —2013《Electrolyte Analyzer》
Product Registered No: XXXXXX Bureau of Guangdong FOOD and Drug 2008

XI-931 T

Electrolyte Analyzer

User's Manual

Caretium Medical Instruments Co., Limited

Registered Address: 7F building 1 Beishan industrial zone Beishan Road Yantian District, Shenzhen;
Manufacture Address: Future Plaza, Building A, 10th Floor, Unit 1002, Nanshan, Shenzhen 518053, P.R.China
Service Unit: Caretium Medical Instrument Co., Limited
Tel: +86-755-25273714 Fax: +86-755-25273096

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Contents

Chapter 1 General

1.1 Application

The electrolyte analyzer (XI-931) applies ISE (Ion Selective Electrode) technology to the measurement of the contents of potassium (K), sodium (Na), chloride (Cl), pH, nCa^{2+}, and CO2 in human blood serum. The machine can also measure the contents of potassium (K), sodium (Na), and chloride (Cl) with diluted urine.

Instrument Models：

a) XI-931A, XI-931AT: K^+、Na^+

b) XI-931B, XI-931BT：K^+、Na^+、Cl^-、CO_2、AG (where AG is calculated item.)

c) XI-931C, XI-931CT：K^+、Na^+、Cl^-、nCa^{2+}、iCa^{2+}、TCa、pH (where TCa is calculated item.)

d) XI-931F, XI-931FT: K^+, Na^+, Cl^-.

d) XI-931D, XI-931DT：K^+、Na^+、Cl^-、nCa^{2+}、iCa^{2+}、TCa、pH、CO_2、AG (where TCa and AG are calculated items.)

Note：The pH value is measured to calibrate the nCa^{2+} value due to the varied pH value will cause the iCa^{2+} value changecn.bing accordingly. In that case, the pH value measured in this machine does not reflect the real pH value of human blood.

1.2 Instrument structure

XI-931 electrolyte analyzer consists of host components, color LCD touch screen, thermal printer, electrode module, and pressure sensor.

1.3 Brief introduction of the instrument

Potassium, sodium, chloride, calcium and CO_2 make up the main composition of body electrolytes. It is a prerequisite of all medical means to keep the balance of human body electrolytes. Therefore, it

is very important to obtain the amount of potassium, sodium, chloride, calcium and CO_2 in patients' body fluid.

In the past, flame luminosity method was widely used to measure the amount of potassium and sodium. In recent years Ion Selective Electrode (ISE) technology has been developed with the application of sensor technology and micro-computer technology. Flame luminosity method not only requires the flammable gas and the compressed air, but also requires sample centrifuging to obtain the patients' serum for dilution and test. While Ion Selective Electrode method can measure the serum directly without any dilution, therefore it shortens the measuring time significantly. In addition, Ion Selective Electrode method has several advantages: faster, more accurate and less sample volume needed. It has become the mainstream technology for electrolyte analysis. XI-931 electrolyte analyzer is specially designed for clinical analysis.

The main features include:

High precision: Guaranteed by long lifetime, high performance electrode and advanced automatic control software.

Good accuracy: Unique calibration programs eliminate systematic errors. Wide linear range.

Low sample volume: 100~150ul per test only

High throughput: Result obtained in less than 60 seconds.

High automation: Automatic aspiration, washing and calibration. Results display and print out automatically. (All semi-auto models can be updated to fully automatic models by adding an auto sampler.)

Easy operation: User friendly software, large color LCD display, touch screen. 24 hours non-stop working mode, suitable for emergency samples.

Large memory: Store the results automatically, easy to review.

Easy maintenance: Advanced design of hardware, fluid tubing system and self-diagnosis software, makes it easy and simple for maintenance and troubleshooting.

Chapter 2 Measuring principles

2.1 ISE theory

The analyzer utilizes Ion Selective Electrode (ISE) technology. Ion Selective Electrode is a type of electrochemical sensor. It converts the ion activity to the electric potential of the electrode. The relation conforms to the NERNST equation.

Following is the NERNST equation:

$$E = E_0 \pm \frac{2.303RT}{nF} Lg(a_i f_i)$$

Note： E ——the potential of the sample

E_0——the initial potential of ISE

R ——gas constant（8.3145.$kmol^{-1}$）

T ——absolute temperature（273 + t ℃）

n ——the charges of measured ion

F ——Faraday constant（96487C.mol^{-1}）

a_i ——the activity of measured ion

f_i ——the coefficient of measured ion activity

The NERNST equation shows that, in certain experimental conditions, the Logarithm of the ion activity has a linear relation with the electrode potential. In addition, different electrode is sensitive to different ions, for example, sodium electrode is only sensitive to Na ions, and potassium electrode is only sensitive to K ions. If potassium electrode, sodium electrode, and chloride electrode are combined together, then K ions, Na ions, and chloride ions in the sample can be measured at the same time.

The key part of the electrode is the sensitive membrane. On one side, it is in contact with the sample, responds to the change of the concentration of certain ions in the sample. On the other side, it is in contact with the internal filling solution, and converts the ionic conduction to the electronic conduction through a silver thread i.e. internal electrode. In addition, there is a reference electrode providing reference potential and forming a complete measuring circuit. Inside the reference electrode there is also an internal electrode. Its potential remains constant when the concentration of the solution changes, so it provides a reference for the measurement of potential differences.

2.2 Measuring principles

2.2.1 ISE theory

The instrument measures the electrode potentials, and the data is processed by the microprocessor to obtain the concentration of a given ion. The measure method is called “standard comparison”. It uses two kinds of standard solutions, one for the calibration of the base point, and the other for the calibration of the slope. The result is obtained from the potentials of the sample and two standard solutions.

Following are the equations:

$$C_X = C_A * EXP\ [(E_X - E_A) / S] \qquad (1)$$

$$S \equiv \frac{E_B - E_A}{Lg\left(C_B / C_A\right)} \qquad (2)$$

Note:

Cx, Ex: the concentration and potential of the sample

C_A, E_A: the concentration and potential of standard A

C_B, E_B: the concentration and potential of standard B

S: the slope of electrode

In order to improve the precision, the contents of the standard solutions should be similar with the blood samples as much as possible.

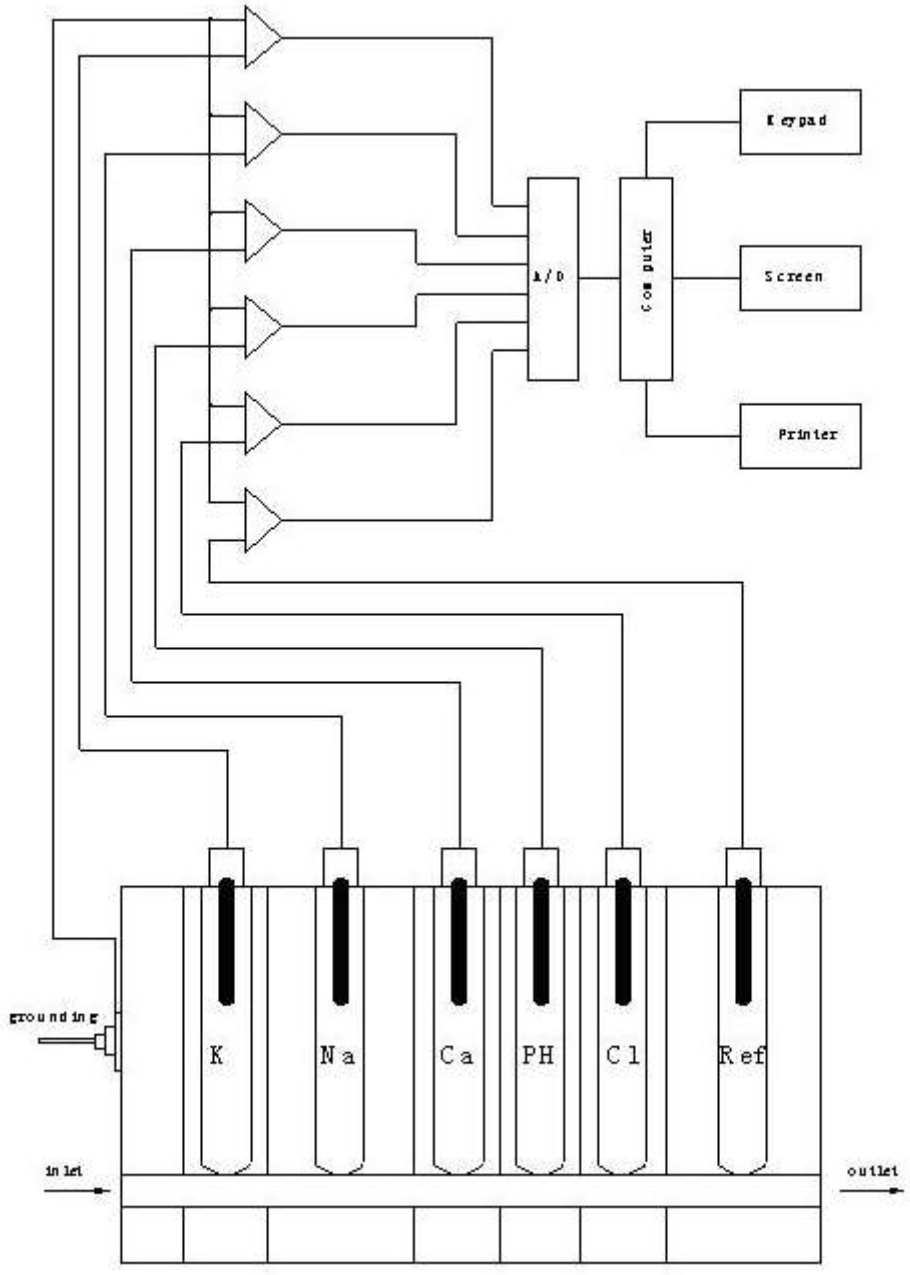


Figure 2.1 Measuring principles

2.2.2 Manometric method (for CO2)

Suitable for XI-931B、XI-931D instrument.

Add certain quantity of blood serum and reagent (lactic acid) into the sealed reaction chamber, the HCO_3^- ions in the serum will participate into the reaction and release CO_2, as a result, the gas pressure inside the reaction chamber will be increased accordingly. The pressure sensor detects the changes and sends the signals to the microprocessor to determine the amount of HCO_3^- ion of serum, and then the amount could be displayed and printed. The instrument uses AB (Actual bicarbonate) stand for HCO_3^- ion. Displayed and printed with CO_2 format.

Chapter 3 Features & Index

3.1 Measuring range & Electrode slope

Electrode	Measuring range/(mmol/L)	Slope range (mV/dec)
K^+	0.50～15.0	27～70
Na^+	30.0～200.0	27～70
Cl^-	30.0～200.0	27～70
Ca^{2+}	0.10～5.00	15～35
CO_2	6.0～50.0	4～20
pH	4.0～9.5(Unit)	27～70

3.2 Sample variety

Serum、Plasma（or whole blood）、diluted urine

3.3 Measuring speed

60 samples/hour

3.4 Index

Parameters	Accuracy(B)	Precision(CV)	Linearity(D)	Stability(S)	Carryover(C)
K^+	≤3.0%	≤1.0%	≤3.0% or ±0.08 mmol/L	≤2.0%	≤1.5%
Na^+	≤3.0%	≤1.0%	≤3.0% or ±2.0 mmol/L	≤2.0%	≤1.5%
Cl^-	≤3.0%	≤1.0%	≤3.0% or ±2.0 mmol/L	≤2.0%	≤1.5%
Ca^{2+}	≤5.0%	≤3.0%	≤3.0% or ±0.04 mmol/L	≤3.0%	≤1.5%
pH	≤3%	≤2.0%	≤5.0%	≤2.0%	≤1.5%
CO_2	≤6.0%	≤3.0%	≤5.0% or ±1.0 mmol/L	≤3 mmol/L	≤10%

3.5 Environment requirements

■ Ambient temperature：(10～30)℃；

■ Relative humidity：(20～85) %；

■ Atmospheric pressure：(86～106)kPa；

■ Avoid electrical interference；

■Avoid direct sunlight；

■Correctly grounding.

3.6 Output

Color LCD display, printer

3.7 Power supply

a.c. 198～242V、50Hz/60 Hz，allowance:±1 Hz

3.8 Power consumption

60VA

3.9 Dimension

Length × Width × Height：490mm×400mm×470mm (Appearance 1)
365mm×320mm×415mm ((Appearance 2)

3.10 Weight

Net weight：8.1kg；Gross weight：16.0kg
Auto sample plate：1.5kg

Chapter 4 Installation

4.1 Instrument installation

4.1.1 Environment requirements

⚠**Note：Please install the machine in the place that is easy to turn on/off the power.**

① XI-931 should be installed on a stable and solid platform that is free of mechanical vibration and away from vibration source.

② Ambient temperature:10ºC～30ºC，relative humidity:20%～85%. High room temperature will reduce the efficiency of cooling and affect performance of instrument. Too high humidity is easy to make corrosion, while too low humidity is easy to produce static interference.

③ The environment should be as free as possible from dust, corrosive gas, loud noises and electrical interference.

4.1.2 Unpacking

① Upon opening the package, check the main unit and accessories against the packing list . If you find anything damage or missing, please contact your local supplier immediately.

② Check if the instrument name and model are matched with the product contract, if not, contact the supplier or our company.

4.2 Power supply

⚠**Note：Please make sure the machine is OFF before installation.**

① Use voltage-stabilized source if the power supply is unstable.

② Make sure the machine is OFF.

③ Connect the machine and socket with power cable.

④ Good grounding.

4.3 Installation of reagent pack

⚠**Note：Do not mix impurities and foreign matters when replacing or refilling the reagent.**

① Check and make sure the reagent pack is suitable for the machine.

② Disconnect red rubber cap from the reagent pack, then insert the pack into the instrument. Shown as figure 4.1.

Figure 4.1

③ After the installation, check if the tubes are connected correctly and reliably.

④ Calibrating for many times to exhaust the remaining reagent and air.

⚠**Note：** If the reagent pack is taken out from the refrigerator, please recover to normal temperature before usage in case it will damage the electrodes.

⚠**Note：Clotted samples are not suitable to the machine, because the clotted sample may cause blockage of the tubes or other problems.**

4.4 Installation of auto plate

The auto plate is optional. It is suitable for XI-931 models.

The installed auto plate is shown as below:

Figure 4.2

① Rise the sample probe

If the probe is down, turn on the power switch, when the probe is risen during initializing, turn off the power.

② Take out the cover

Pull out the white rotary knob near the cover with left hand and rotate left or right for about 45°until the knob is bulged; then take out the cover with the right hand. See figure 4.3.

Figure 4.3

③ Pull out the data line behind the cover.

Figure 4.4

④ Connect the data line

Insert the data line into the socket of auto plate, make sure the connection is reliable.

Figure 4.5

⑤ Connect the plate with frame

Connect the plate with frame as figure 4.6 shows.

Figure 4.6

⑥ Lock the auto plate

After connecting with the frame, hold up the plate with right hand, rotate the white rotary knob left or right for 45° until the knob is recessed, then the plate is locked.

Figure 4.7

⑦ Fix the sampler

Put the sampler on the auto plate. Make sure the small hole of sampler (position 1 of figure 4.8) is matched with the embossed point of auto plate (position 2 of figure 4.8).

Figure 4.8

Chapter 5 Work interface and operation

Do not restart the machine immediately after turn off. Please restart at least one minute later, or it may damage the power and the boards.

5.1 Startup interface

Turn on the power switch, and the printer will print the version. Screen is shown as figure 5.1.

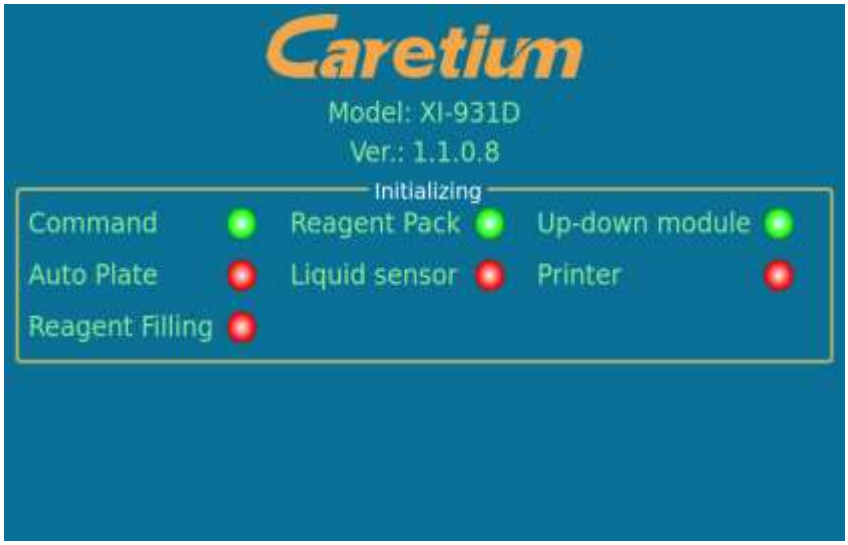


Figure 5.1

System will finish the self-test in following order: Command, Reagent pack, Up-down module, Auto plate, Liquid sensor, Printer, Reagent Filling. If self-test passed, the indicator light turns green; otherwise, the light stays red.

For the semi-auto mode, the auto plate indicator light stays red because there is no auto plate.

5.2 Dormant interface

Without operation for 20 minutes, the system will go into dormant state automatically, screen is shown as figure 5.2.

Figure 5.2

Once entering dormant state, the instrument will calibrate electrodes automatically every two hours during dormant period. Click wake up within 30 minutes of dormant time, the machine will wash the tubes and return to the interface before dormant state. Click wake up after 30 minutes, the machine will calibrate electrodes first, then return to the interface before dormant state.

5.3 Operation interface

Operation interface consists of main function keys area, sub-interface display and operation area and the prompt area (See Figure 5.3).

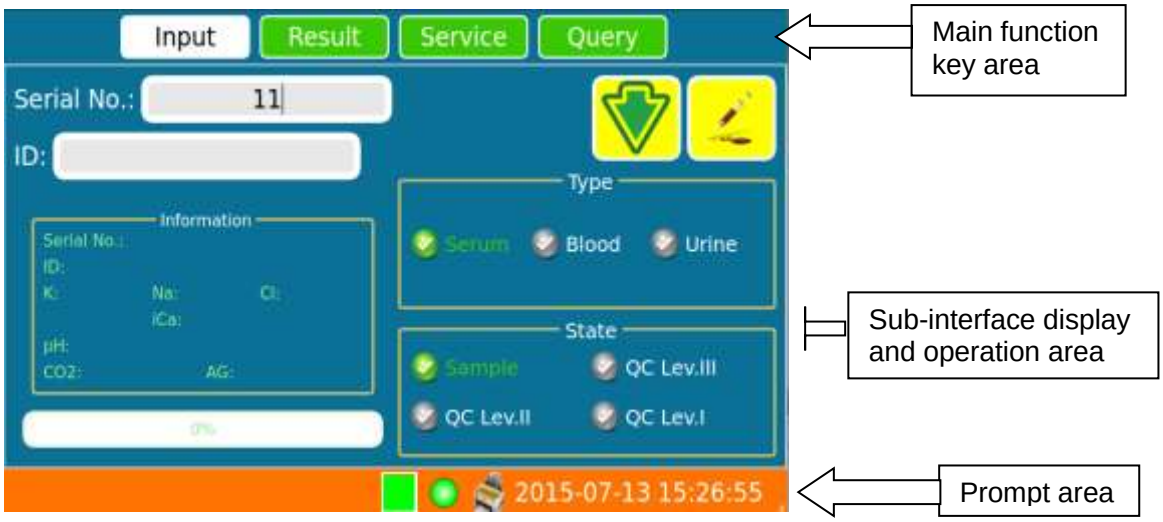


Figure 5.3

■ **Main function keys area**

Consists of Test, State (only displays in automatic mode), Result, Service, Query. Clicking each key can enter related function interface respectively.

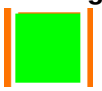
■ **Sub-interface display and operation area**

This area displays the sub-function of main function. User can operate the machine in related interface.

■ **Prompt area**

This area consists of Date & Time, printer status, system status, error and reagent remains.

Meaning of the icons：



Reagent remains. Displays green when the reagent pack remains more than 20%, and turns yellow when it remains more than 10% but less than 20%; However, when the reagent pack remains less than 10%, it turns black.

The system is free(has no operation)；When the ball is red, the system is busy.

Printer is normal；

Printer is damaged or has been closed.

5.3.1 Main function keys area

5.3.1.1 Test

a. Interface of semi-auto mode（Figure 5.4）

图5.4

Serial No.：Start from number 1 every day, and increase automatically after each measurement.

ID：Input if necessary. Two ways to input: one is to input through bar-code scanner, and another way is clicking the display column then input the ID in new dialog box. The empty ID has no influence to the measurement.

Type, State：Select the sample type and state. The defaults are Serum and Sample.

> **If select "Urine" as sample type, before measurement, please dilute the urine sample (1:1) with diluent that supplied by Caretium.**

Aspiration：Click  ，the probe will lift up, then put the sample under the probe and click the prompt dialog box to finish the aspiration. When the probe needs to fall down, click  to let the probe down.

When the measurement finished, the information box in the lower left side displays the result, and the printer prints the result at the same time.

b. Interface of automatic mode（Figure 5.5）

Figure 5.5

Adds：Add more than one measurement with the same sample type.

Click Adds, select the Start position and End position then click Yes in screen as Figure 5.6. If the

hole has been used in current plate, the hole will not be displayed in the screen, and cannot be selected either. For example, if hole 1 and 2 have been input before, there are no position 1 and 2 displayed.

Figure 5.6

Add：Add the measurement with different sample type.

Delete：Delete one added measurement in the list (select the added measurement that needs to be deleted, then click Delete to finish.)

Delete All：Delete all the added measurement in the list just by clicking Delete All.

Click 

，the machine will start the measurement from the smallest Hole No..

During the test，if user wants to measure emergency sample, select “Emergency”, put the sample on the hole E1 or E2 according to the Hole No. displayed, then click Add, the system will measure the emergency sample after finishing the current sample. After measuring the emergency sample, the system will measure the rest.

For the auto plate mode, if the machine successive test for no less than five samples and has no more adds, the system will enter Maintenance interface to run clean protein. When finish, click Close, then the system will calibrate for once, otherwise, the system stays at Maintenance interface.

Click 

, the machine will start test by automatically detecting all the sample cups on the plate.

Notes about the position and Serial No. of emergency sample:

For the first emergency sample of the current day, put it on the plate hole E1, and the second sample put on hole E2, the third one on E1, and so on. That is, odd number sample put in hole E1 and even number sample in E2. The serial No. for emergency sample will increase after every emergency measurement, and it will recover to E1 for the first emergency sample of next day.

5.3.1.2 State

This interface only displayed in automatic mode.

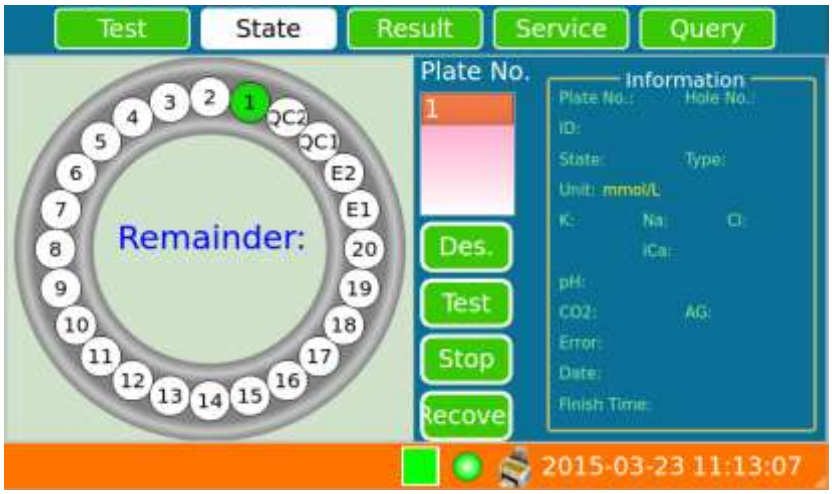


Figure 5.7

This interface displays the test state of samples added on the plate. Select the number under **Plate No.**, the virtual plate will display all the holes' states of that plate, such as testing, waiting for test, finished, etc. The test states are displayed with different colors. Selecting the No. of hole on the virtual plate, the sample information will appear in information box on the right side.

Des: The description of the state color, see Figure 5.8.

Figure 5.8

Test: Select the plate No. that has been input, click Test to measure the plate first.

Stop: When measuring, click Stop can pause the tests after finishing current test.

Recover: If user wants to continue the rest tests that have been paused, click Recover.

5.3.1.3 Result

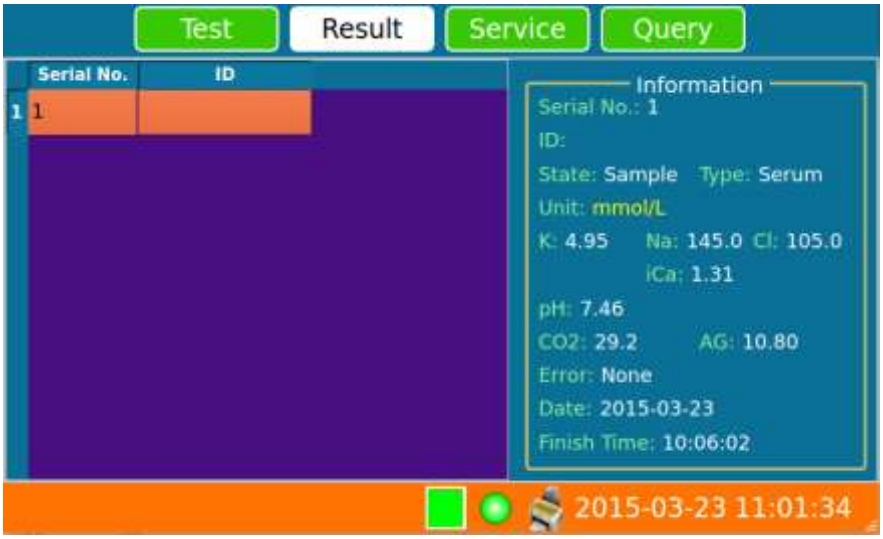


Figure 5.9

All the measured information and results are displayed in this interface.

5.3.1.4 Service

Figure 5.10

a. Calibration：Click Calibration will enter the interface that user can run the calibration and new reagent pack register. Screen is shown as figure 5.11.

Figure 5.11

Electrolyte：Click Electrolyte，system will run two points calibration of electrodes（K、Na、Cl、Ca、pH）.The slopes will be printed out and displayed in this screen after calibration. The potential of the electrode also displayed in the screen to help users know the liquid states and electrodes performance.

CO_2 Cal.：There are two aspirating modes: semi-auto and automatic mode.

Semi-auto mode：Click CO_2 Cal.，the probe lifts up, put AB solution under the probe then operate according to the screen prompt. After aspiration, the system starts CO2 one point calibration. System automatically compares the calibrating slope and the stored slope, if the difference between the results is large, the screen prompts to aspirate again (this prompt will not appear more than twice), then calibrates and displays the slope.

Automatic mode：Click CO_2 Cal.，make sure that the AB solution is put on Cal. Hole, then the probe aspirates the solution to calibrate. The same with semi-auto mode, if the difference between the results is large or the result is out of range, the system will rotate the plate and aspirate again without prompt.

Review：The system saves and displays the latest electrode slope results. Click the result will appear all the potential read during the calibration. Shown as Figure 5.12.

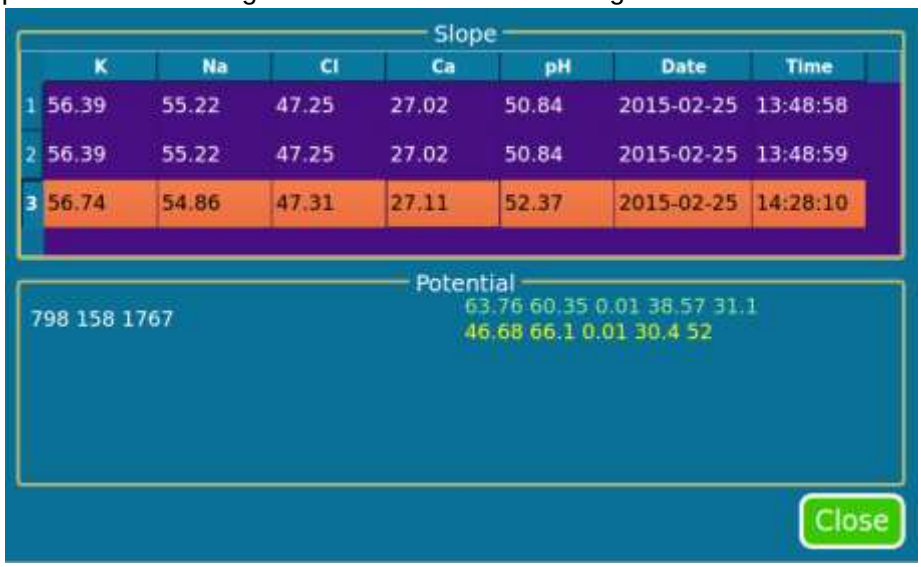


Figure 5.12

Review CO_2：The system saves and displays the latest CO2 slope results. Shown as Figure 5.13.

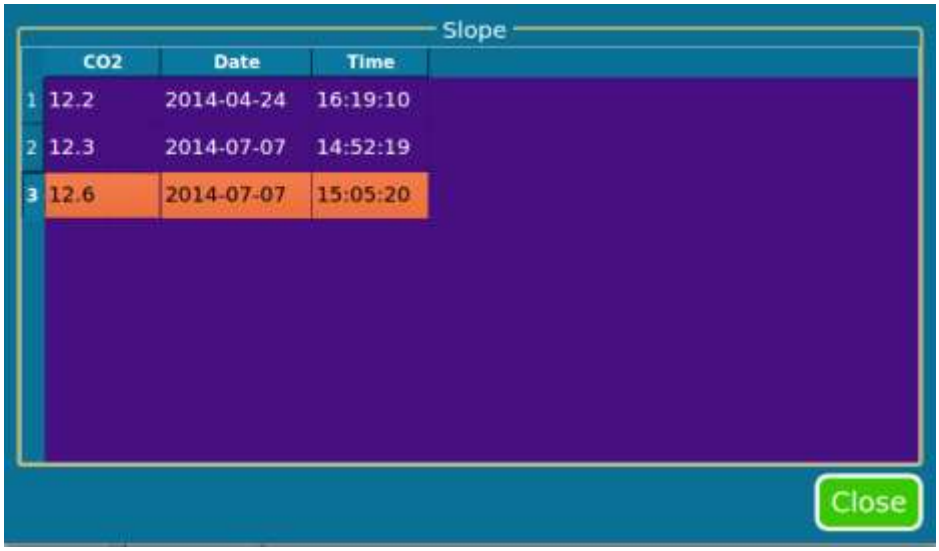


Figure 5.13

Regist: After replacing the reagent pack, there two ways to register the new pack: restart the machine or use Regist function.

If do not restart the machine, just click Regist , so the machine aspirates A standard solution, B standard solution and R solution. After that, the tubes will be filled up with new reagent. The system will read the card information inside the pack and displays the remains volume with percentage format. Then the system will run one electrode calibration program.

1. If the remain volume is less than 20%, the screen will pop-up a dialog box "There is not enough reagent". If the remain volume value turns red (0%), please replace reagent pack immediately.

2. If have replaced the new pack or run maintenance, debug program, please calibrate for two or three times.

★ Calibration is one necessary step before measurement. If do not calibrate or the calibration do not passed, the prompt area will display "Electrode CO2 ?"

Calibration includes: electrodes and CO2 calibration.

■ Electrodes calibration

When startup, the machine calibrates automatically, after that, click Electrolyte to calibrate for once or twice more no matter whether the slopes are passed or not. Compare the calibration slopes.

Requirements:

a. All the electrode slopes should be in normal range. The ranges are printed in the right side.

b. The difference between two successive calibrations is less than 2.0 for the same item.

■ CO_2 calibration

Run CO_2 calibration for two or three times after electrodes calibration.

Requirements:

a. The slope should be in normal range. The ranges are printed in the right side.

b. The difference between two successive calibrations is less than 2.0.

1. If the results are not in normal range after calibration for many times, please check and troubleshoot. More information can be found in chapter 8 (Troubleshooting).

2. Do not measure the samples if the calibration results do not match the requirements, or the measure result is invalid. There are words prompted in the screen before measurement.

b. Factor：When the sample measurement results have fixed bias, modifying the factor can eliminate. Shown as Figure 5.14.

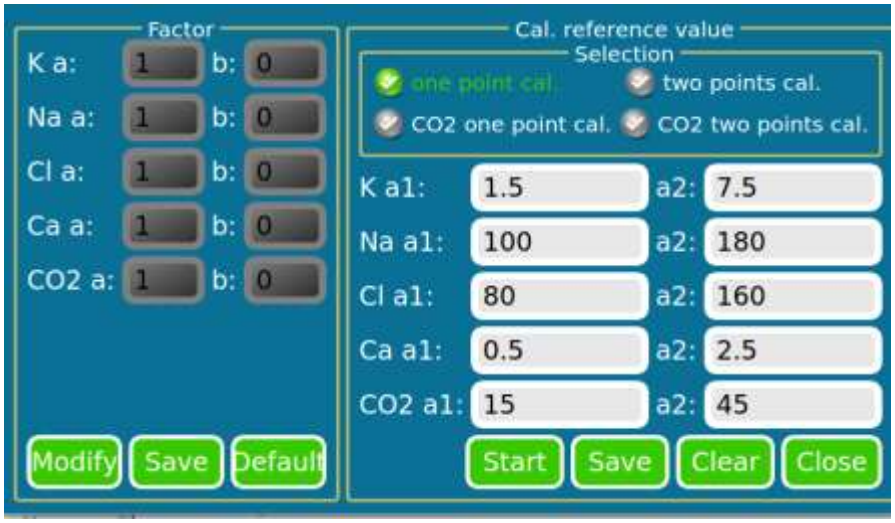


Figure 5.14

Two ways to modify: manual modification and automatic modification.

■ **Manual modification**

Click Modify，then click Yes in the prompt dialog box, the factors turn white, in that case, input the new factors.

Measure the calibrator (or controls) as sample, then the test result divided by target value can get the “a” value.

Measure two level calibrators (or controls) and use function (e.g.: INTERCEPT function in EXCEL) to get “b” value.

Manual modification usually bases on clinical experience.

■ **Automatic modification**（Aspirate modes: semi-auto and automatic mode）

Includes one point calibration and two points calibration.

◇ **One point cal.**：Modify “a” value only.

Use one level calibrator (or control), and mid-value level calibrator is recommended. Input the target value and click Save .

Semi-auto mode：Select “One point cal.”，click aspirate icon, measure the calibrator or control as sample following the screen prompt, when finish, the screen prompts and saves the new factors.

Automatic mode：Select “One point cal.”，click aspirate icon, ensure the calibrator or control has been put on hole “Rinse/CAL”. The machine rotates the plate and aspirates, then starts the measurement, when finished, the screen prompts and saves the new factors.

◇ **two points cal.**： Modify both “a” and “b” value.

Use two level calibrator (or control), high level and low level are recommended. Input the target value.

When select two point calibration, there are requirements for difference of the two level target：K^+>2.0mmol/L, Na^+>20mmol/L, Cl^->20mmol/L，Ca^{2+}>0.3mmol/L，CO_2>10mmol/L. If the difference do not match the requirement, the screen will prompt and do not allow to run the calibration program.

Since not all the calibrators(or controls) have coexist K^+,Na^+,Cl^-，Ca^{2+} and CO_2 items, the instrument calibrates K^+,Na^+,Cl^- , Ca^{2+} items and CO_2 separately.

Select “two points Cal.”, check if the low value calibrator is in hole “Rinse/CAL”, and high level calibrator in hole “QC 2”,after that, click aspirating icon, the instrument will measure low calibrator first, then high level calibrator. When finished, the screen prompts and saves the new factors.

Click Default can recover the default value(a=1,b=0).

Calibrating the factors can affect the test result, please be cautious when operating.

c. QC

This interface displays the QC data, screen is shown as Figure 5.15.Three level QC are allowed. Mean and SD value need to be set. Click Save M/SD after input the value.

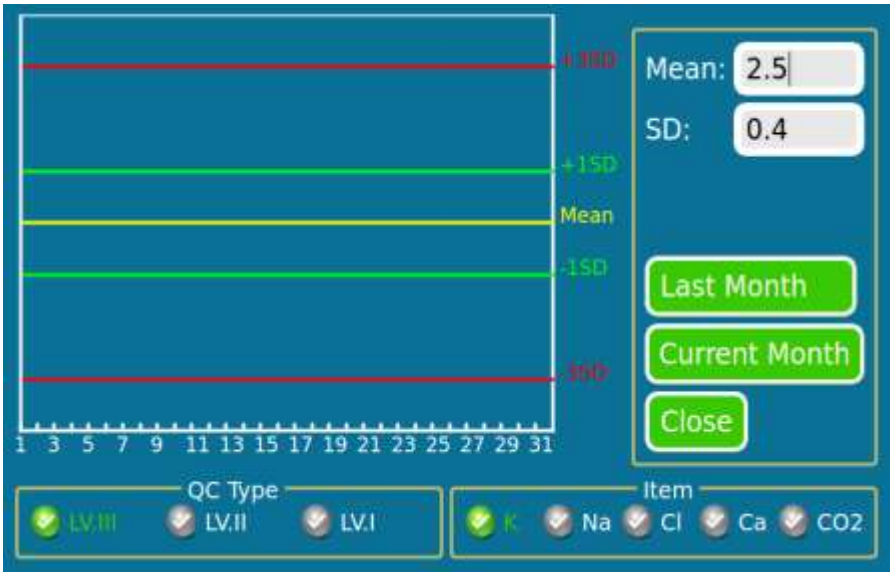


Figure 5.15

d. Settings

This interface can set the date & time, select the language and revise the reference value. Screen is shown as figure 5.16.

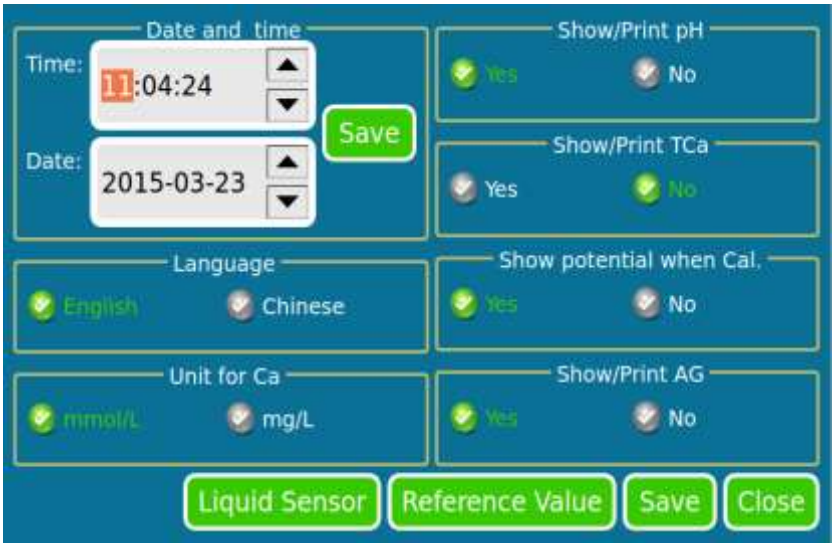


Figure 5.16

Date and time: Change time and date, click Save, and restart the machine following the prompt, otherwise, there may be some errors in later measurement or operation.

Language：After changing the language, click Save and restart the machine to make the setting become effective.

Unit for Ca：Choose mmol/L or mg/L according to clinical needs, and the printout will print the chosen unit. The default unit is mmol/L.

Show/Print pH：Printing pH or not is selective. The default is “Yes”, means the printout result will show pH result.

Show/Print TCa：Printing Tca or not is selective. The default is “Yes”， means the printout result will show pH result.

Show potential when cal.：Potential is displayed or not during calibration is selective. The default is “Yes”

Show/print AG：Printing AG or not is selective. The default is “Yes”， means the printout result includes AG result. AG means anion gap, it’s a calculated value. Formula: AG=n(Na^+)-n(Cl^-)-n(CO_2)，“n” means the concentration of the item.

Exit：This is for debugging and only used by engineer. If user clicks by accident, the operation system will close, that is, the screen displays black but the power is on. In that case, turn off the power switch then restart to recover the operation system.

Liquid Sensor：When the positioner is invalid, user can manually locate the liquid position in tubes. This is to ensure enough sample volume without bubble, for example, the detection channel will be filled up with liquid from K electrode to Ref electrode. Click Liquid Sensor and input the value in the pop-up box, then select Start， screen is shown as Figure 5.17. The machine absorbs standard A solution, so user can check if the channel is filled with liquid. Suggestion: The end of the liquid should stay in the location with 2cm from Ref electrode outlet. This is to ensure the correct aspiration volume.

Before clicking Close， please touch Save to save the setting.

Since the location value depends on the length peristaltic pumps tubes, please run this

program at regular intervals to ensure the correct aspiration volume, because the length may change along with the using time.

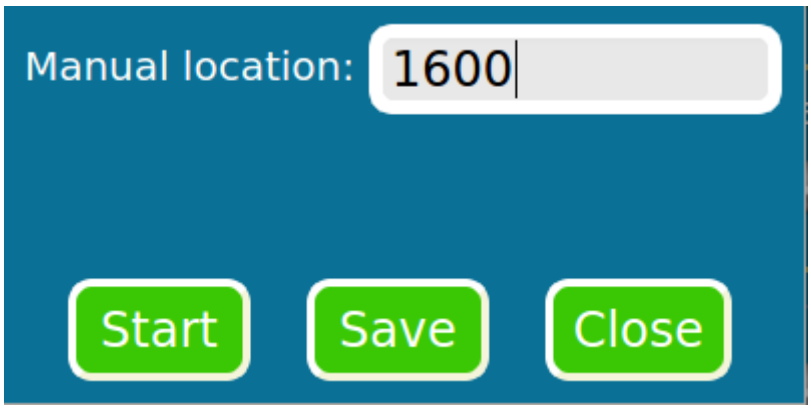


Figure 5.17

If locate manually, please run CO2 calibration again, or the CO2 measure results are unreliable.

Reference Value：Set the normal range for each item.

Click Reference Value, then pop-up a new box as Figure 5.18, input the value and click Save to finish.

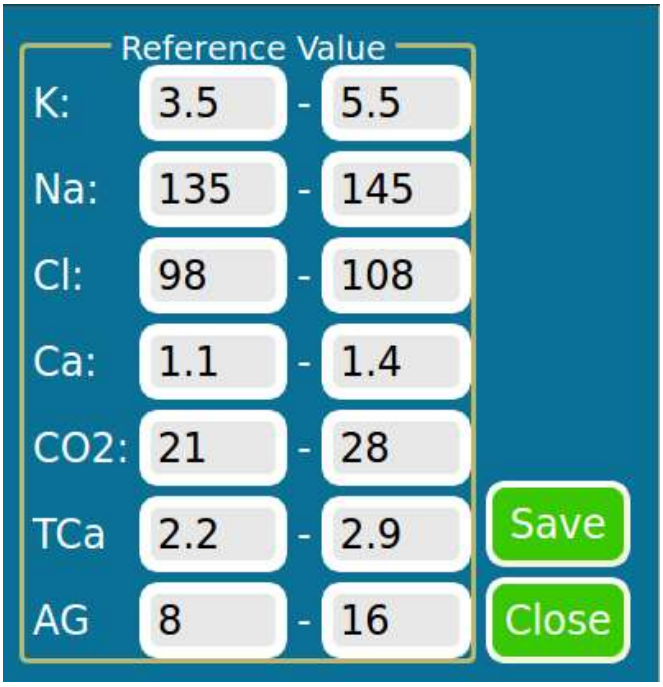


Figure 5.18

★ Click Save in settings interface is to save the settings except the settings of date and time that need to restart the machine. However, user needs to click Save in Liquid Sensor and Reference Value screen to save the settings.

e. Maintenance：Run protein cleaning and Na adjust programs. Screen is shown as Figure 5.19.

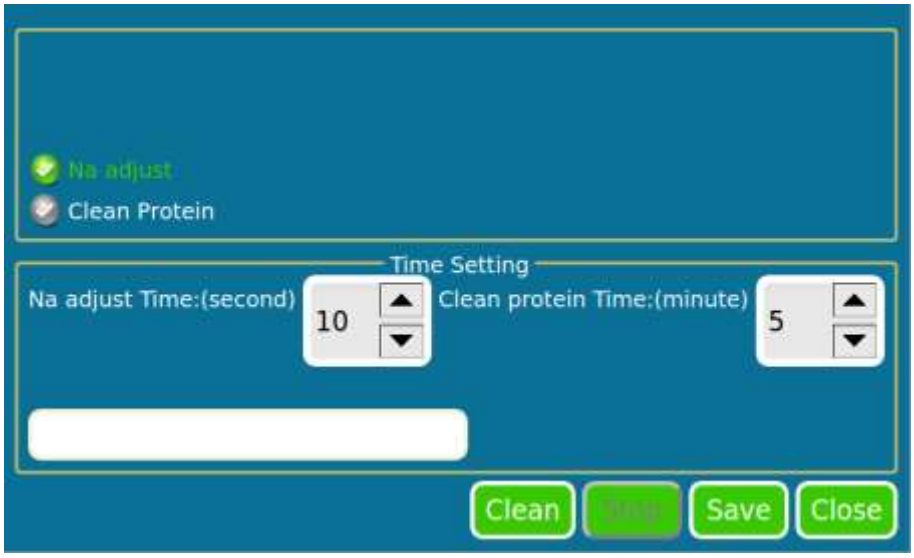


Figure 5.19

Set and save the time of Na adjust and Clean protein. Suggestion: Na adjust time should not more than 10 seconds, and Clean protein time no more than 5 minutes. If the cleaning result is unsatisfied, run the program again. “Na adjust” solution and “Clean protein” solution have some damage to the electrodes, so it is not recommended to soak internal electrode for long time.

Select “Na adjust” or “Clean protein”, click Clean, then the machine prompts to aspirate Na adjust solution or Clean protein solution as sample and finishes the program in the setting time.

Click Close, if user has not clicked Clean, the system returns to Service interface without other operation, otherwise, the system will calibrate for once.

f. Send Data： Send all the test results of current day to a computer through RS-232 port. The detailed information for the transmission protocol between the machine and computer are described in Appendix.

Click Send Data, screen is shown as below.

Select “Yes”, the machine will send a test record to the computer when the measurement is finished.

Select “No”, the machine does not send the test result.

“Total Records” means the amount of the test results in current day.

Click Send, all the results will be sent to the computer.

Figure 5.20

g. Debug：See Figure 5.21. This function is for engineers and experience users. They can detect the moving parts and liquid. When some malfunction happened, use this function can proceed the troubleshooting.

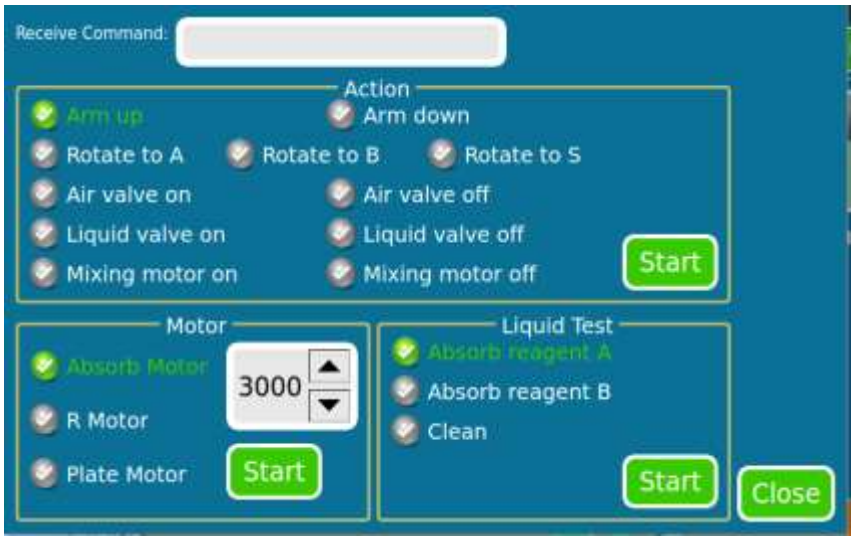


Figure 5.21

h. Potential：Screen is shown as Figure 5.22. The system absorbs standard A, standard B solution from reagent pack, or aspirates sample manually, then click Read, the screen will show the potential of each electrode. Click <<Adjust or Adjust>>, makes the liquid back or forward. This program helps engineers and experience users understand the performance of electrodes and liquid sensor.

★The normal potential of electrodes should be above 30mV.If all the electrodes potential are smaller than 30mV, it means the Ref electrode is getting aged and should be replaced.

How to judge the performance of liquid sensor: When there is only air instead of liquid inside the liquid sensor, the potential called high value; when it is filled up with liquid, the potential called low value. If two times low value less than the high value, the liquid sensor is working normally, otherwise, the sensor is invalid.

Click Read, the potential of each electrode displayed circularly, and the potential will stable at normal range after 30 seconds.

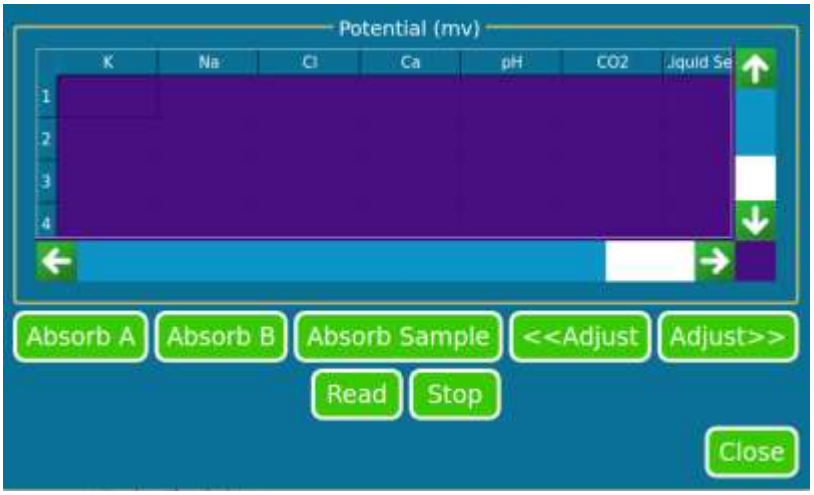


Figure 5.22

i. Printer：Printer on or off is optional. The default is “On”. Click Test can test the performance of the printer. “Print voltage when test” provides the choice to print out electrode voltages of both reagent A and sample in test process, which helps engineer to perform machine maintenance. Screen is shown as Figure 5.23.

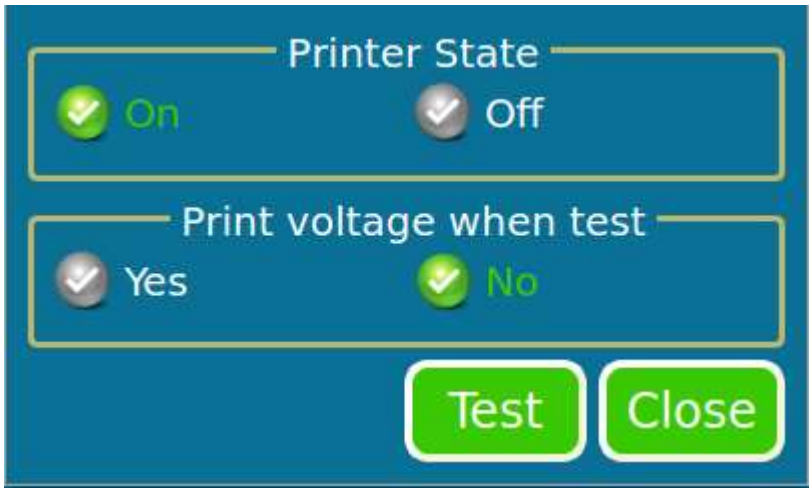


Figure 5.23

5.3.1.5 Query

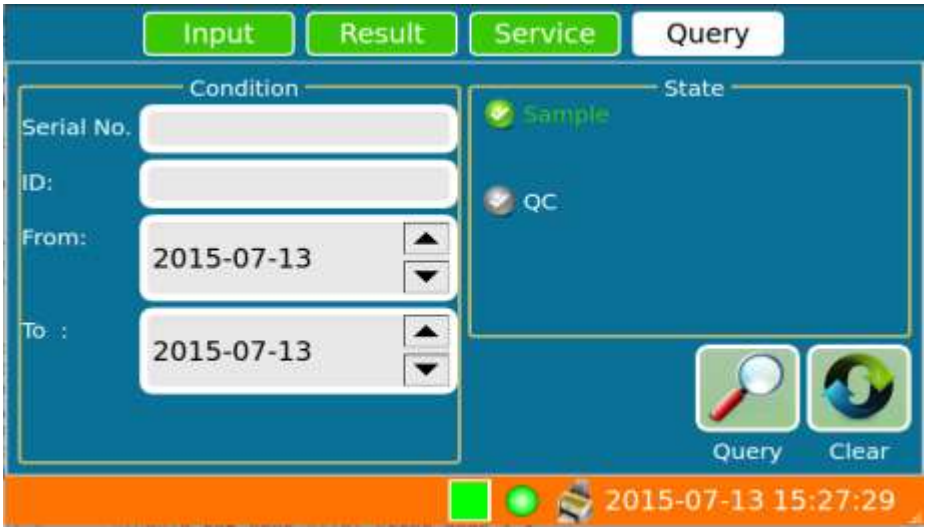


Figure 5.24

User can query the test or results by inputting the query condition. Change the date “From” ”To”, user can query the results tested in this period; Change the date and input Serial No. or ID can query pointed test record.

Clear：Touch this key can clear the query condition. “Serial No.” and “ID” become empty and “From” “To” display current date.

Chapter 6 Precautions

6.1 Operation precautions

a. The analyzer is designed to work continuously for 24 hours a day. No need to shut down the machine every day.

b. Do not use the standard solutions for flame luminosity. They include strong acid and other supplements that may damage the electrodes.

c. Not all commercial controls are suitable for ISE measurement. Some of them contain too much chemical additives that may interfere in the measurement.

d. The bubbles should be excluded during the sample aspiration; otherwise the results will be unreliable.

e. If the ambient temperature fluctuates for more than 10 degree, the instrument should be calibrated again.

f. Discard the reagent if mildew or deposition found.

g. Perform the routine maintenance according to the instructions.

h. Every electrode has printed its own lot number, if the number cannot be recognized, our company will not ensure the quality.

6.2 Sample Collection and handling

Sample collection and handling must be carried out by the professionals. Always avoid the hemolysis. In addition, the following points should be noted:

1. The serum or plasma can be stored in the refrigerator, but they must be warmed up to the room temperature before test.

2. When preparing the blood serum samples, do not add any materials like the surface active agent that may interfere in the measurement or even damage the electrodes.

Note：When the machine is scrapped, please deal with according to the requirement of local environmental protection administration.

Chapter 7 Maintenance

Note：* Clean inside the instrument when the measurement of current day is finished.

*** Use special cleaning solution produced by Caretium.**

7.1 Daily maintenance

a. If the slope of electrode Na is smaller than 45, please proceed Na adjust.

b. Pay attention to the reagent residual volume; replace the reagent pack if necessary.

c. If there are less than 20 samples every day, please calibrate manually before off duty.

d. If there are more than 10 samples every day, please proceed “Clean protein”, once with weekly cleaning solution.

7.2 Weekly maintenance

a. Run “Clean protein” once a week if more than 25 samples measured every day. If less than 20 samples measured every day, then the user just need to run the program every 2-3 weeks. Run “Na adjust” program if the slope of Na electrode is less than 45.

b. Check the potential and judge/decide if Ref electrode needs to be replaced.

7.3 Monthly maintenance

a. How to clean sample probe and liquid combiner

Click the aspirating icon, then the probe lifts up. Take off the tube that connected with the probe, then clean the internal probe with a needle; Clean the external probe with a clean cotton swab and ethanol until there is no obvious attachment. Take off the liquid combiner and clean with needle, duster and water.

b. How to clean the detection channel of electrodes

Clean the channel with cotton thread, duster, and so on. However, do not clean the channel

with hard objects.

Caution：Do not clean the internal channel with needles.

c. Check the tubes

Make sure the connection is reliable. Check if there is protein inside the sample tube, pump tubes and waster tube. If there is protein inside the tubes, please clean or replace them. Check the tube connected with liquid combiner, if there are some foreign matters, clean or cut off 1-2mm.

7.4 Check the tubing system

Note：* Check peristaltic pump tubes every day, and replace if have used for three month.

*** Make sure the peristaltic pump tubes are provided by the manufacturer.**

If the aspirating speed and volume are abnormal, check the tubing system to see if there is any leakage.

a. Enter Service → Debug, run Liquid Sensor program.

b. Observe the flow situation of sample probe, liquid combiner and detection channel of electrodes.

c. If the tubing connection loose, then bubbles can be found near the connector. Connect the tubing again.

d. If somewhere between the electrodes leaks, then disassemble the electrodes and check the gasket.

7.5 Replace the electrode

Note：Please use the electrodes and filling solution produced by manufacturer.

a. Counterclockwise loosen plastic nut in the right side of the electrode box, remove the electrode. Shown as below:

Figure 7.1

b. Reload new electrode and re-tighten the plastic nut in the right side of electrode box.

7.6 Maintenance when it needs to be maintained or stop using

Note：* If the machine needs to be maintained or stop using, please clean and disinfect thoroughly in case of some danger happens during the transportation or disposal.

*** Use the clean solution produced by Caretium.**

If the machine needs to be maintained or stop using, please clean and disinfect thoroughly. This is to clean the remaining to avoid the blockage.

Clean and disinfect methods are the same with 7.3.

Chapter 8 Troubleshooting

8.1 Slope of electrodes or test result abnormal

Cause	Solution
1. The electrode is not activated or the activating time is insufficient	Calibration for more than once
2. Power supply voltage fluctuates	Use UPS or power stabilizer
3. Unreliable grounding	Use special grounding wire, and check the connection of the grounding wire
4. Humidity too high in electrode box or there is much dust inside	Lower the humidity or move the dust
5. Poor connection of the electrode contact	Check and connect again
6. Reagent contaminated or invalid	Replace the reagent pack
7. More protein in liquid tubes	Run protein cleaning program
8. Incorrect positioning	Check and clean the tubes, or check the positioning
9. The reference filling solution is not enough	Refill the solution
10.Electrode does not work	Replace the electrode

8.2 Slope of CO2 or test result abnormal

Cause	Solution
The detection system leaks	Clean or replace the tubes, mixing chamber cap, drain valve outlet
Insufficient CO_2 standard solution	Replace CO_2 standard solution
Pressure sensor is broken	Replace the pressure sensor
Abnormal mixing	Clean mixing chamber or replace the motor
Pump S sticks or long stretches	Rebound or replace the tubes
Aged tubes of drain valve or the valve can not be closed	Replace tubes or drain valve
Air outlet valve leaks	Replace the tubes or air outlet valve

8.3 Aspiration abnormal

Cause	Solution
Aspirating tube loose or broken	Connect again or replace it
Pump tube sticks or broken	Restore the tube
Pump tube blocked	Clear the blockage
The gasket between the electrodes does not placed properly or missing	Place the gasket properly
The electrode assembly leaks	Tighten the assembly again

Chapter 9 How to clean and disinfect the auto sampler

If the sampler is contaminated by serum, please disinfect it.

Take off the auto sampler, soak it in 2% “84 disinfectant solution”（or 2% glutaraldehyde solution） for 30 minutes, then clean it with water. When it is dried, put the sampler on the plate. External of the plate can be scrubbed with disinfectant solution.

Chapter 10 Notes for clean protein solution

There are two kinds of clean protein solution: daily cleaning solution (blue) and weekly cleaning solution (colorless). There is only weekly cleaning solution for semi-auto analyzer. This solution can remove the protein from the tubes, especially for the fibrous protein. It is slightly alkaline and has little side effect to ISE electrodes.

After cleaning protein, please run calibration for many times until the slopes are stable.

If not used, the solution should stay in somewhere cool, dried and without light.

Chapter 11 Notes for QC solution

QC solution is only used to test the performance of the analyzers produced by Caretium, and the test results should in the range of the solution. The results are not suitable for the accuracy test of analyzer. Also, the solution should not be used to calibrate the machine.

Appendix Standard output interface instruction

（1）Features

Electrical characteristics：EIA RS-232C

Transmission：asynchronization

Stop length: 1 bit

Data bits length： 8 bits

Parity bit：None

Speed： 19200 baud rate

（2）Data format

Example：

1,1,6901028001984

,Sample,Serum,4.96,148.4,105.7,mmol/L,1.34,1.32,2.61,7.36,0.00,42.70,Normal,2013-08-17,15:34:05,15:37:20

Instruction：

Serial No.，Hole No.，ID，Sample type，Serum，K result，Na result，Cl result， Ca result，iCa result，nCa result，TCa result，pH result，CO_2 result, AG result，error，Year-Month-Day，Input time，Finish time

(3) Pin connection