Ver Date：20220820

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

XI-931

Electrolyte Analyzer

User's Manual

Caretium Medical Analyzers Co., Limited

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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 analyzer can also measure the contents of potassium (K), sodium (Na), and chloride (Cl) with diluted urine.

Analyzer 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 analyzer does not reflect the real pH value of human blood.

1.2 Analyzer structure

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

Appearance 1

Appearance 2

1.3 Brief introduction of the analyzer

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 analyzer 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:

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

$$S = \frac{E_B - E_A}{Lg(C_B/C_A)} \quad （2）$$

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.

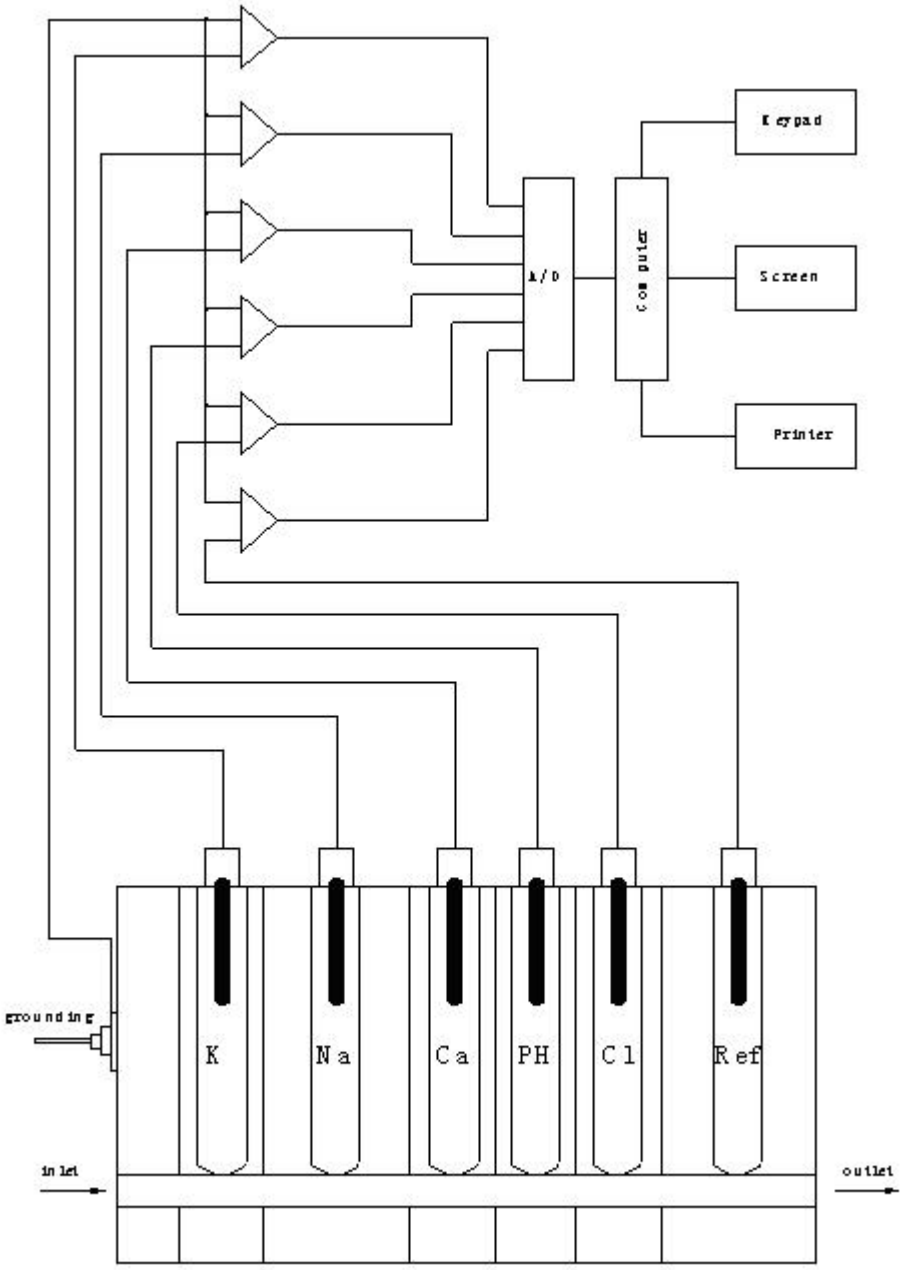

Figure 2.1 Measuring principles

2.2.2 Manometric method (for CO2)

Suitable for XI-931B/T、XI-931D/T analyzer.

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 analyzer 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

AC 110/220V、50Hz/60 Hz，allowance:±1 Hz

3.8 Power consumption

60VA

3.9 Dimension

Length × Width × Height：420mm×350mm×440mm (Appearance 1)

400mm×320mm×430mm ((Appearance 2)

3.10 Weight

Net weight：8.1kg；Gross weight：16.0kg

Auto sample plate (optional)：1.5kg/set

Chapter 4 Installation

4.1 Analyzer installation

4.1.1 Environment requirements

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

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

② Ambient temperature:10°C～30°C，relative humidity:20%～85%. High room temperature will reduce the efficiency of cooling and affect performance of analyzer. 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 analyzer name and model are matched with the product contract, if not, contact th e supplier or our company.

4.2 Power supply

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

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

② Make sure the analyzer is OFF.

③ Connect the analyzer 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 analyzer.

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

Figure 4.1

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

④ Calibrating for several times to flush out any residual reagents and air in the system.

⚠**Note：** If the reagent pack is taken out from the refrigerator, please warm it up to room temperature before use to prevent damage to the electrodes.

⚠**Note：** Please don't test coagulated samples, as it can lead to blockages in the instrument's internal tubing and other issue**.**

4.4 Installation of auto sampler (without auto barcode reader)

The auto sampler is optional. It is suitable for XI-931/T models.

The installed auto sampler is shown as below:

Figure 4.2

① Rise the sample probe

If the probe is not raised, please turn on the power switch. After the instrument initializes and the sample probe is lifted, turn off the power switch.

② Take out the cover

Using your left hand, pull out the white knob located on the left side of the instrument, and rotate it 45° to the left (or right) until it protrudes; with your right hand, gently pull out the lower cover as shown in the 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 sampler, make sure the connection is reliable.

Figure 4.5

⑤ Connect the sampler with the instrument

Connect the sampler with the instrument as shown in figure 4.6.

Figure 4.6

⑥ Lock the auto sampler

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

Figure 4.7

⑦ Secure 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

4.4 Installation of auto sampler (with auto barcode reader

The auto sampler is optional. It is suitable for XI-931/T models.

The installed auto sampler is shown as figure 4.9

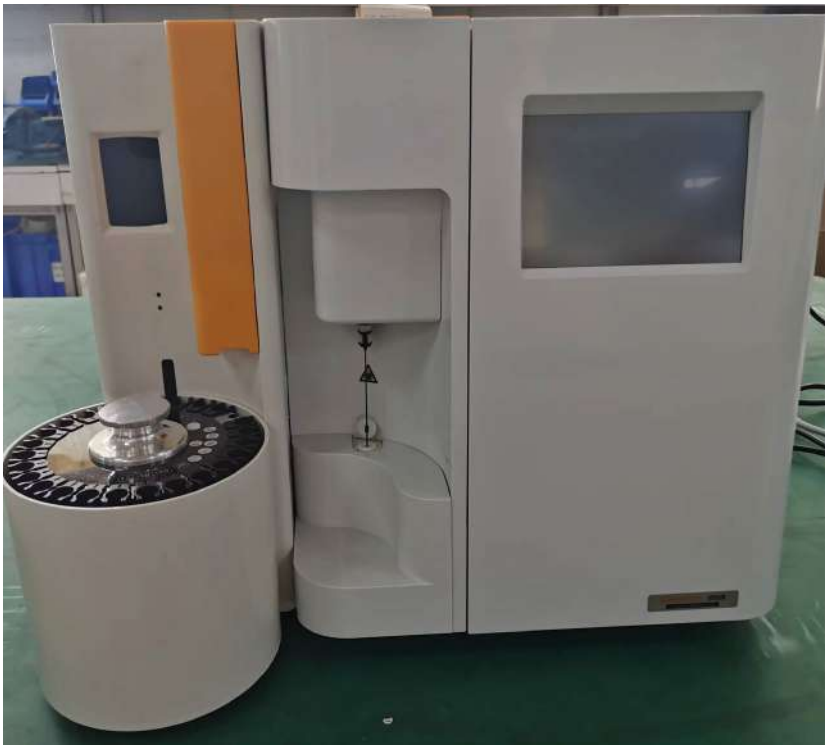

Figure 4.9

① Connect the main unit and autosampler with wire below (figure 4.10), see figure 4.11, 4.12

Figure 4.10

Figure 4.11

Figure 4.12

② remove the lower cover,

- First, pull out the white lever at the bottom left side of the analyzer.
  See figure 4.13, 4.14

Figure 4.13

Figure 4.14

- Then pull out the lower cover slowly. See figure 4.15

Figure 4.15

③ Connect the liquid flow

- Connect the upper tube of the auto sampler to the upper tube connection pin on the analyzer, see figure 4.16, 4.17

Figure 4.16

Figure 4.17

- Then pass the lower tube of auto sampler through the bottom of the analyzer and connect it to the tube at the bottom of the analyzer.
  See figure 4.18, 4.19

Figure 4.18

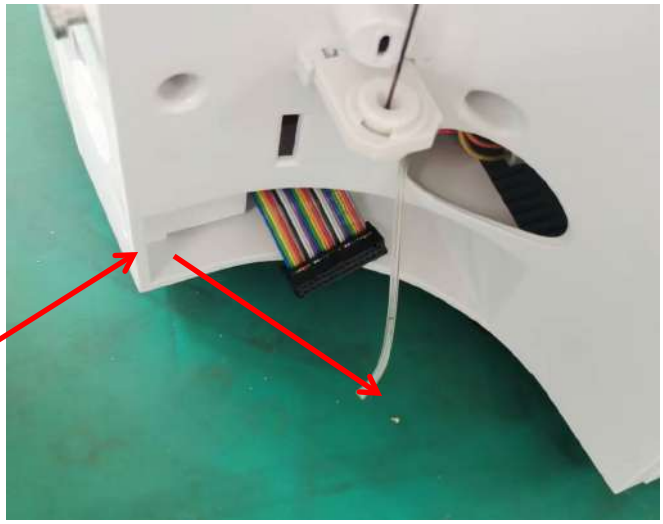

Figure 4.19

- Assemble the lower cover back after connecting the tubes.

④ Connect the auto sampler with the analyzer

- Align the two studs(figure 4.20) on the left side of the analyzer with the small holes(figure 4.21) on the side of the auto sampler and insert them

  See and

Figure 4.20

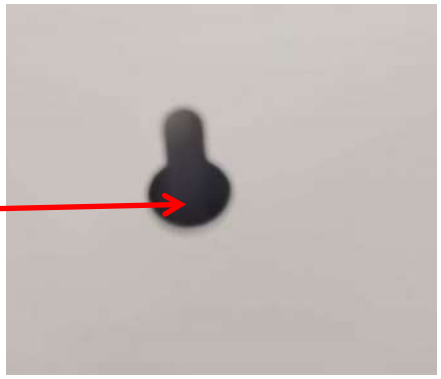

Figure 4.21

⑤ Start the auto sampler

Note: The auto sampler must be powered on before the analyzer. Otherwise, it will not be recognized by the analyzer.

- The yellow indicator light will illuminate after starting up.
  See figure 4.22

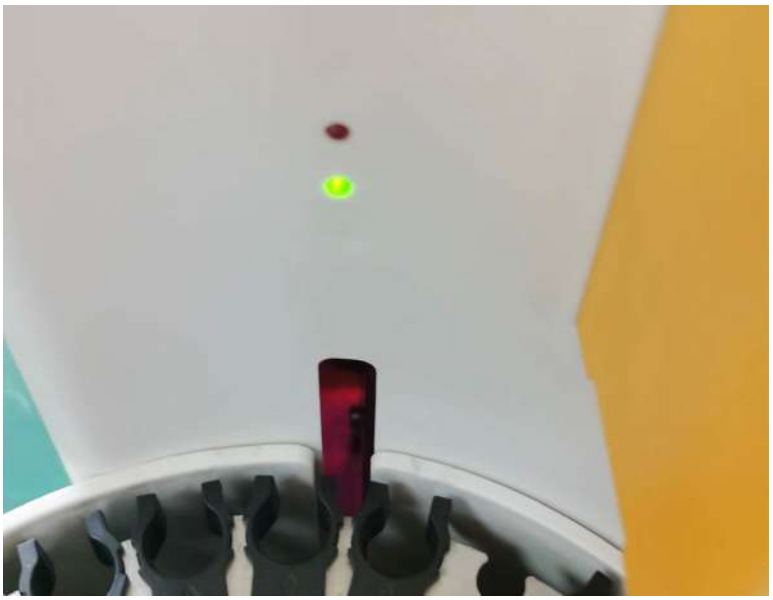

figure 4.22

Chapter 5 Work interface and operation

Do not restart the analyzer 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.

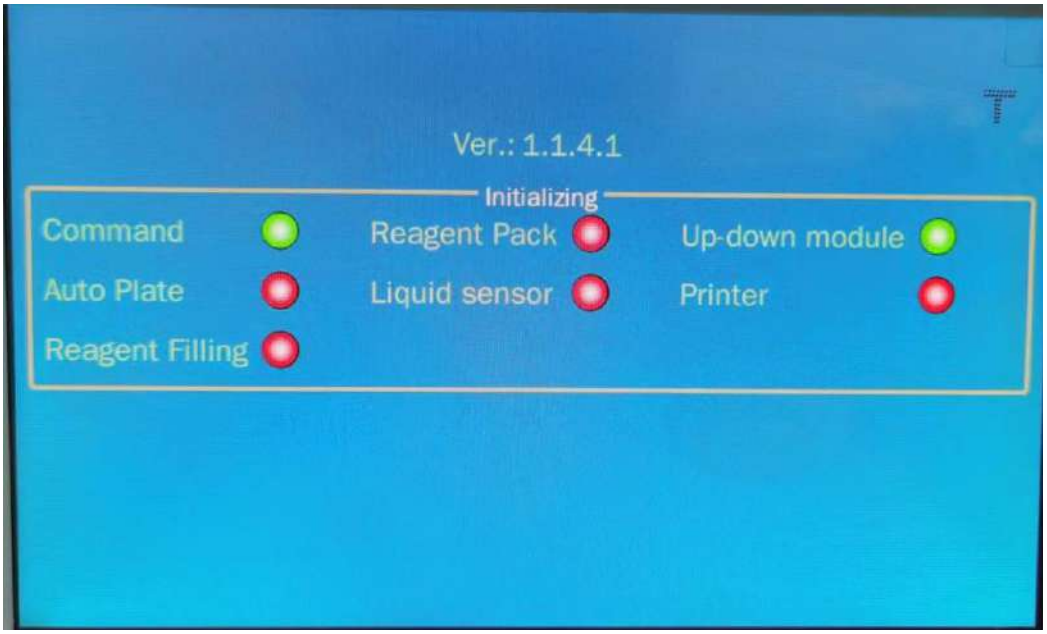

Figure 5.1

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 sampler.

5.2 Standby Mode

If there is no operation for more than 20 minutes, the analyzer will enter into “standby” mode, the screen is shown as figure 5.2.

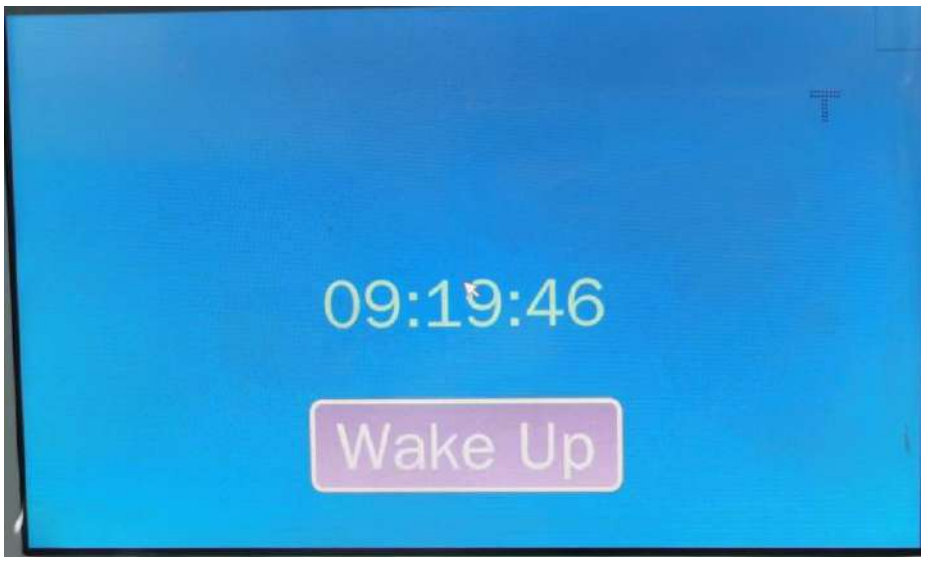

Figure 5.2

Once entering Standby state, the analyzer will calibrate electrodes automatically every two hours during standby time. Click wake up within 30 minutes of standby time, the analyzer will clean

the tubes automatically and return to the interface before standby mode. Click wake up after 30 minutes, the analyzer will the analyzer will clean the tubes automatically and calibrate electrodes first, then return to the interface before standby mode

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).

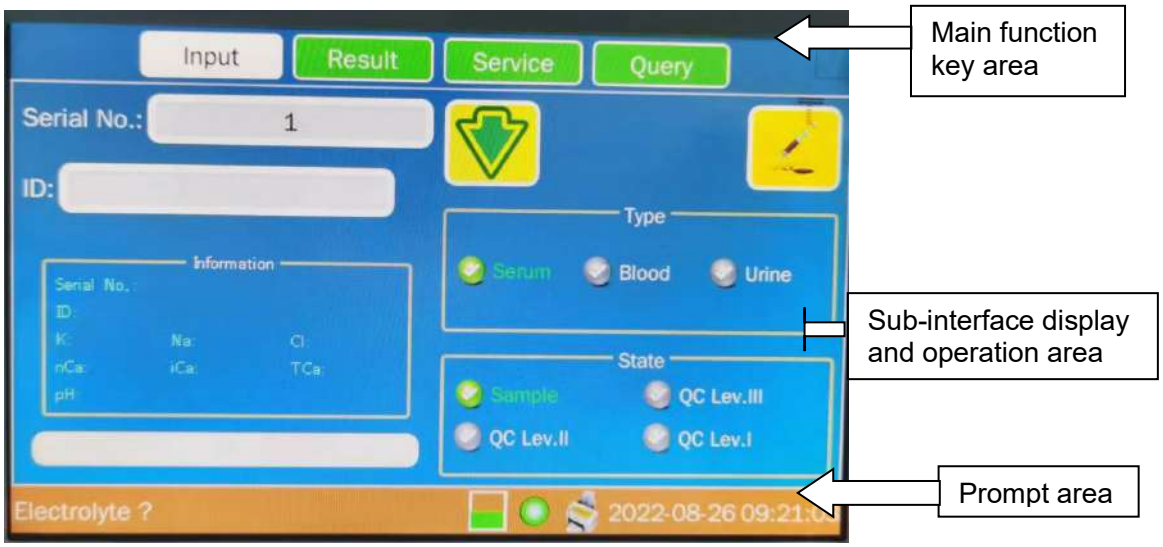

Figure 5.3

■ 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 analyzer 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 idle (no operation)； When the ball is red, the system is busy.


Printer is normal；


Printer is damaged or has been turned off.

5.3.1 Main function keys area

5.3.1.1 Test

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

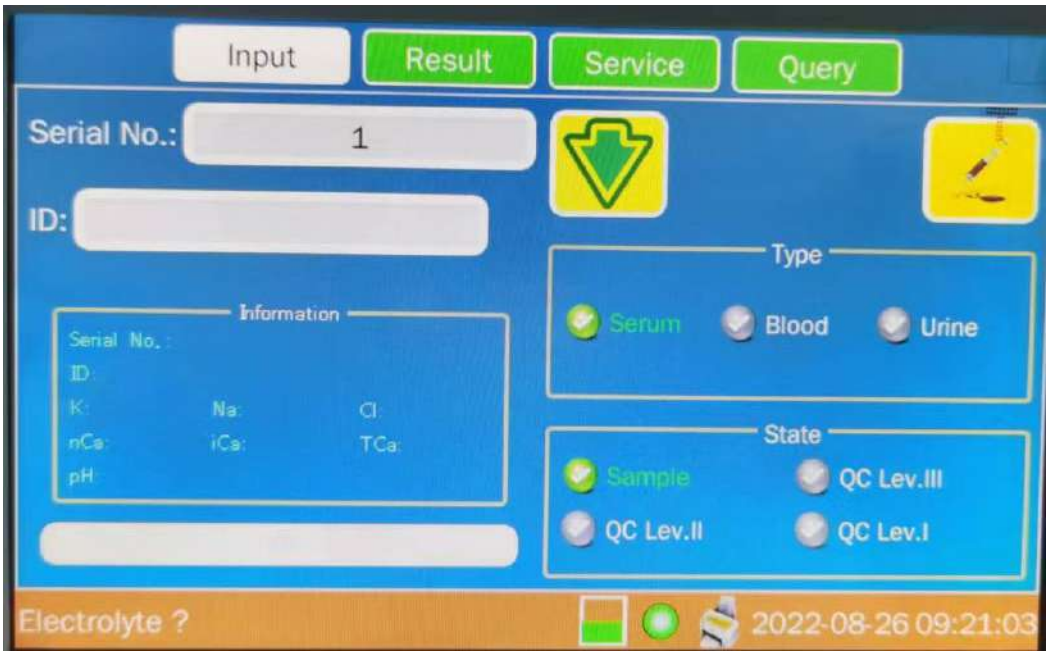

Figure 5.4

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

ID：Input if necessary. Can be input through bar-code reader or manually input the ID in new dialog box. The measurement can be done without inputting ID.

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 sample probe will lift up, then put the sample under the probe and operate according to instruction on the prompt dialog box to finish the measurement . When the probe needs to fall down, click  to let the probe down.

After the measurement is finished, the result will be shown in the information box at the lower left side and printed by the printer 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.

Figure 5.6

Users can add multiple samples in batches by simply clicking on the starting and ending hole. If some holes have been used in current plate, then these hole numbers will not be displayed on 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.

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 analyzer 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 in order

For the auto plate mode, when the total number of consecutive measurement samples is greater than or equal to 5 and no more continuous measurements are performed, the system will automatically switch to the Maintenance interface to perform the protein cleaning procedure. Once the cleaning procedure is finished, click Close, then the system will calibrate for once automatically. If not click Close, the system stays at Maintenance interface.

Click 

, the analyzer 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.

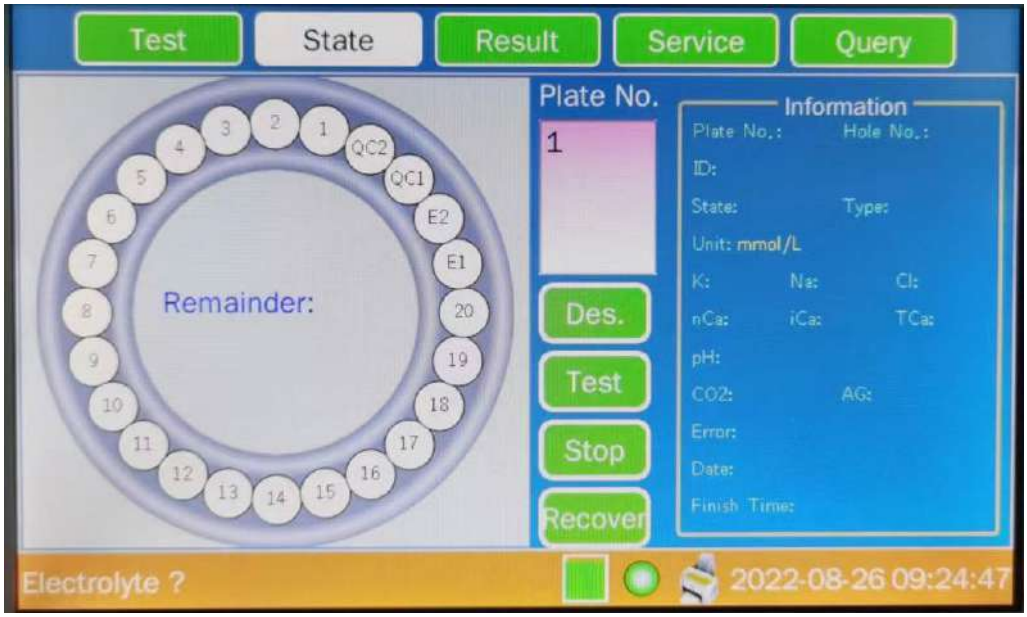

Figure 5.7

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.

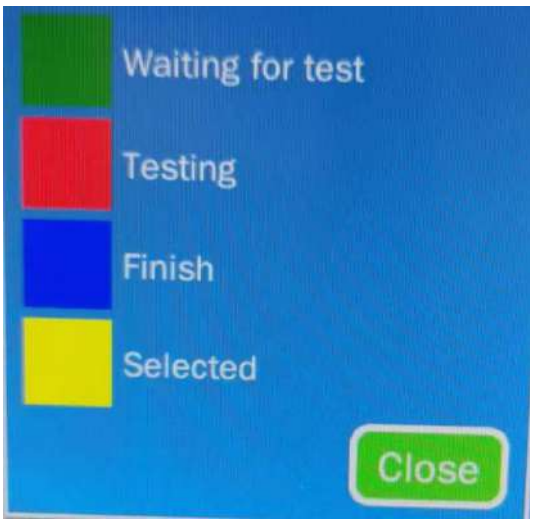

Figure 5.8

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

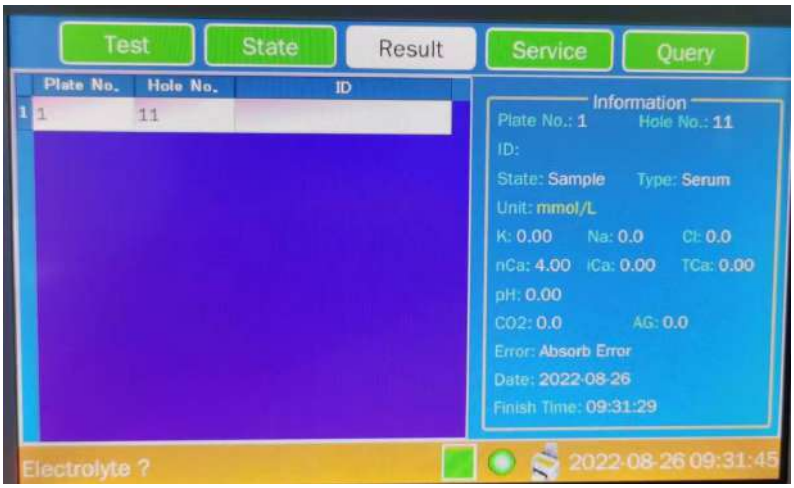

Figure 5.9

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 electrode calibration and register new reagent pack . 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 on 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 automatically. 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 3 electrode slope results. Click the result of one certain electrode, all the potential reading result of this electrode during the calibration will be displayed . Shown as Figure 5.12.

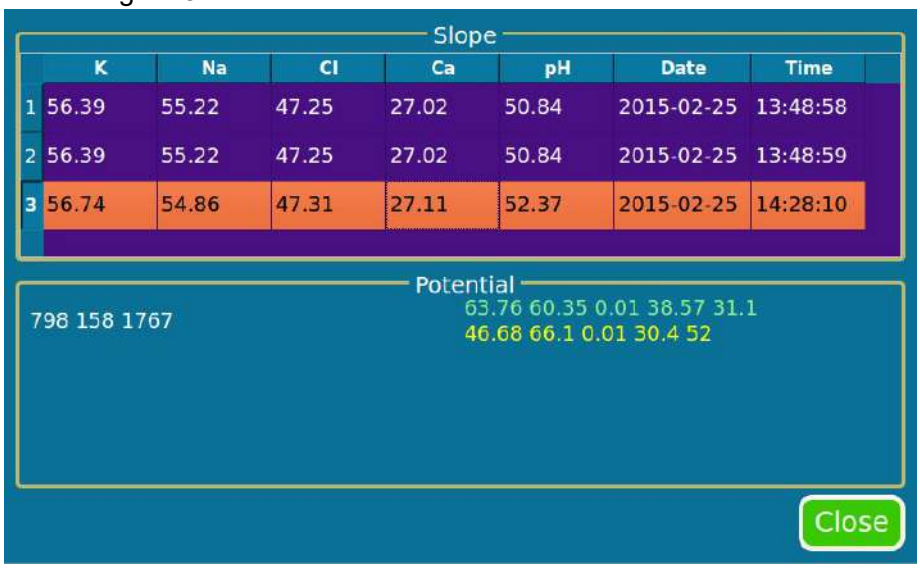

Figure 5.12

Review CO_2：The system saves and displays the latest 3 CO2 slope results. Shown as Figure 5.13.

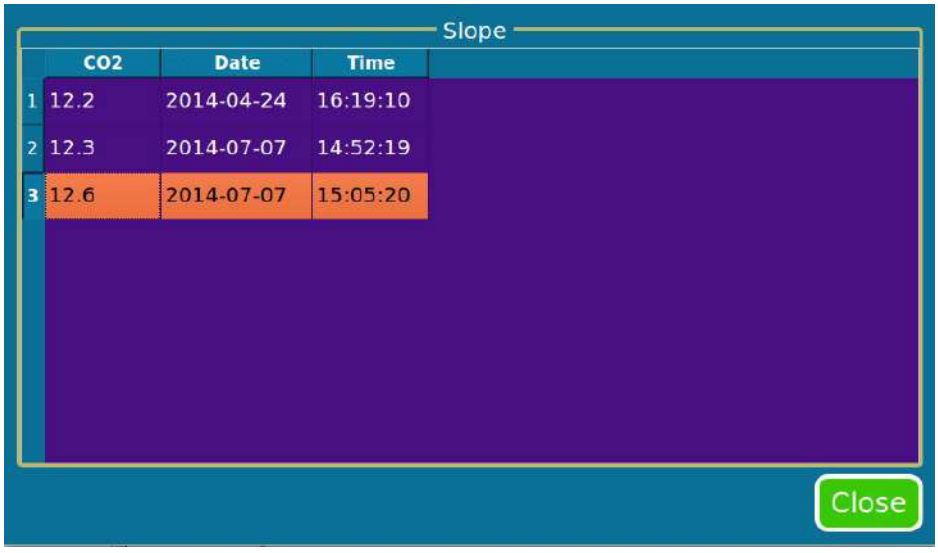

Figure 5.13

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

Restart the analyzer without power off the analyzer, just click Regist . Then the analyzer aspirates Standard A, Standard B and R solution to fill up the liquid flow tube with the new reagent completely.

The system will read the card information inside the pack automatically and displays the remains volume in % format. Then the system will run electrode calibration automatically for once.

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 manually.

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

Calibration includes: electrodes and CO2 calibration.

■ **Electrodes calibration**

After automatically initially calibration when startup, click Electrolyte to calibrate for once or twice more no matter whether the slopes are passed or not. Compare all the calibration slopes.

Requirements for all the slopes：

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 for CO_2：

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 meet the requirements because the measure result will be invalid. There are words prompted in the screen before measurement.

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

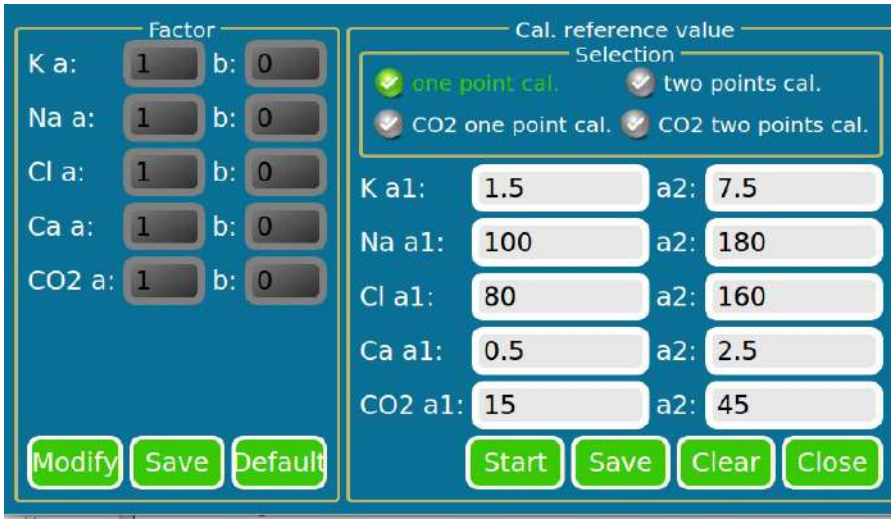

Figure 5.14

There are 2wo ways to modify: manual modification and automatic modification.

■ **Manual modification**

Click Modify，then click Yes in the prompt dialog box, the factors turn into white(modifiable) from black (unmodifiable) . Click the factor need to modified and input the new value.

Measure the calibrator (or QC solution) as sample, using the nominal values (or target values) of the calibration standards (or QC Solution) divided by the test results, the result is referred to as the "a value."

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

Manual modification is typically based 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 analyzer 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 analyzer 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 analyzer 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.

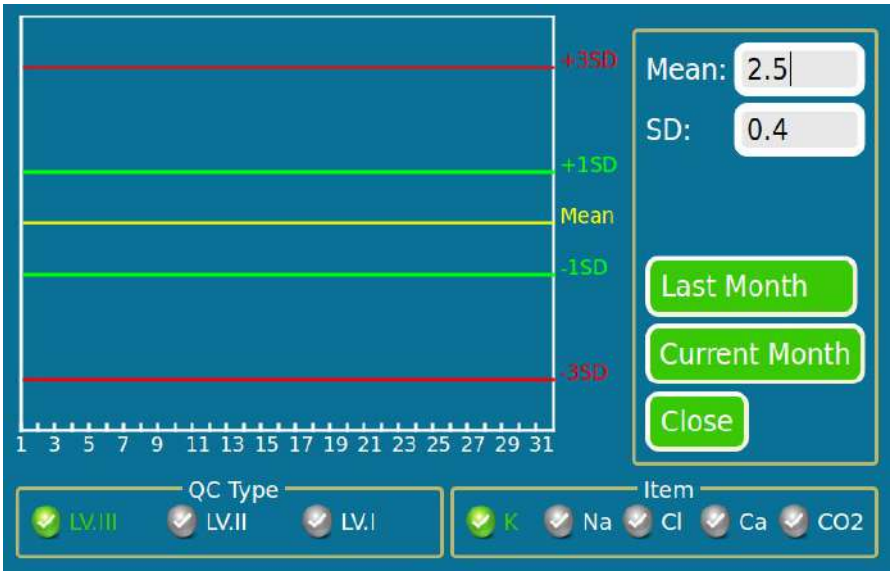

Figure 5.15

d. Settings

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

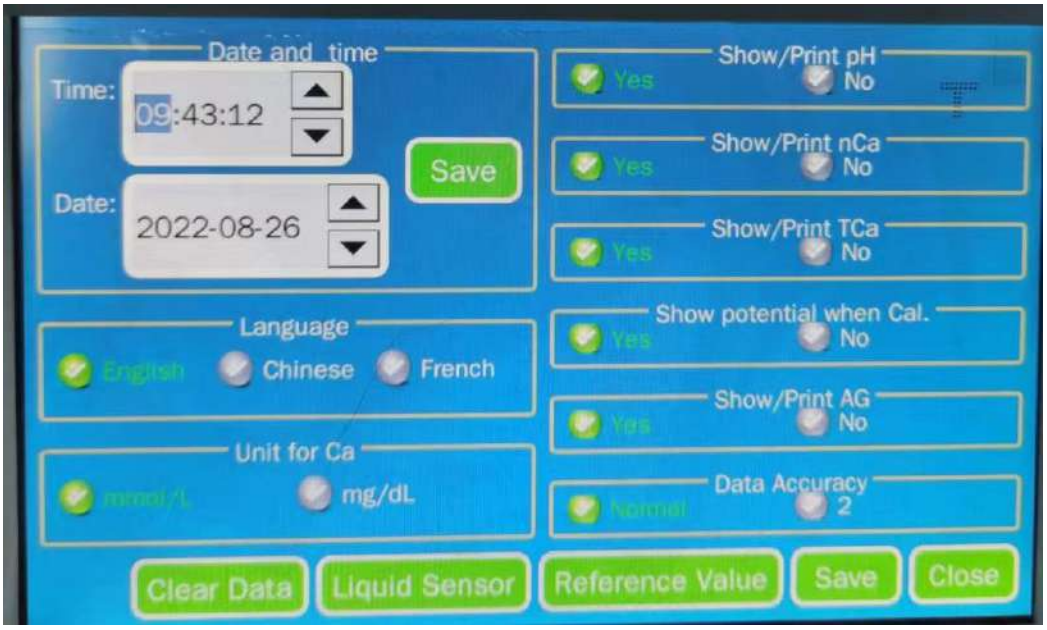

Figure 5.16

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

Language：After changing the language, click Save and restart the analyzer 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 iCa：Printing iCa or not is selective. The default is “NO， means the printout result will NOT show iCa result.

Show/Print TCa：Printing Tca or not is selective. The default is “Yes”， means the printout result will show TCa 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 to aspirate enough sample volume without bubble, for example, the detection channel will be filled up with sample from K electrode to Ref electrode. Click Liquid Sensor and input the value in the pop-up box (shown as Figure 5.17), then select Start， The analyzer absorbs standard A solution automatically, so user can check if the channel

is filled with liquid.

Suggestion: The end of the liquid should stay at the location about 2cm from Ref electrode outlet. This is to ensure that the volume of each subsequent sample meets the measurement requirements.

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.

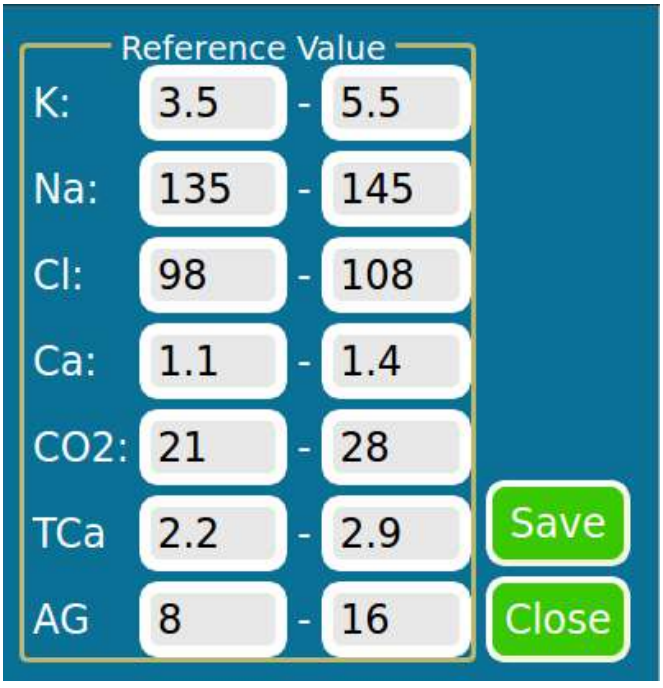

Figure 5.18

★ Click Save in settings interface is to save the settings. This is to ensure that, apart from changing the time and date, which prompts a restart of the analyzer for the modifications to take effect, all other saved changes made on the main interface will be effective immediately.

And for modifications made to sub-interface functions (manual positioning, reference values), they will not take effect unless the 'Save' button is clicked within the popup window that appears in each respective sub-interface.

e. Maintenance：Perform protein cleaning and Na adjust procedures. Screen is shown as Figure 5.19.

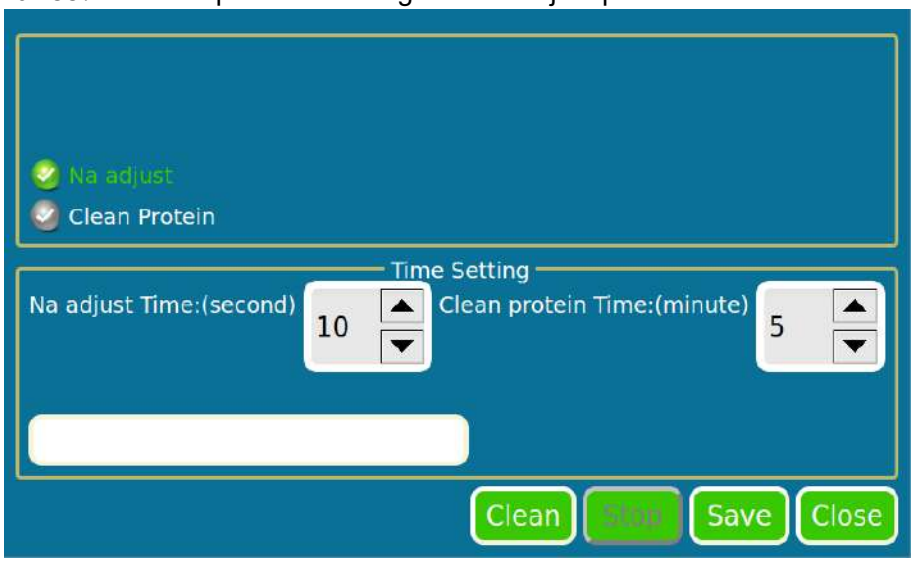

Figure 5.19

The user can set and save the soaking time for Na conditioner solution and protein cleaning solution.

Recommendation: Soaking time for Na conditioner solution should not exceed 10 seconds, and for Protein Clean solution, it should not exceed 5 minutes. If the cleaning result is unsatisfied, run the program again. Na conditioner solution and Protein cleaning solution have some damage to the electrodes, so it is not recommended to soak internal electrode for long time. If the results after adjustment or cleaning are not satisfactory, you can achieve improvement by re-executing the adjustment or cleaning procedure. Due to a certain degree of damage that Na conditioner solution and protein cleaning solution may cause to the electrodes, prolonged soaking in the electrode channels is not recommended.

Select “Na adjust” or “Clean protein”, click Clean, the analyzer will prompt to aspirate Na conditioner or Protein cleaning as the sample (in the fully automatic mode, it will prompt if the sample is in the 'Calibration' position on the sample tray and, upon confirmation, automatically aspirate), then, within the specified time, automatically complete the adjustment or cleaning procedure."

When exiting this interface by clicking the Close button, if no adjustment or cleaning has been

performed within the interface (the Clean button has not been clicked), it will exit to the 'Service' main interface without taking any action. However, if the analyzer has executed at least one adjustment or cleaning procedure within the interface (the Clean button has been clicked), the analyzer will automatically perform an electrode calibration procedure before exiting."

f. Send Data：*Send all the test results for the day to the computer through RS-232 port. For details on the communication methods between this analyzer and the computer, refer to Appendix 1*

Click Send Data, screen is shown as figure 5.20.

- Select “Yes”, After the completion of individual sample testing, you can transfer the results of the single sample test to the computer.".
- Select “No”, the analyzer does not send the test result.
- “Total Records” the total number of sample test results can be transmitted on the 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, this interface provides functionality for prompt troubleshooting and relevant actions.

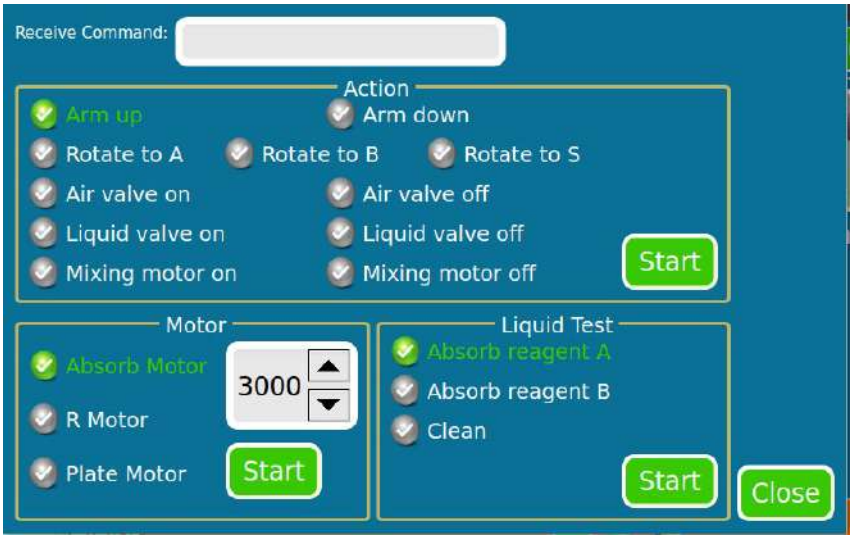

Figure 5.21

h. Potential：Screen is shown as Figure 5.22.

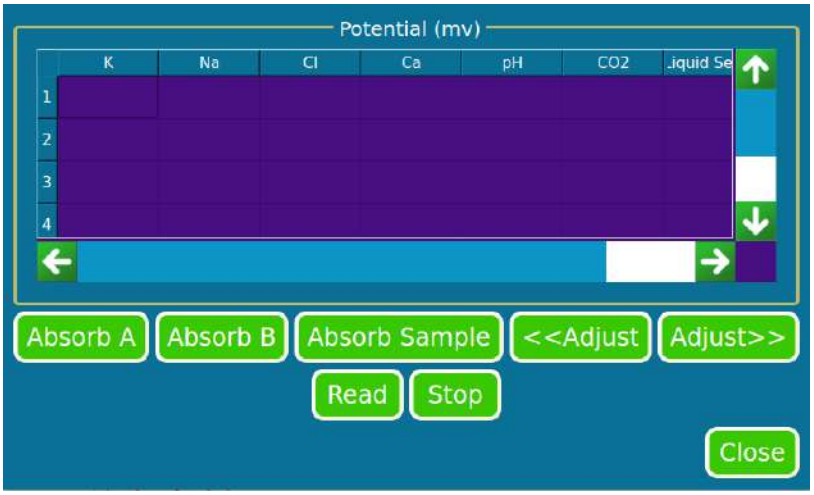

Figure 5.22

By automatically aspirate Standard A solution, Standard B solution from the reagent package, or manually aspirate from sample, the potential of different liquids in the electrode channels can be measured.

Click Read, the screen will show the potential of each electrode。

The user can move the liquid forward or backward by clicking “Adjust>>” or “<< Adjust”. This procedure helps engineers or experienced users to assess the performance of electrodes or liquid sensors.

★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 measured potential value is called high value; when it is filled up with liquid, the measured potential value is called low value. If two times low value less than the high value, the liquid sensor is working normally,

otherwise, the liquid sensor is malfunctioning.

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

i. **Printer State**：Printer on or off is optional. The default setting is “On”.
Click Test can test the performance of the printer.

ii. Print voltage when test: The default setting is “No”. Choose “yes”, the measured potential value of both reagent A and sample will be printed out together with each result. This function helps engineer to perform analyzer maintenance. Screen is shown as Figure 5.23.

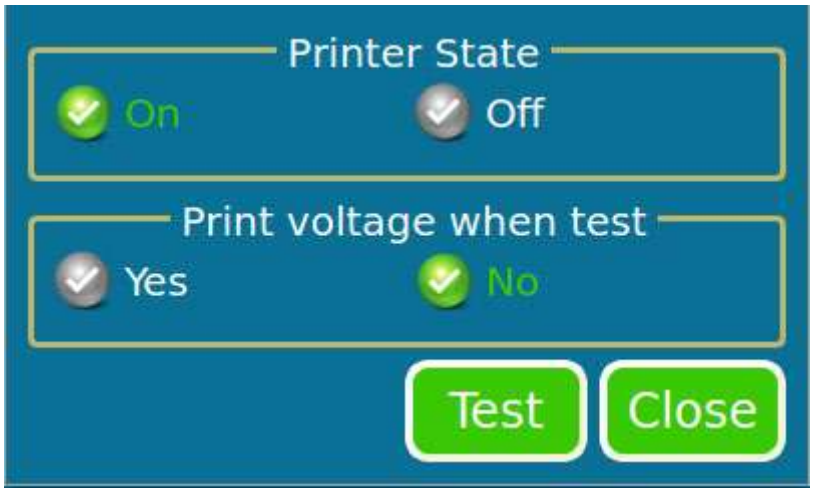

Figure 5.23

5.3.1.5 Query

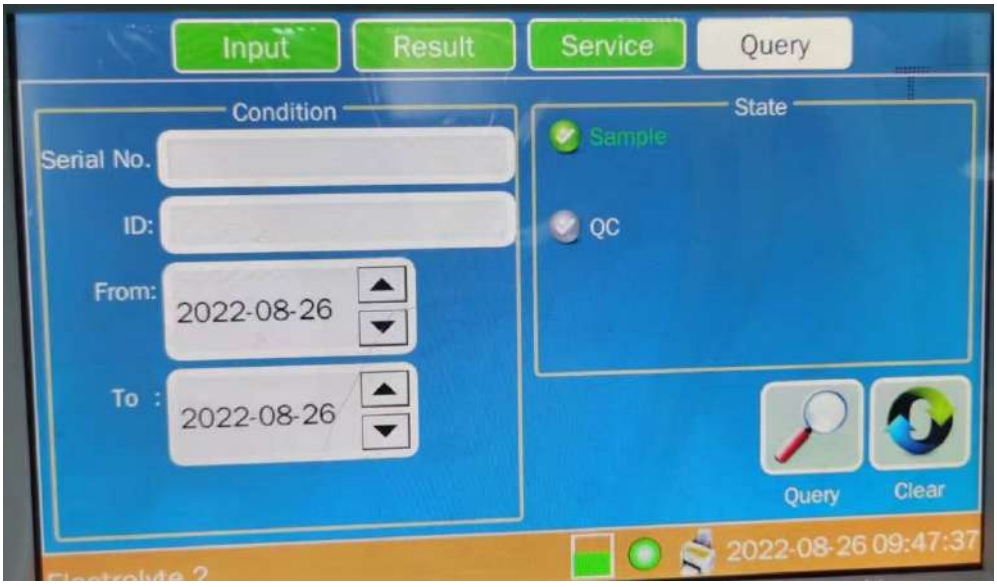

Figure 5.24

The user can query all measured samples or quality control results under different conditions with diverse search criteria. The user can search for sample results within a specific date range by using the Start (“From”) date and end (“To”) date. Additionally, you can inquire about any sample result for a specific day by using the start date, end date, sample number, or ID number.

Clear：After querying results, if the user need to search for results under different conditions, clicking "Clear" button will restore the query interface to its initial state (both the Serial No. and ID number will be cleared, and the dates will be displayed as the current day).

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 analyzer every day.

b. When replacing the printing paper, please turn off the power.

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

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

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

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

g. Discard the reagent if mildew or deposition found.

h. Perform the routine maintenance according to the instructions.

j. Every electrode has printed its own lot number, if the number cannot be recognized, our company will not guarantee 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 analyzer is scrapped, please deal with according to the requirement of local environmental protection administration.**

Chapter 7 Maintenance

Note：

*** At the end of each day's work, the interior of the instrument should be cleaned**

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

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 50 samples every day, please proceed “Clean protein”, once with daily cleaning solution.

7.2 Weekly maintenance

a. Run “Clean protein” once a week if more than 75 samples measured every day. If less than 30 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 wash block

Click the aspirating icon, the sample probe lifts up. Disconnect the aspiration tube with the sample probe, then clean the inner wall of the sample probe with the provided cleaning needlel; Dip a clean cotton swab in anhydrous ethanol and gently wipe the outer wall of the sample probe until no visible residues are present. For the wash block, remove it and clean it using a cleaning needle, ear syringe and distilled water.

b. How to clean the detection channel of electrodes

Clean the channel of each electrode and aspiration base with soft materials such as cotton thread or ear syringe

Caution：Do not clean the internal channel with needles.

c. Check the tubes

Make sure the connection of all the tubes and connectors are reliable.

Check the inner walls of the aspiration tube, pump tube, and waste tube for the accumulation of proteins.

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.

If protein accumulation is observed, manual cleaning or replacement is required. Check the connection of the tube below the wash block and examine whether there are any foreign objects on its inner wall. If any foreign objects are found, they need to be removed or trimmed by 1-2mm.

7.4 Check the tubing system

⚠**Note：* Check peristaltic pump tubes every day, and replace it every 3 months.**

*** 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 condition of sample probe, liquid distributor and the electrode channel.

c. If a significant number of bubbles are observed at a certain connection point within the tubing, it indicates a leak at that location. Please remove the bubble immediately. 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. Install 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 analyzer 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 analyzer 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 or test result of electrodes 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 too 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. Too much protein in liquid tubes	Run protein cleaning program
8. Incorrect positioning	Check liquid flow, clean the tubes check the positioner
9. The electrode filling solution is insufficient	Refill the solution
10.Electrode does not work	Replace the electrode

8.2 Slope or test result of CO2 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 Adhesion or excessive stretching	Rebound or replace the tubes

The tubes of drain valve are aged 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 adhesion or broken	Restore or replace the tube
Pump tube blocked	Clear the blockage
The gasket between the electrodes does not placed properly or missing	Place the gasket properly
Washing block blocked	Clean the washing blcok

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 rinse it with water. Put the plate back on the sampler after dry thoroughly. The external surface can be wiped down with the disinfectant solutions mentioned above.

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 repeatedly until the slopes are stable.

When this solution is not in use, store it in a cool, dry place, away from 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 analyzer.

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