



## ELECTROLYTE ANALYZER

ANA61-06A



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# 1. Brief Introduction

Please read the safety notes and related sections carefully before installing and using the instrument.

## 1.1 Operator's Qualification

The operator should be trained in formal training and also be the professional person who grasps the skill of safety operation. For clinical trial, the instrument should be used under the management of administrators.

## 1.2 Serviceman's Qualification

When installing, maintaining and repairing the instrument, the maintenance personnel must be trained by manufacturer or corresponding level training, should master the daily operation of the user's manual and the professional operation of service manual .

## 1.3 Electronic / Mechanical Part

- The operator should not open the instrument cover, only the repair person can complete the maintenance and repair of instrument;
- If the instrument cover is opened, do not to repair instrument under the booting status to prevent electric shock;
- Lifting mechanism belongs to the movement components of the instrument, do not insert the hand when it moves.
- There are two fuses with the specification T2.0A 250V;
- The installation of instrument must be equipped with reliable power outlet to ensure safety;
- If there is abnormal occurred when the power supply is on or in the process of operation, you should immediately turn off the power, then can turn on again to operate after checking the machine well.

## 1.4 Biochemical Part

All samples and waste liquid are considered as potential biological pollution and source of infection, and the materials and apparatus which contacts with those shall be handled according to related disinfection and isolation method .Waste liquid should be properly handled under the guidance of the safe and responsible person, and shall not be treated freely, and the waste liquid shall be recovered by the special person, and shall be treated according to the relevant provisions of the environmental protection. Operators should avoid contact with the reagent directly, you should work according to the clinical laboratory chemicals used in the safety precautions, and should wipe out the reagents on the instrument at any time.

## 1.5 Accuracy and Precision Of Measurement Method

For the normal use of the instrument, you should measure the quality control and measure the instrument during measurement. Make sure that the sample does not include the blood clot or other solid things. If solids are inhaled, it will lead to inaccurate measurement results or instrumental blockage.

## 1.6 Operation And Maintenance

- During the instrument operation and maintenance period, please operate according to the instructions strictly, don not touch the other parts of instrument;
- Don't let the sample stay in the electrode and pipeline for a long time, it should be fully of reagents to prevent clogging when it is not used;
- When operate the instrument, do not touch sensitive parts such as electrode, pressure sensor and so on, otherwise it will cause measurement error.

# 2. Installation

## 2.1 Overview

ANA61-06A electrolyte analyzer is used to measure  $K^+$ ,  $Na^+$ ,  $Cl^-$ ,  $Ca^{2+}$ ,  $TCO_2$ , PH (only used for calcium ion calibration, not as a result of human pH) of serum, plasma (whole blood), diluted urine sample, and calculates the results of Ion calcium(nCa), total calcium (TCa) and anion batch(AG) .

This instrument is a electrolyte analyzer which uses ion selective electrode method (ISE) and the pressure measurement method to measure the concentration of ion and total carbon dioxide ( $TCO_2$ ), it can measure the above items quickly and accurately, the analysis results are displayed on the LCD, and can be printed out by the built-in printer.

This instrument is composed of an analysis system, a monitor(LCD), a printer, and an sampling injection system, which has bubble detection function.

## 2.2 Packing

The packages for ANA61-06A electrolyte analyzer are two cartons:

Packing Box	Goods
Big packing box	ANA61-06A electrolyte analyzer and standard accessories
Small packing box(match)	Sampling system, sampling turntable

Table 1

The packing box should be handled carefully to avoid damage. If there is any damage or loss of the parts, please inform the supplier immediately.

No.	Name	Specifications	Quantity	Remarks
1	Calibration Solution A(CAL A)	400ml/bottle	3 bottles	
2	Calibration Solution B (CAL B)	200ml/bottle	1 bottles	
3	Electrode Activation Solution	15ml/bottle	2 bottles	
4	Electrode De-protein Solution	15ml/bottle	2 bottles	
5	R Reaction Solution	200ml/bottle	1 bottle	
6	Calibration Solution C (CAL C)	15ml/bottle	1 bottle	
7	Bottle Cap		4 pieces	

8	Waste Liquid Bottle		1 piece	
9	Pump Pipe		2 pieces	
10	Sealed Ring for Reagent Outlet		2 pieces	
11	Print Paper		1 roll	
12	Power Supply		1 piece	
13	User's Manual		1 piece	
14	Sample Cups		50 pieces	Match
15	Packing List and QC Approved		1 piece	
16	Adapter	12V	1 piece	

Table 2

## 2.3 Installation

### 2.3.1 Requirements

- 220V~50Hz 40VA;
- The power requires 220V~50Hz 40VA;
- With the wiring socket and the proper voltage required in the range of instruments, to enable the instrument work stably and safely;
- The installation area requires no strong electromagnetic interference, clean, stable and no vibration, avoid sunlight;
- It should be installed in spacious place, in case of meeting emergency in the installation ,you can turn off the power supply in time;
- The ambient temperature stays 5~40℃, the maximum relative humidity is not more than 85%.

Note: you can restart the machine after the instrument is switched off at least 5 seconds to avoid the current impact causing instrument damage!

## 2.3.2 Instrument Installation

### 1. Host Installation

- Open the packing box to take out the instrument carefully, and take out plastic foam from the instrument.
- Open the front cover of instrument, set aside to take care of it;
- Take out each one bottle of calibration solution A, calibration solution B and R reaction solution, unscrewed the cap, tear apart the aluminum film, put the solutions into the corresponding position, insert the special-purpose cap and tighten the cap.
- Pull out the shield to enable the pump is connected with the reference electrode joint (installed well before factory);
- Cover the front cover of instrument, access the cable, check whether the working voltage can meet the requirements, start up operation.

### 2. Sampling Injection System Installation

- If the user chooses the instrument with automatic sampling system, please install the auto sampling system as following steps:
  - Open the smaller box, take out the sampling system and signal line;
  - Unscrew the two fixed screws of the bottom of the instrument, insert
  - two slots of the sampling system into two screws of the bottom of the instrument;
  - Insert one end of signal line into the socket of bottom of the instrument , insert the other end of signal line into the socket of the bottom of the sampling system to keep signal line smooth .
  - Turn on the instrument, sampling system axis will turn automatically , then stop after turning , sampling system positioning pin (stainless steel short rod on rotating shaft)should aim at sample needle, if there is no alignment, loosen the screw of the "sampling system positioning pin seat", slightly adjust "sampling system positioning pin seat" until sampling system positioning pin aim at sample needle .
  - Make the sample turntable "0" position through sample needle and make the locating pin hole on the sample tray aim at "sampling system positioning pin", and install it to the bottom, if the sample needle is not on center of the "0" position of sample tray, remove the sample tray, readjust the position of sampling system base or the position of the "sampling system positioning pin", until the sample needle is on the center of "0" position of sample tray, tighten two fixed screws of the bottom of the instrument .
- Note: Before the instrument package is thrown away, ensure all the contents are taken out.

## 2.4 Check before acceptance

Please contact the manufacturer or seller immediately if the instrument has problem.

## 3. Working Principle

### 3.1 Overview

The instrument measures the concentration of potassium, sodium, chlorine, calcium and pH by using ion selective electrode method, and measures the total carbon dioxide by using the method of pressure measuring.

### 3.2 Working principle of ion selective electrode method

The ion selective electrode is a kind of electrochemical sensor, which can transform the ion activity variation in the solution to the variation of electrode potential, which is related to the Nernst equation:

$$E = E_0 + \frac{2.303RT}{nF} \lg a_x f_x$$

E=electric potential of ion selective electrode in measuring solution E<sub>0</sub>=electric potential of ion selective electrode in standard electrode n=The number of charges of ions to be measured

R=Gas constant T=Absolute temperature F=Faraday constant a<sub>x</sub>=Measured ion activity

f<sub>x</sub>=Measured ionic activity coefficient

The relationship between the logarithm of the activity of the ion in solution and the electrode potential is linear.

In one kind of electrolyte solution, most salt exist in the form of ion. The electric exchange reaction occurs between the selective electrode and the associated ion, The potential of the ion selective electrode changes with the concentration of ions in the sample, while the reference electrode does not change with the sample concentration, which can always provide a constant reference potential. So the potential difference is formed between the ion selective electrode and the reference electrode, and changed with the variation of ion concentration in solution. The concentration of the corresponding ion can be calculated by the Nernst formula.

ANA61-06A electrolyte analyzer measures the ion concentration of K, Na, Cl, Ca,, pH by using two-point calibration method. First measure two solutions with known concentrations: Calibration solution A and Calibration Solution B (hereinafter referred to as CAL A and CAL B), the potential of the two solution is measured by the electrodes, a calibration curve is established by these two potentials, and then the potential of the sample is measured, and the ion concentration of the sample is calculated from the calibration curve.

$$S_{ion} = \frac{E_B - E_A}{\lg(C_B / C_A)} \quad C_X = C_A * 10^{(E_X - E_A) / S_{ion}}$$

Among:

CX & EX: Concentration and potential of ions in the sample CA & EA: concentration and potential of CAL A

CB & EB: concentration and potential of CAL B

Sion: The electrode slope measured by two kinds of calibration solution.



## 4. Structure Description

In the following sections the described in detail of the various parts of the instrument will shown.

### 4.1 Instrument

The instrument has the automatic detection function for semi-auto and automatic. The instrument is connected with a sampling system by using a signal line as the automatic one. While pull out the signal line under the sampling tray as a semi-auto one.

### 4.2 The front and right side of the instrument.



Figure 1

1.Electrode holder 2.Liquid air valve 3.A/B valve 4.Sample pump 5.Mixer

6. Pressure sensor 7.Waste gas valve 8.R solution pump 9. Waste liquid valve Note:

Liquid air valve: control the inhalation between Cal A/B and air. A/B valve: control the inhalation of CAL A and CAL B.

### 4.3 Sampling Parts

There are 25 position at the sample tray, including 20 sample position, 2 QC position (QC1 ,QC2), 1 Emergency position (ST) and 1 flush position (FLUSH), and 1 start zero position (sample needle inserting position).

## 4.4 Electrode

The electrodes must be assembled in a specified order (K, Na, Ca, pH, Cl, REF). If the order is wrong, it will report the wrong result. The left and right side nuts of electrodes are movable type, so the fixed nut must be tightened during installation, or the leakage of the electrode will cause to cause the unstable instrument. REF electrode will cause KCl crystallization for a period of time, it is a normal phenomenon, does not affect the use age.

## 4.5 CO2 Analysis System

Carbon dioxide(CO<sub>2</sub>) analysis system include sensor, reactor, waste gas valve, R reaction pump, waste liquid valve.

## 4.6 Printer

When replacing the printing paper, move the middle groove to open it and replace printing paper.

## 4.7 Behind of Instrument

Part respectively: power switch, power socket, 232 interface data output



Figure 2

## 4.8 Display and operation keys

The main menu displays wait action

<p>Test</p> <p>Search</p> <p>Item</p> <p>Set</p> <p>Self CK</p> <p>QC</p>	No: <input type="text"/>	<input checked="" type="checkbox"/> Auto	Age: <input type="text"/>
	Name: <input type="text"/>	Sex: <input checked="" type="radio"/> Male <input type="radio"/> Female	
	<input checked="" type="radio"/> Blood analysis		
	<input type="radio"/> QC analysis <input type="text" value="202010"/>		
	<input type="radio"/> Two points ion CAL		
	<input type="radio"/> TCO2 CAL		
	<input type="radio"/> Maintain <input type="text" value="Activation"/>		
	<input type="radio"/> mV check		
	Blood analysis, Press YES		
	<input type="button" value="Save"/> <input type="button" value="Print"/>		<input type="button" value="YES"/>
	Waiting operation 2021-07-26 13:04 V1.0.0		

Figure 3

## 4.9 Pipeline Diagram

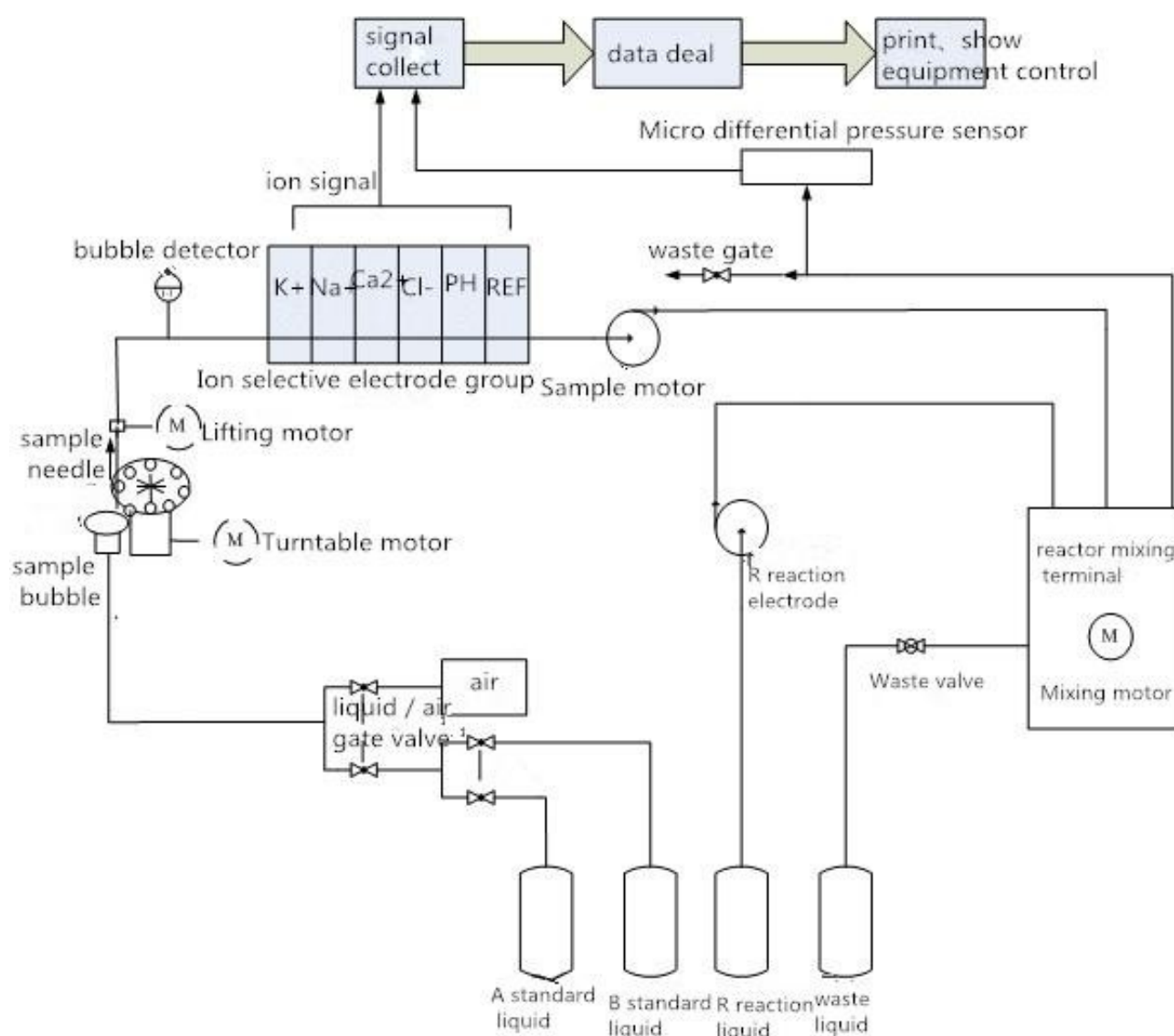


Figure 4

# 5. Instrument Operation

## 5.1 Preparing before starting

Check the instrument connection, ensure the cable connected with the instrument properly.

Ensure whether the corresponding reagent placed on the right place, waste liquid bottle is connected, to avoid self pollution, environmental pollution and pollution of instrument;

Check print paper: before starting the daily work, check whether there is enough paper check printer;

## 5.2 Boot Up

After the preparation is completed, open the power switch behind equipment. In the process of turning on the power supply and operation, if it is abnormal, you should turn off the power immediately, you can turn on the power supply after the qualified engineer checking it has no problem. The determination can be acted after half an hour, to ensure that the instrument can obtain accurate and reliable results.

Note: the instrument has automatic and semi automatic detection function, the sampling system with a signal line connected with the instrument is automatic, unplug the signal line sampling base is semi automatic.

### 5.2.1 Power On Self Test

After the instrument is opening, the basic information is displayed. Then the instrument does self-test, after that, it displays activation electrode".

The screenshot shows the instrument's self-test interface. The left sidebar contains icons for Test, Search, Item, Set, Self CK, and QC. The main area displays input fields for No., Name, Age, and Sex, along with checkboxes for Auto and Male/Female. Below these are radio buttons for Blood analysis, QC analysis (with a text input '202010'), Two points ion CAL, TCO2 CAL, Maintain (with a dropdown menu showing 'Activation'), and mV check. A large blue box in the center displays 'System is normal'. At the bottom, there are navigation buttons: '<', '>', 'Save', 'Print', and a large 'YES' button. The status bar at the very bottom shows 'Self checking', the date '2021-07-27 05:14', and the version 'V1.0.0'.

Figure 5

### 5.2.2 Activated electrode

The new instrument does not need activation. After the instrument is used for a period of time, Na electrode slope down, pH electrode MV is rising, when measures the sample, it will affect the accuracy, when Na electrode slope is too low, pH electrode MV is too high and it need electrode activation.

After pour the activation liquid into the sample cup and put into the sample disc "FLUSH", press "YES", it shows:

Figure 6

After activation, press "YES" ,it displays sample pump calibration, press "NO", the instrument displays two ion calibration.

### 5.2.3 Sample pump calibration

During the sample pump using process, the pump tube is aging, resulting in changes in uptake, to ensure that the sample accurately uptake, apparatus is provided with a pump calibration and the default number of steps. Sample pump calibration Click start → continue, can check the sample pump is normal, in addition, this page can read millivolt value, can the lift motor, sample machine and disc motor is normal, check the liquid air valve, A/B valve is normal, check the stroke switch can be found.After the pump calibration, instrument calibration displays two ions".

Figure 7

### 5.2.4 Two ion calibration

Click 2 ion calibration ,click "YES", instrument display:

No:  ☒ Auto Age:   
 Name:  Sex: ☒ Male ☐ Female  
☐ Blood analysis  
☐ QC analysis 202010  
☒ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain Activation  
☐ mV check  
 < > Save Print YES  
 Two point ion calibration in progress 2021-07-26 13:14 V1.0.0

Figure 8

A calibrator MV values is displayed , then it displays:

No:  ☒ Auto Age:   
 Name:  Sex: ☒ Male ☐ Female  
☐ Blood analysis  
☐ QC analysis 202010  
☒ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain Activation  
☐ mV check  
 < > Save Print YES  
 Two point ion calibration in progress 2021-07-26 13:14 V1.0.0

Figure 9

B standard MV value shows after two times A. B calibration standard solution concentration measurement A. After finished, next machine will do TCO2 calibration.

## 5.2.5 TCO2 calibration

Insert C standard solution into the sampling needle and press "YES", the instrument display:

No: 20210726001 ☒ Auto Age:   
 Name:  Sex: ☒ Male ☐ Female  
☒ Blood analysis  
☐ QC analysis 202010  
☐ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain Activation  
☐ mV check  
 < > Save Print YES  
 Self checking 2021-07-26 12:06 V1.0.0

Figure 10

Then do TCO2 calibration the second time and measure the concentration of C standard solution. After passed, then back to the main menu.

5.2.6 Abnormal condition may occur in system calibration

(1) The two ion cannot pass and it is abnormal,one of the brackets is the control electrode, and the instrument displays:Press "YES" to restart. Re calibration is still not through, it shows that the instrument is fault, please see 8 fault exclusion".

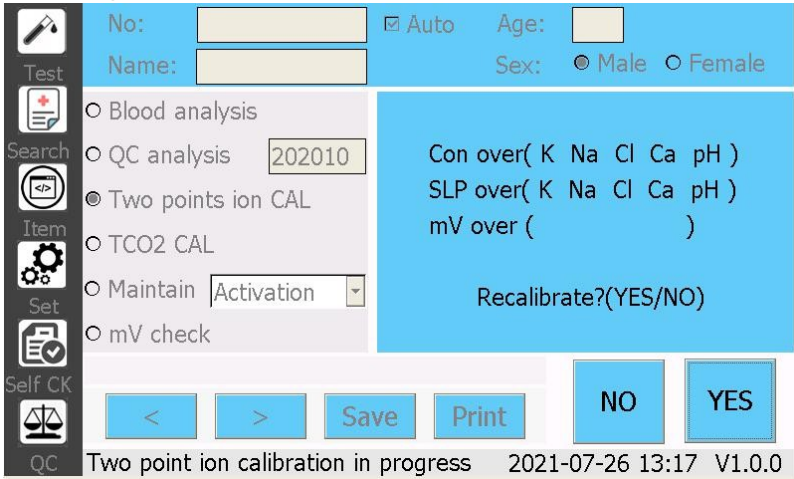


Figure 11

If the mV of TCO2 is out of setting range, the instrument displays the TCO2 mV is abnormal. Press"YES", re-calibration again. TCO2 slope instability or abnormalities may be due to: instrument is not steady;the pump aging cause instability in the absorption;the reactor is not good, please see the "8 fault excluded". Special emphasis: check the instrument having the bubble, calibration is going on without dealing , the instrument will draw abnormal slope and MV, calibration system also fails, in this case, measurement samples will be submitted to the wrong results, so if there is a bubble ,you must deal with.

Standard calibration system						
	K	Na	Cl	Ca	PH	TCO 2
concentration	4±0.15	140±3.5	100±3.5	1.25±0.15	7.38±0.10	30±2.0
slope	30~90	30~90	20~80	10~45	30~90	23.3~90
MV	40~150	40~150	40~150	40~150	40~150	7~27

Table 3

5.3 Setting

Press [Set] on the main menu,enter the setting menu:  
Note: no operation beyond dormancy setting time, the instrument enters dormancy. The sleep setting time can be changed in the Settings menu. If sleep can click on the mouse or touch the LCD screen to wake up, the instrument will automatically carry out two-point ion calibration after wake-up.



Date and Time: 2021-07-27 08:59 ☒ Buzzer sound  
 Institution: renmin Tester: liming  
 Dormancy: ☐ Never ☒ 1 hour ☐ 2 hour ☐ 4 hour **Save**  
 Printer: ☒ built-in ☒ CO2 Test ☐ Auto print  
 From 2021-07-20 To 2021-07-27 **Clear Data**  
 Start No: 8 **Save**  
 Reagents motor step: 375 **Save**  
 Sample cup motor step: 160

Figure 12

### 5.3.1 Slope and intercept

(1) Set A/B

Press [Item], it displays:

Set A/B Print Item/Normal Range  
 Slope (A):  
 K 1 Na 1 Cl 1 Ca 1 pH 1  
 TCO2 1  
 Intercept (B):  
 K 0 Na 0 Cl 0 Ca 0 pH 0  
 TCO2 0  
 Del A/B Save

Figure 13

In general, the slope does not need to be adjusted. In order to meet the requirements of clinical accuracy, the intercept can be adjusted to improve accuracy. After the input points are

(2) Delete A/B

Set A/B Print Item/Normal Range  
 Slope (A):  
 K 1.00 Na 1.00 Cl 1.00 Ca 1.00 pH 1.00  
 TCO2 1  
 Intercept (B):  
 K 0.0 Na 0.0 Cl 0.0 Ca 0.0 pH 0.0  
 TCO2 0  
 Del A/B Save

Figure 14

The analysis result is influenced by the measuring method and system error, a slope / intercept procedures to calibrate the measurement results. The formula is as follows:

$$X_{\text{calibration}} = A X_{\text{test}} + B$$

Type:  $X_{\text{calibration}}$  = After calibration results



Xtest=The results of the determination directly A=Slope

B=Intercept

The calculation method of slope and intercept:

The two known target samples (worthy of the two samples must have some differences in concentration) were determined, the results.

$$A = \frac{X_{s2} - X_{s1}}{X_{m2} - X_{m1}}$$

If only one known target value of the sample, only the intercept (b) calibration, although not on the slope (a) calibration, usually to meet the requirements of accurate measurement.

### 5.3.2 Search

Search:search data, print results, select delete data, single select delete data, view slope and millivolt values

No	Name	K	Na	Cl	Ca	pH	TCO2
----	------	---	----	----	----	----	------

Figure 13

### 5.3.3 Print report

Click [Set] to select automatic printing.

Print items, reference range directly click on the change. The normal range of printing human body has been set up when the instrument leaves the factory, and the user can modify it according to the need.

Item	Normal Range
K	3.5 - 8
Na	135 - 145
Cl	97 - 107
iCa	1.15 - 1.35
nCa	1.15 - 1.35
TCa	2.3 - 2.7
pH	7.35 - 7.45
TCO2	20 - 31
AG	8 - 16

Figure 14

### 5.3.4 Adjust the down steps of sampling needle

Click[set] to adjust the down steps of sampling needle ,then click [save].

The screenshot shows a control interface with a sidebar on the left containing icons for Test, Search, Item, Set, Self CK, and QC. The main area displays the following settings:

- Date and Time: 2021-07-27 09:59
- ☒ Buzzer sound
- Tester: liming
- hour: [ ] Save
- ☐ Auto print
- From: 2021-07-20 To: 2021-07-27 Clear Data
- Start No: 8 Save
- Reagents motor step: 375 Save
- Sample cup motor step: 160

An "Input Panel" is overlaid on the interface, showing a numeric keypad with letters assigned to numbers (e.g., 1: q, 2: w, 3: e, 4: r, 5: t, 6: y, 7: u, 8: i, 9: o, 0: p) and a numeric keypad (0-9, ., /, \, ^, \_).

Figure 15

Note: The instrument uses the belt type lift motor as default. If no special situation, the user can not change the current motor settings freely. During the use of the process, if the down movement of lift motor is abnormal, you should adjust it by 10 steps as unit. If the down steps number beyond the specified number of steps(Normal range: $>0, \leq 400$ ), the instrument will resume the default value.

## 5.4 System calibration

### 1. Two point ion calibration

Two point ion calibration is used to determine the slope of the electrode and to determine whether the slope, millivolt and concentration of each electrode are in the specified range. Two point ion calibration must be done in the following cases:

- every day before the instrument works;
- Abnormal measurement results;
- instruments work continuously for four hours;
- replacement reagents;

2. Sample pump calibration: same as 5.2.3 sample calibration, users do not need to calibrate every day, only in the replacement of pump pipes or abnormal suction volume calibration, can be calibrated half a month.

## 5.5 Instrument maintenance

### 1.Electrode activation,the same as 5.2.2 Electrode activation 2.Electrodes Deproteinization

Click “Yes”,displays:

No:  ☒ Auto Age:   
 Name:  Sex: ☒ Male ☐ Female

☐ Blood analysis  
☐ QC analysis   
☐ Two points ion CAL  
☐ TCO2 CAL  
☒ Maintain   
☐ mV check

Insert deprotein 1S

< > Save Print YES

The electrode is deproteinizing 2021-07-26 13:21 V1.0.0

Figure 16

This process will take a few minutes to clean the electrodes, the mixer and the pipelines, and then carry out two ion calibration, the same as 5.2.4.

#### Note: About Electrodes Deproteinization

The instrument should carry out Electrodes Deproteinization process after measurement each day, then full fill the sample cup with de-protein solution, and it would be very helpful to keep electrodes' life & test accuracy.

### 5.5.1 Data display

#### 1. Showing Slope, displays:

No:  ☒ Auto Age:   
 Name:  Sex: ☒ Male ☐ Female

☐ Blood analysis  
☐ QC analysis   
☒ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain   
☐ mV check

Slope

K	Na	Cl	Ca	pH
70.9	43.2	36.8	35.4	67.1

< > Save Print YES

Two point ion calibration in progress 2021-07-27 09:31 V1.0.0

Figure 17

#### 2. Showing mV, displays:

No: 20210726001 ☒ Auto Age: Sex: ☒ Male ☐ Female

Name:

☐ Blood analysis  
☐ QC analysis 202010  
☒ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain Activation  
☐ mV check

mV				
K	Na	Cl	Ca	pH
89.1	63.0	90.7	67.0	75.7

< > Save Print YES

QC Two point ion calibration in progress 2021-07-26 12:35 V1.0.0

Figure 18

Note::The electrode mV of K, Na, Cl, CA and pH is between 40 - 120 mV (except pH upper limit is 140 mV), if the pH electrode is higher than 140 mV, it can not be declined even after activation, the electrode should be renewed. If all electrodes are lower or higher ,the reference electrode should be renewed. TCO2 is between 7 -27 mV, calibration can not pass beyond the range, the reagent should be renewed.

### 3. Concentration Display

No: 20210726001 ☒ Auto Age: Sex: ☒ Male ☐ Female

Name:

☐ Blood analysis  
☐ QC analysis 202010  
☒ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain Activation  
☐ mV check

Conc(mmol/L)				
K	Na	Cl	Ca	pH
4.01	140.8	100.4	1.26	7.38

< > Save Print YES

QC Two point ion calibration in progress 2021-07-26 11:58 V1.0.0

Figure 19

### 4. Clear Data

Main menu lower point settings enter this page point to clear the data, empty all data start number from 1:

Note: Delete patient sample data, it should be double checked, once you press the YES, the data will be permanently deleted. If not sure, return to the main menu.

## 5.5.2 mV check

Reagent (usually A calibration solution), point "YES", pump rotation suction sample to show the current reagent potential:

The millivolt value is refreshed every 1 second. If an electrode is not stable for more than 15 consecutive refreshes (more than 0.5 mV), the electrode needs to be maintained or replaced. If you want to exit the millivolt check, click NO" to return to the main menu.

No: 20210726001 ☒ Auto Age:   
 Name:  Sex: ☒ Male ☐ Female

☐ Blood analysis  
☐ QC analysis 202010  
☐ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain   
☒ mV check

2		mV		
K	Na	Cl	Ca	pH
113.3	115.3	127.3	101.0	83.2

< > Save Print NO

Potential check in progress 2021-07-26 12:28 V1.0.0

Figure 20

The instrument begins to measure after inhaling the sample, see "6.2 Measurement ".

## 5.6 Emergency

Insert Emergency into ST position of sample plate, then press [ST], displays:

No:  ☒ Auto Age:   
 Name:  Sex: ☒ Male ☐ Female

☒ Blood analysis 1 - 5  
☐ QC analysis 10008  
☐ Two points ion CAL  
☐ Activation  
☐ Deproteinized  
☐ mV CAL

Please wait

< > Save Print ST NO

Samples are being analyzed 2020-11-10 10:10 V1.0.0

Figure 21

Measures will start after sample is absorbed into the instrument, details as 6.2 measurement shows (note: no emergency operation in semi-automatic instrument)

# 6. Measurement

## 6.1 Prepare conditions

Operate the instrument strictly according to the guidance.

### 6.1.1 Process blood sample

(1). Safety: Follow the basic rules when collecting samples, and master blood collection techniques.

(2). Sample requirement

Usually, taking venous blood. For serum determination, the sample should be stewing at least 30 minutes after the acquisition of the centrifugal test.

As whole blood or plasma, should use lithium heparin as anticoagulant that does not affect the value of electrolyte. Other anticoagulants, such as alkaline anticoagulant heparin, EDTA, citric acid salt, oxalate, the electrolyte is an big influence. Therefore, they can not be used as an anticoagulant.

The samples in cold storage must be restored to room temperature before using it.

Note: All samples must be free of hemolysis, otherwise will increase the value of potassium ion. The sample collector must mark the collected samples according to related requirements.

### 6.1.2 Process serum

(1).Serum(serum blood): serum is the translucent liquid that separates from blood coagulation. The essence of blood coagulation is the transformation of soluble fibrinogen into insoluble fibrin. Fibrous protein is thin and filamentous. Interwoven into a network, the network include a large number of blood cells, forming blood clots. Blood coagulation after 30 minutes to 1 hour, blood clots platelet contractile contractile proteins, the clot retraction harden, clear fluid extrusion, become serum. The difference between serum and plasma, is that serum is lack of fibrinogen and blood coagulation factors, but it adds a small amount of blood clotting process by platelet release.

(2). Processing requirements: in order to save time, it can centrifugal (4 minutes, 2500rpm) to separate the serum. And take measure to prevent hemolysis.

### 6.1.3 Process urine

Since each exclusion of urine concentrations are different, it is necessary keep urine in last 24 hours and collect into a container,Test urine that diluted with double deionized water.

### 6.1.4 QC sample

It is highly recommended that user should make quality control regularly with qualified QC products, in which,  $\text{Cl}^-$ ,  $\text{TCO}_2$  and  $\text{K}^+$  should adopt freeze dry quality control serum as quality control material,  $\text{Ca}^{2+}$  and pH should adopt QC material that bases on water.

## 6.2 Measurement

The calibration of the instrument system should pass normally in order to guarantee the reliability of the measurement results.

### 6.2.1 Analysis

1.Sample analysis Click “Yes”

No:  ☒ Auto Age:   
Name:  Sex: ☒ Male ☐ Female  
☒ Blood analysis  
☐ QC analysis 202010  
☐ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain Activation  
☐ mV check  
Blood analysis, Press YES  
< > Save Print YES  
Waiting operation 2021-07-26 13:04 V1.0.0

Figure 22

### 6.2.2 QC

Under the main menu, enter the QC menu, click “Yes”

No: 20210726001 ☒ Auto Age:   
Name:  Sex: ☒ Male ☐ Female  
☐ Blood analysis  
☒ QC analysis 202010  
☐ Two points ion CAL  
☐ TCO2 CAL  
☐ Maintain Deproteinize  
☐ mV check  
Insert QC 3S  
< > Save Print YES  
Analyzing QC 2021-07-26 13:31 V1.0.0

Figure 23

(2). QC statistics

Under the QC menu, press the QC

QC report could be made after measuring QC products in same batch number for more than 5 times, the report includes MEAN, SD and CV, press [Print]. If you delete a quality control result, select this result point to delete.

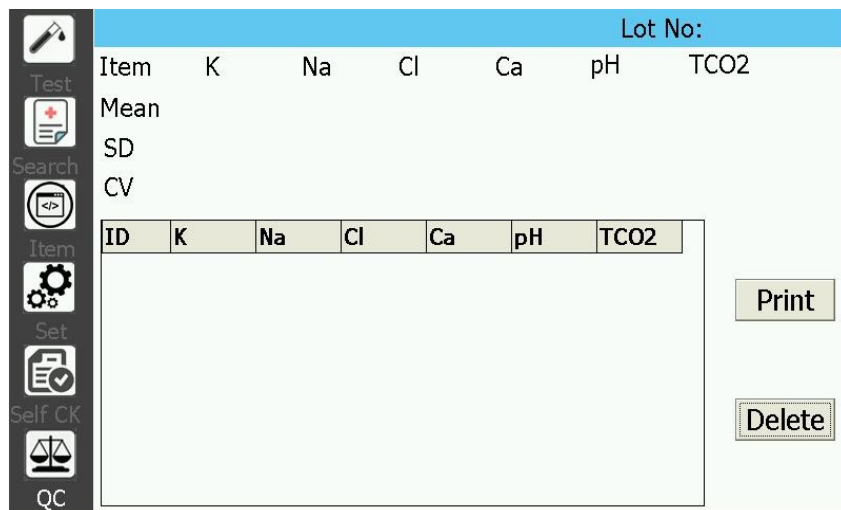


Figure 24

## 7. Maintenance

### 7.1 Daily Maintenance

- Check the A standard solution, B standard solution whether need to change.
- After each time replacement the reagent , must be keep the pipe inserted into the bottom of bottle, for fear of it can not absorb the standard solution, and to do the system calibration.
- Fill the sample cup with the protein solution.

### 7.2 Regular Maintenance

1. In the maintenance menu for instrument maintenance, see the treatment method 5.5
2. Check the pump tube aging, aging need to replace the pump tube.

NOTE: Electrode normal life about 2 to 3 years, proper maintenance, longer life, usually in normal temperature, dry conditions can be stored, the electrode contacts do not touch the solution, especially the chemical solution, the replacement standard see 5.5.1

### 7.3 The treatment of instrument idle

If there is a long time that don't use electrolyte Analyzer, please maintenance it according to following;

- Take off all the reagent bottle, cover the lid of the bottle, empty the waste water and put it back;keep the special bottle cap;
- Loosen the pump tube
- Turn off the power, clean the equipment, cover it well.



## 7.4 Reagents usage Instruction

- Reagents should be installed in a fixed position, do not be in the wrong bottle pipe to cause the mixed reagent.
- Among them: Validity period of A standard solution, B standard solution and R reaction solution is 2 years Under normal temperature, away from light and sealed conditions; Validity period of C standard solution is 12 months, users can not use expired reagents.
- After opening, A standard solution, B standard solution and R reaction solution should be used within three months, C standard solution should be used within a month.
- Please use special caps in the course of using to prevent reagents from volatilizing. It will cause the analysis results not accurate.
- Unknown reagents and quality control products shall not be measured, in particular, the standard liquid of flame photometry.

## 8. Trouble shooting

### 8.1 Summary

This chapter does not describe all the problems, so, for those ones that cannot be solved or need to remove the instrument cover to repair, the user must contact the company's after-sales service and maintenance personnel, the company's maintenance service engineer or appointed distributor repair the equipment, or the user send the instrument back to company to repair.

### 8.2 The instrument does not work

The reason causing the instrument not working

Power failure, power outages, socket is not reliable, fuse fuse, power damage; Motherboard damaged, replace it;

### 8.3 Maintenance of instrument Accessories

- After using the machine for some time, you need remove part of the accessories to maintain it.

#### 8.3.1 Electrode

- In use, electrode might be blocked or changed, in that case, you need to remove or replace it.
- If the electrode is blocked, the whole electrode is inserted into the end of the electrode with a syringe, and the other end is provided with a liquid.
- If need to replace the electrode, directly remove it, and replace the electrode needed to be changed, then install them according to priority.

Note: protein removal treatment of Cl electrode, protein in the sample is easily attached on the Cl electrode, which will affect the slope of the Cl electrode, then cause the inaccurate measurement results, in this situation, please remove the electrode, the method: pull out the box Gently, get it out of the machine carefully, unscrew the nut of REF electrode tip, translate the whole set of electrodes into a single

electrode, take out Cl electrode, suck protein liquid with syringe to rinse Cl electrode back and forth, the depth of the insertion electrode must not exceed 5mm, and recover it according to order. Also the sealing ring can not be lost, each nut of the electrode tip must be tighten.

### **8.3.2 Silica gel column**

First move sample needle to the top using hands, then remove the instrument of sample entering tray, then unplug the liquid outlet pipe at the bottom, press the cover of the liquid with the left hand, clockwise unscrew the base of liquid outlet with the right hand. Unscrew and remove the red silica gel column, recover it after replacement.

## **8.4 System calibration is not going through**

### **8.4.1 Two-point ion calibration is not going through**

Two-point ion calibration failure includes 3 situations: Electrode slope, electrode millivolt, electrode concentration overturn

#### **(1) Electrode slope and Electric potential overrun**

- Strong electromagnetic interference from the outside, eliminate the interference source, cover good sealing cover.
- There is leakage between the electrode, tighten electrode or replace the seal ring.
- The electrode and the amplifier are not in place, check the contact on the electrode to see whether it is fully linked with the elastic contact of the box.
- Reagent contamination, change the new A standard and B standard.
- Reference electrode damage, replace a new one.
- Amplifier damage, replace a new one.

#### **(2) Single electrode overturn**

- Activate the electrode without activation liquid
- Electrode de-proteinization
- Corresponding electrode is damaged, replace it.
- Amplifier is damaged, change it

#### **(3) Single electrode mV overturn**

- Whether single electrode is connected with amplifier well
- Single electrode is damaged, change it
- The amplifier is damaged, change it
- (4) Concentration of single electrode overturn
- Power supply voltage instability cause electrode concentration overrun, need to install the power supply.

- Electrode is not stable, carry out electrode de-proteinization or activate electrode, if it has no effect, you should change single electrode.
- The amplifier is not stable, change it

## 8.5 Sample measurement is abnormal

### 8.5.1 Poor stability of measurement

Poor stability of measurement means that Repeatability of machine is bad. Possible reasons:

- Power soon, the instrument is not stable yet.
- Power supply is not stable, add Regulated power supply.
- Poor stability of electrode, maybe the electrode is old or damaged, if the stability of all the electrode is bad, refer to the electrode damage.
- Enlarged box is not stable, replace the it

### 8.5.2 Poor accuracy of measurement

- Test without system calibration or calibration failure, operate system calibration until it pass.
- All the calibration of test project is bad, you should consider changing the electrode.
- The reagent goes bad, change it.
- Set A/B

## 8.6 Block Remove

Possible blocking position and the method of drainage:

(1) liquid outlet the blocking caused by the sample needle repeatedly adhesion with serum, method is to raise the sample needle from the flow inlet, and then pull out the bottom pipe of the liquid outlet, add water with syringe to the liquid outlet until a smooth flow shoot out from liquid outlet.

(2) Add the needle to the electrode, power off the machine after rising the needle to a certain height, pull off the left-side transparent tube of the electrode, Using syringe inject water into the transparent until the liquid flow out from the sample needle.

Note: Don't wet the instrument with the water that is out of the transparent pipe (especially the electrode box).

(3) Electrode: The ends of the electrodes are the same as before, remove the pump pipe from the sample pump and pull out one section, add water to flush with a syringe, until the needle has a liquid outflow.

## 9. Appendix

### 9.1 Explaining of C1

CI get measured results by titration and colorimetry, it should be consistent with electrode method measuring results, but as part of the frozen dried quality control serum with preservatives have certain interference effect on chloride electrode, usually causing the results higher, therefore it is proposed that the determination of freeze dried quality control serum should be determined one or more than one batch fixed value ones, set the slope (a) and intercept (b), then measuring chamber of quality control (QC) lyophilized quality control serum. So it is strongly recommended that users don't use containing preservative quality control serum, professional quality control serum should be adopted, such as Landox, Bole etc.

## 9.2 Explaining of Ca and PH

Standard ionized calcium (nCa): Determination of Ca in the sample of the ionic calcium (iCa). Normally human's serum ionized calcium concentration maintain in a narrow range, about 1.10mmol/L-1.35mmol/L, Due to the effect of centrifugation and anticoagulant, the dissolved CO<sub>2</sub> in serum of collected samples will be released into air, the pH value gradually increase, so the measured value will be 7.6-8.0. parts of ionized calcium of serum will be combined with protein to become protein-bound calcium, which will cause the measured concentration of iCa to decrease. In order to eliminate the external error, when the instrument measure the ionized calcium of the sample also will measure the pH of serum, calculate the difference ( $\Delta$ PH) between the determined PH value with the normal PH value of human body(7.40), then according to the formula to calculate the value of protein-bound caused by the increasing of difference and plus the value with actual value of iCa. The obtained is a iCa eliminated exogenous errors and in human normal pH (7.4), often referred to the standard calcium (nCa). PH is only for the correction of ionic calcium, and the PH in the instrument print report has no clinical significance.

## 9.3 Technology data

Performance index

test items	blood sample test range mmol/L	Urine sample test range mmol/L	Precision	Accuracy
K	0.50-15.00	5.0-150.0	≤3.0%	CV≤1.0%
Na	30.0-200.0	10.0-350.0	≤3.0%	CV≤1.0%
Cl	30.0-200.0	10.0-300.0	≤3.0%	CV≤1.0%
Ca	0.10-5.00	-----	≤0.3	CV≤1.0%
PH	4.0-9.00	-----	≤0.15	CV≤1.0%
TCO <sub>2</sub>	4.0-70.0	-----	≤3.0	CV≤2.0%

Table 4

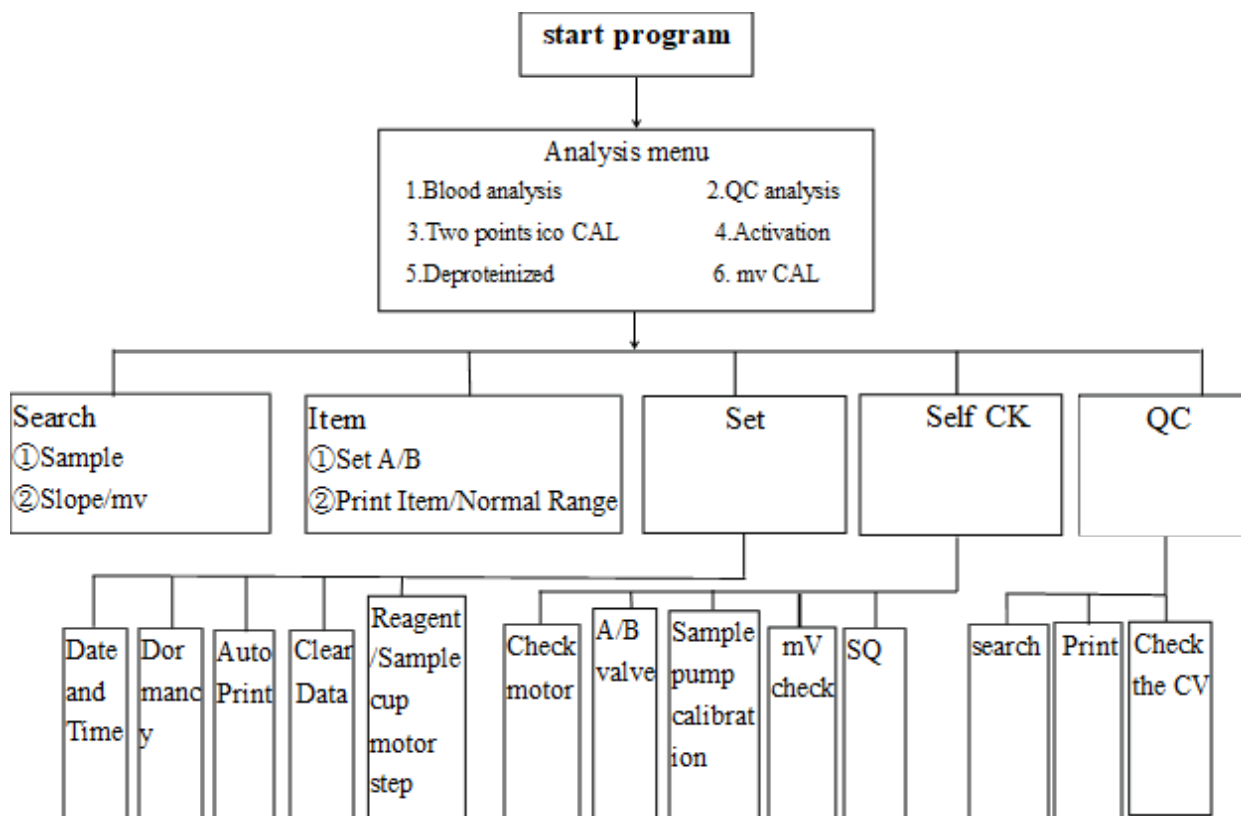
Other parameters: Test time ≤45s include absorbing sample and flushing time. Sample mode 、 serum、 plasma(whole blood)、 diluted urine. Sample volume 160uL. Data output、 LCD display and built-in thermal printer.

working condition: Temperature:15°C - 30°C ; humidity:85; power supply: 220V 50HZ, 40VA;

Dimension:335mm×270mm ×330mm; weight:7 kg without sample adding system;

Work condition:5 year

## 9.4 General Framework



## 9.5 Reservoir

ANA61-06A of electrolyte analyzer should be stored in the original box 5 -40°C, the relative humidity of indoor air is not more than 85%.The air should not be corrosive gas and direct light , stacking layer is not more than 5.

## 9.6 RS232 interface specification

(1) Signal

stitch	instruction	abbreviation	direction
2	RXD	RX	input
3	TXD	TX	output
5	signal ground	GND	

Table 5

Note:

(1).number of stitch refer to connector DB-9P 2.RI don't need to be connected (2)communication parameters

baud rate	57600
stop-bits	1
data-bits	8
parity digit	none

(2) data format

Start	1	STX (0X02)
Wrap	1	0Xa
Serial number	11	20201110001
Wrap	1	0Xa
Item Abbr.	16	K#####
Wrap	1	0Xa
result	6	4.00##
Wrap	1	0Xa
unit	8	mmol/l##
Wrap	1	0Xa
Hint	1	#
Wrap	1	0Xa
Item Abbr.	16	Na#####
Wrap	1	0Xa
result	6	140.0##
Wrap	1	0Xa
unit	8	mmol/l##
Wrap	1	0Xa
Hint	1	#
Wrap	1	0Xa

Item Abbr.	16	Cl#####
Wrap	1	0Xa
result	6	100.0##
Wrap	1	0Xa
unit	8	mmol/l##
Wrap	1	0Xa
Hint	1	#
Wrap	1	0Xa

Item Abbr.	16	iCa#####
Wrap	1	0Xa
result	6	1.25##
Wrap	1	0Xa
unit	8	mmol/l##
Wrap	1	0Xa
Hint	1	#
Wrap	1	0Xa
Item Abbr.	16	nCa#####
Wrap	1	0Xa
result	6	1.25##
Wrap	1	0Xa
unit	8	mmol/l##
Wrap	1	0Xa
Hint	1	#
Wrap	1	0Xa
Item Abbr.	16	Tca#####
Wrap	1	0Xa
result	6	2.48##
Wrap	1	0Xa
unit	8	mmol/l##
Wrap	1	0Xa
Hint	1	#
Wrap	1	0Xa
Item Abbr.	16	PH#####
Wrap	1	0Xa
result	6	7.38##
Wrap	1	0Xa
unit	8	mmol/l##
Wrap	1	0Xa
Hint	1	#
Wrap	1	0Xa
End	1	ETX(0X03)

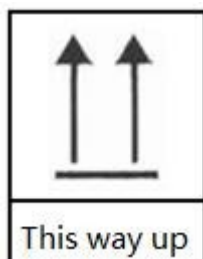
Character with insufficient length use space to fill on the right side, the above #" indicates

space.

Note: debugging can use the super terminal software the coming with computer system, transmission format is ASCII mode, set transmission parameters please refer to system help. USB connection mode can be used to connect the serial port (computer need to download the USB to the serial port driver). The company only ensure the normal communication between instrument and computer,if users need a complete report, and manage it together with the determination report of other laboratory and instruments, which need to install laboratory information management system (LIS) ",only in that way, the data could be ensured to use normally, and timely feedback to the doctor or the patient.

## Appendix One: The package indicative marks

1. This way up



2. Keep dry



3. Handle with care



4. IVD



5. Net weight: 5 Kg

6. Volume: 335mm×270mm ×330mm



# Appendix Two

## Packing List

Item	NO.	Items	Unit	Qty	Remark
Standard configuration	1	Analyzer Unit	unit	1	
	2	Automatic sampling turntable	pc	1	match
	3	Calibration Solution A (400ml)	bottle	3	
	4	Calibration Solution B (200ml)	bottle	1	
	5	Electrode Activating Solution (15ml)	bottle	2	
	6	Electrode De-protein Solution(15ml)	bottle	2	
	7	Electrolyte Analysis Solution (TCO 2 Calibration Solution)	bottle	1	
	8	Electrolyte Analysis Solution (TCO 2 Reaction C Solution)	bottle	1	
	9	Bottle Cap	pc	3	
	10	Waste Liquid Bottle	pc	1	
	11	Pump Pipe	pc	2	
	12	Sealed Ring for liquid outlet	pc	2	
	13	Print Paper	pc	1	
	14	Power Cable	pc	1	
	15	Sample Cup	pc	50	match
	16	User's Manual	pc	1	
	17	Packing List & QC Approval	pc	1	
	18	Adapter	pc	1	

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