

XI-921

Electrolyte Analyzer User's Manual



Caretium

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Chapter 1 General

1.1 Scope of application

This series electrolyte analyzers are automated, microprocessor controlled analytic instruments that apply ISE (Ion Selective Electrode) technology to the measurement of the contents of potassium (K), sodium (Na), chloride (Cl), calcium (Ca), lithium (Li), pH and HCO_3^- (AB) in human body liquid.

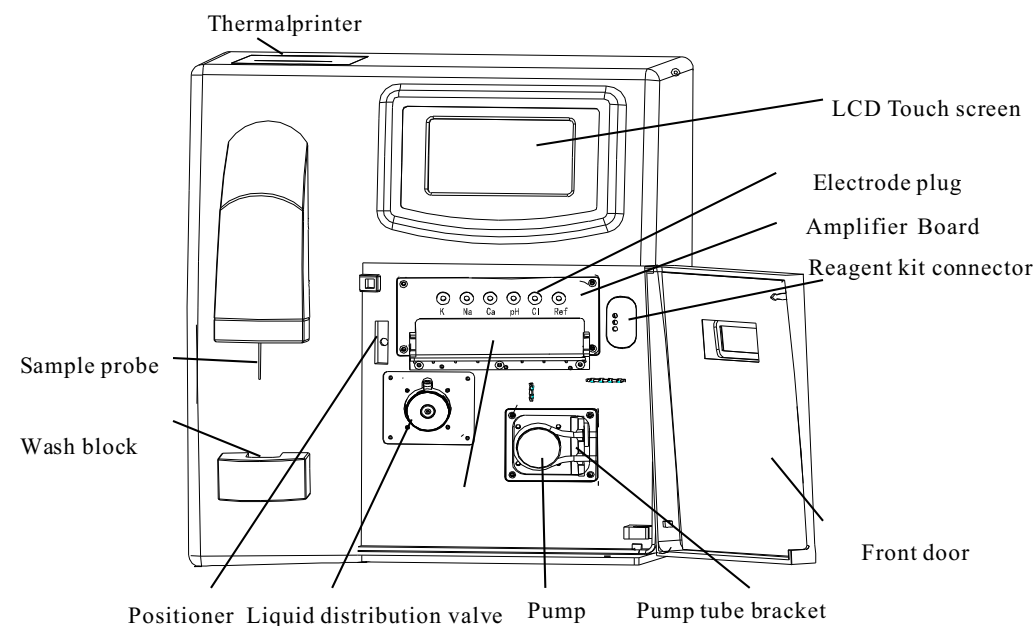
Instrument Models:

- a) XI-921FT: K, Na, Cl
- b) XI-921AT: K, Na,
- c) XI-921BT: K, Na, Cl, & HCO_3^- (AB)
- d) XI-921CT: K, Na, Cl, Ca, PH
- e) XI-921DT: K, Na, Cl, Ca, PH, AB
- f) XI-921ET: Li, K, Na, Cl

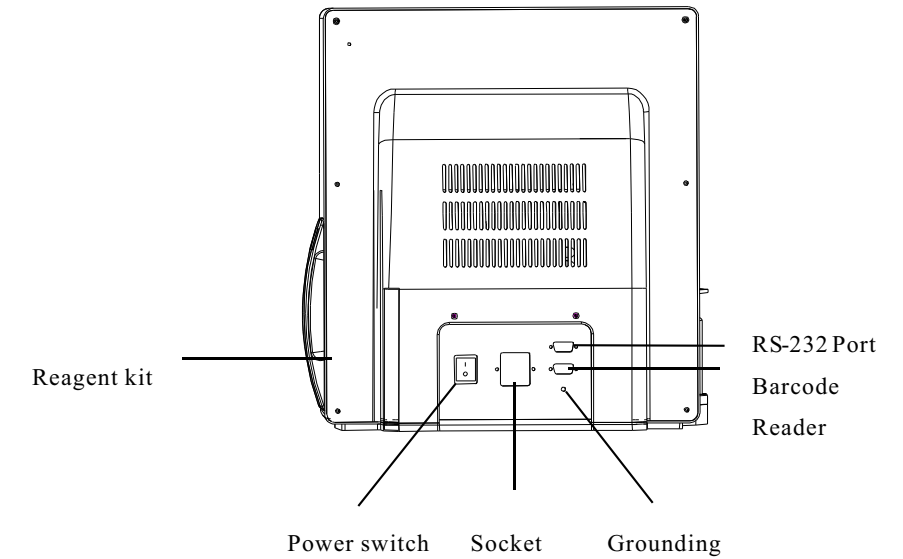
Note: XI-921□T Model, “T” – “Touch Screen” function

1.2 Instrument structure

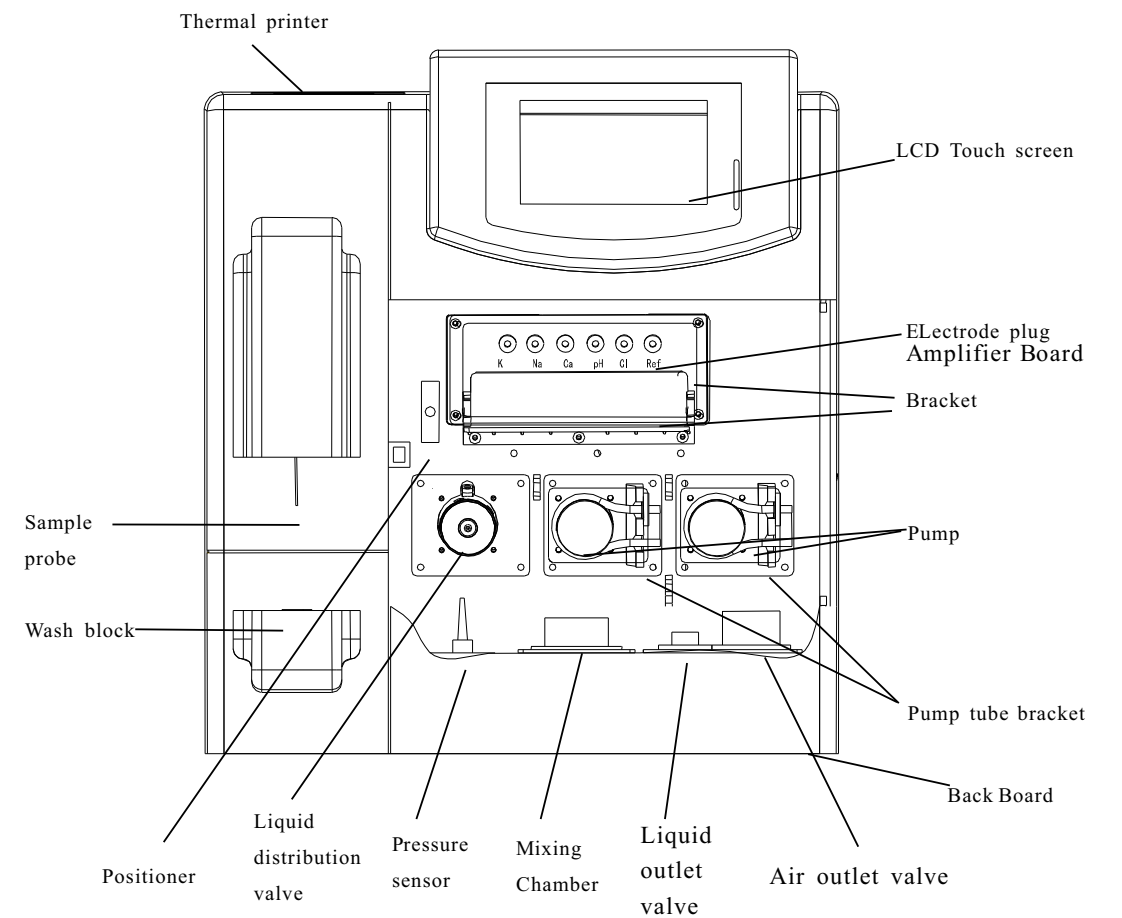
- a) XI-921FT, XI-921AT, XI-921CT, XI-921ET consists of mainframe, LCD touch screen, printer, electrodes and reagent kits etc.
- b) XI-921BT, XI-921DT consists of mainframe, LCD touch screen, printer, electrodes, electrochemical sensors, and reagent kits etc.

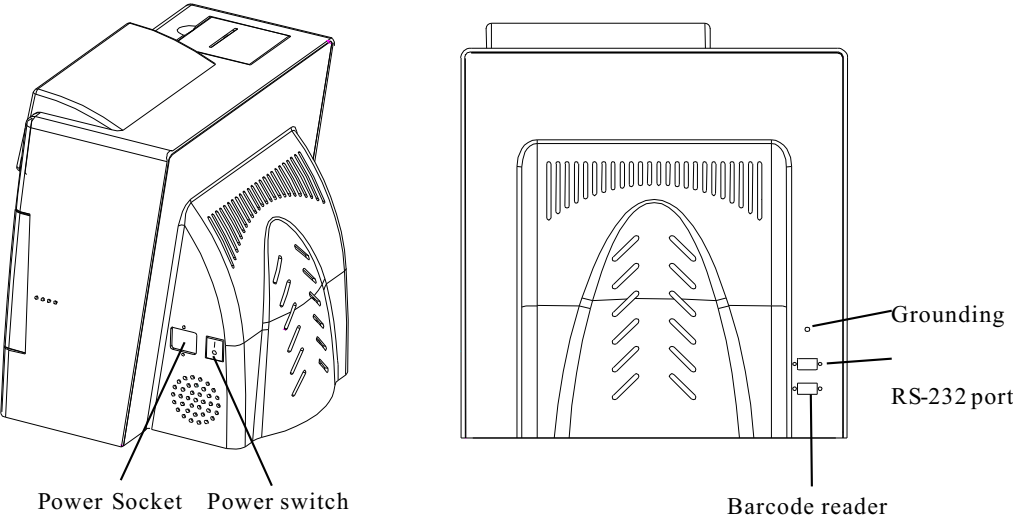


XI-921AT, XI-921CT, XI-921ET, XI-921FT model front pictures.



XI-921AT, XI-921CT, XI-921ET, XI-921FT model back picture.





- Easy operation: User friendly software, large LCD display, touch screen. 24 hours non-stop working mode, suitable for emergency samples.
- Large memory: Up to 200 patient results stored on board, easy to review.
- Easy maintenance: Advanced design of hardware, fluid tubing system and selfdiagnosis software, makes it easy and simple for maintenance and troubleshooting.

1.3 Brief instruction of the instrument

Potassium, sodium, chloride, calcium and HCO_3^- make up the main composition of body electrolytes. It is a prerequisite of all medical means to keep the balance of human body electrolytes. And it is very important to obtain the amount of potassium, sodium, chloride, calcium and HCO_3^- 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 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.

These series electrolyte analyzers are specially designed for clinical analysis. The main features include:

- High precision: Guaranteed by long lifetime, high performance electrode and advanced automatic control software. Unique calibration programs eliminate systematic errors. Wide linear range.
- Low sample volume: 150 μl 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 models can add auto sample plate, updated to auto sampler models.

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, that 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 being 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 point to measure the potential differences.

2.2 Measuring principles

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

Following are the equations:

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

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

Note:

C_X , E_X : the concentration and potential of the sample

C_A , E_A : the concentration and potential of standard A

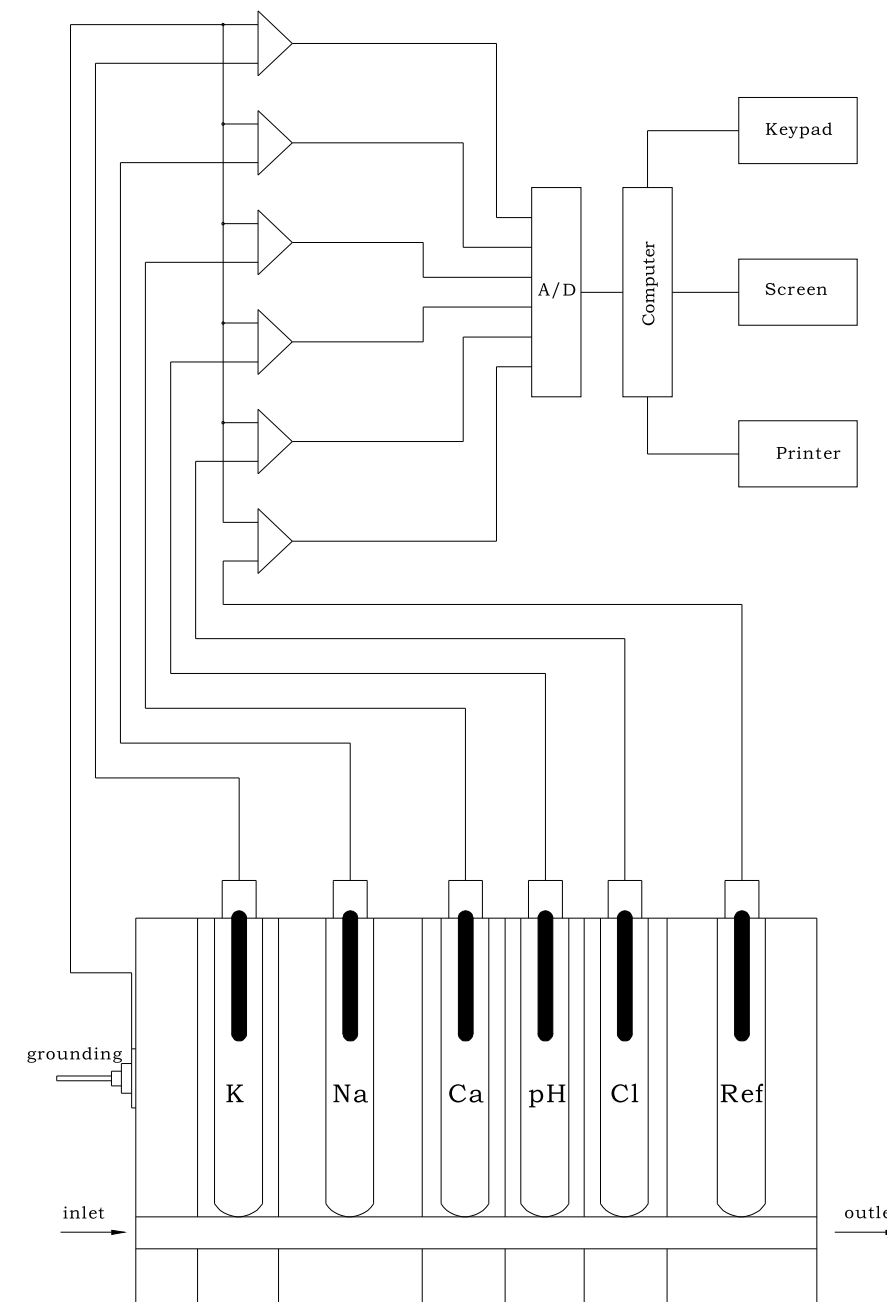
C_B , E_B : the concentration and potential of standard B

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.

2.3 Manometric method (for HCO_3^-)

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



Chapter 3Features & 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
pH	7.0~9.0(Unit)	27~70
Li ⁺	0.3~3.0	12~67
HCO ₃ ⁻ (AB)	6.0~50.0	4~20

3.2 Sample variety

Serum、Plasma (whole blood) or Urine

3.3 Measuring speed

60samples/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	≤1%	≤2.0%	≤5.0%	≤2.0%	≤1.5%
Li ⁺	≤5.0%	≤5.0%	≤5.0% or ±0.1 mmol/L	≤5.0%	≤5.0%
HCO ₃ ⁻	≤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) %;
- AtmosphHeric pressure: (86 ~ 106)kPa;
- Avoid electrical interference;
- Avoid direct sunlight
- Correctly grounding

3.6 Output method

LCD with backlight, printer

3.7 Power supply

AC220/110V± 10%, 50/60 Hz

3.8 Power consumption

60VA

3.9 Dimension

Length 440mm
Width 410mm
Height 510mm

3.10 Weight

Main Unit: 7.2 kg
Gross Weight: 12.2 kg
Auto sample plate: 1.5kg

Chapter 4 Installation

4.1 Environment requirements

- 1) The instrument should be installed on a stable and solid platform that is free of mechanical vibration and away from vibration source.
- 2) The environment should be as free as possible from dust, corrosive gas, loud noises and electrical interference.
- 3) Avoid placing the instrument in direct sunlight or in front of a source of heat or vent.
- 4) Ambient temperature: 15~32°C, relative humidity: <85%.
- 5) The power supply should be AC220/110V ± 10%, 50/60Hz ± 1Hz
- 6) Power supply and grounding should be connected correctly.

4.2 Unpack

- 1) Check accessories refer to the packing list, contact supplier immediately if there is any damage or missing parts.
- 2) Check instrument name and model code, please contact supplier if there is any part not match.

4.3 Installation of new electrodes

- 1) Electrode assembly of new instrument has been installed and tested in good condition, before shipping.
- 2) Check if the filling solutions are sufficient or carry bladders.

Replace & check electrodes

- 1) Assemble the electrodes with the rubber gasket according to figure.
- 2) Put them through the axis, and then tighten the nuts firmly.
- 3) If the filling solutions are insufficient, remove the internal electrodes and fill in correct filling solutions (K filling solution for K electrode, Ca filling solution for Ca electrode, Na/Cl filling solution for Na, Cl and pH electrodes, and reference filling solution for reference electrode).
- 4) Clean and dry the electrodes with soft tissue.
- 5) Install the whole electrode assembly to the electrode holder.
- 6) Connect the electrode lead wires and the grounding wire to the corresponding plugs according to figure 3.



- 1) **Do not mix up the electrodes!**
- 2) **Replaced internal electrode must not be used without distilled water rinsing.**

- 3) **Away from metal goods**
- 4) **80~90% solution is sufficient**
- 5) **Do not touch electrode membranes by any hard subjects.**
- 6) **Lapping electrodes to eliminate bladder**
- 7) **Electrode installation must be follow figure 2.**
- 8) **Do not mix up K、Ca、Na、pH、Cl solutions**

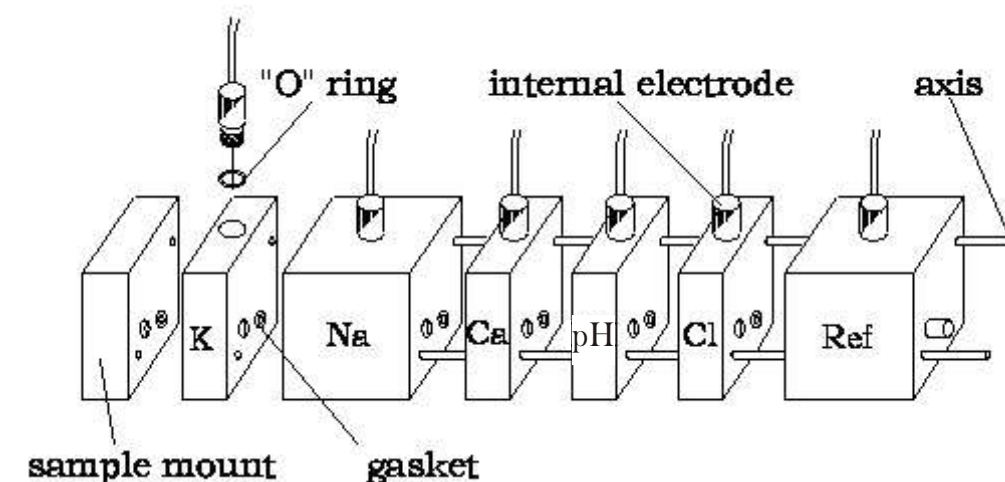


Figure 2

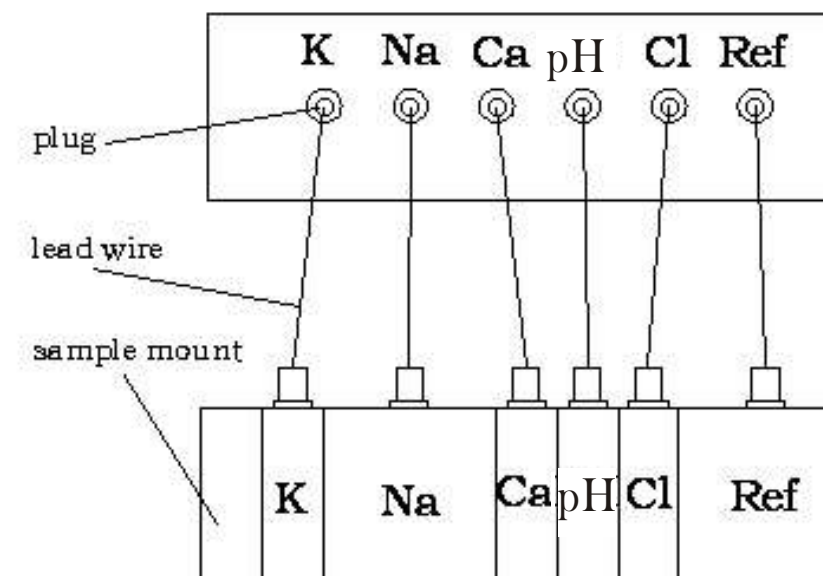


Figure 3

4.4 Installation of the tubes

Connect the tubes according to figure 4. Figure 5 is the tube connection diagram for CO₂ reaction chamber (for HCO₃⁻)

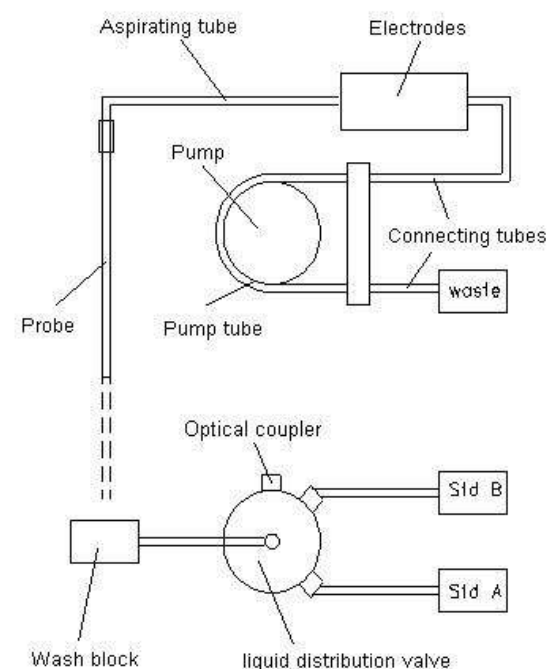


Figure 4

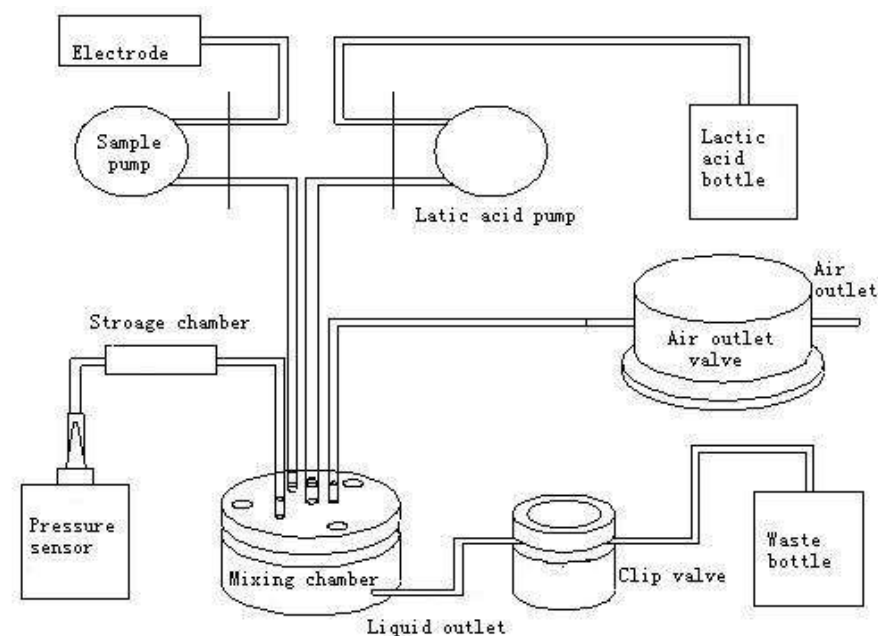


Figure 5

4.5 Installation of the reagents

1. For external reagent pack user: take off rubber cap of external reagents, connect tubes according to outlet marks.
2. For internal reagent pack user: stretching the rubber cap, insert reagent package.
3. XI-921BT、XI-921DT model user, should discharge waste water into the external waste bottle (W).
4. Reagent bottle user: open each bottle cap (A std、B std、Lactic acid solution) insert covered pipette into reagent bottle, screw down cap, and then connect corresponding inhaling tube to the stainless steel tube.
5. Insert waste water tube to "W" waste bottle, screw down cap.
6. Finally, check out the whole tubing system.

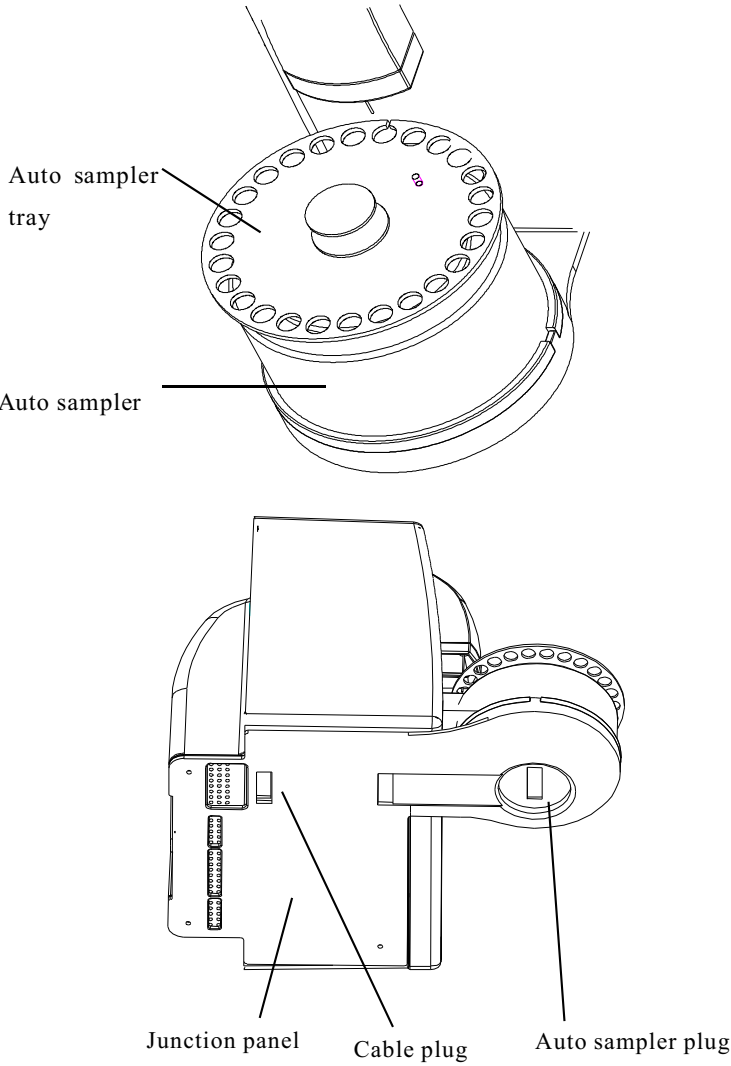
! After taking out standard、control、filling solutions or other reagents from the refrigerator, please wait for a moment until they warm up to the room temperature, to prevent the damage of the electrodes. Be careful not to contaminate the reagents during the installation or replacing.

4.6 Installation of the printing paper

1. Insert the paper support on the stand.
2. Insert the paper into the guide slot.
3. Make sure the thermal side of the paper faces downward.
4. Pull up the lever on the right, rotate the knob until the paper comes out, then push the lever down; or touch "Paper" on the service menu until the paper comes out.

4.7 Installation of the auto sampler (for auto sampler models only) According to figure 5.

- 1) Tilt down the instrument, connect cable to the data cable plug of main unit;
- 2) Put the main unit on the junction panel, connect cable to auto sampler plug;
- 3) Put sample tray on the top of auto sampler.



⚠ During self-testing, do not put sample tray on auto sampler, if the auto sampler rotate anomaly, to prevent sample probe damage; remove auto sampler、 junction panel and data cable when problems occur, auto electrolyte analyzer turns into semi-analyzer; please contact our distributor directly.

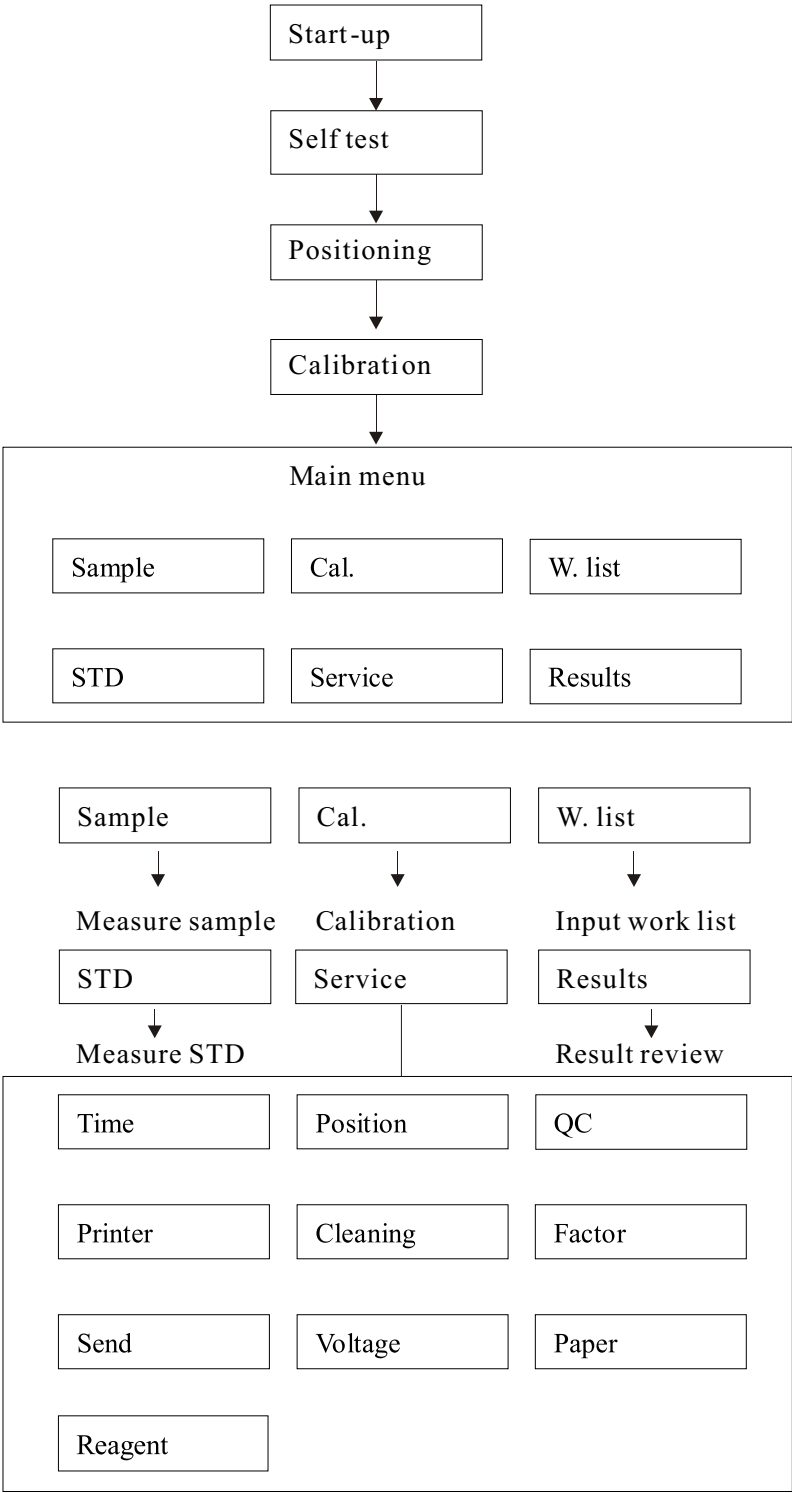
4.8 Connect to power supply

- 1.AC220V ± 10%, 50/60Hz ± 1Hz (Unstable power users, need to add the regulated power supply to make sure the input voltage is at correct level).
- 2.Make sure the power switch is at OFF position.
- 3.Connect the instrument to the power supply with the power cable.

⚠ The instrument must be grounded properly.

Chapter 5 Operation

5.1 Flow Chart of the operating procedure



5.2 Startup and self-test

After the instrument being correctly installed, turn on the power and boot up the instrument, the screen displays:

Initialization...

The instrument carries out the self-test for the positioner, printer and auto sampler. The sample probe will lift up, and the screen displays:

Auto position OK
Printer OK
Sample tray not detected

- Notes:
- 1. For auto sampler models, it will show Sample tray “OK” if the auto sampler is correctly installed.
 - 2. The initialization will halt if any error detected on the liquid distribution valve, elevator switch or optical couplers.

When the initialization finishes successfully, the sample probe comes down, and a few seconds later, the screen displays:

Measure ISE STD.....

It indicates the instrument is carrying out the calibration. The system checks the positioner' voltage, pump pulse numbers and electrode potentials. The screen displays:

1032... (the positioner's voltage (in mV) when calibrating without liquid, up to 3 readings)

127... (the positioner's voltage (in mV) when calibrating with liquid, up to 3 readings)

2094 2100... (the pump pulse number corresponding to the sample volume, up to 4 readings)

70.36 68.08 73.77 33.75 69.1 (the potential of each electrode when Standard B aspirated)

53.98 73.56 66.59 26.15 95.1 (the potential of each electrode when Standard A aspirated)

.....

..... (The potentials with standard B and standard A displayed in turn, up to 3 times)

When the calibration finish, the screen displays:

Slope		
K:	54.5	OK
Na:	52.3	OK
Cl:	51.6	OK
Ca:	25.5	OK

And the results will also be printed out as below:

TIME: 2005-03-30 10:08
SLOPE
K: 54.5 (27-70)
Na: 52.3 (27-70)
Cl: 51.6 (27-70)
Ca: 25.5 (15-35)
pH: 55.6 (26-70)
AB: 11.4 (4 - 20)

Note: if the slope of an electrode is unstable, it will display “Fluc.” on the right side. If the slope of an electrode is abnormal, it will display “X” on the right side.

The normal ranges of the slopes are:

K:	27-70 mV/dec	Ca:	15-35 mV/dec
Na:	27-70 mV/dec	pH:	27-70 mV/dec
Cl:	20-70 mV/dec	Li:	12-67 mV/dec
AB:	4-20 mV/dec		

After the calibration, the screen will display the main menu:

Main Menu			05-10-20 16:10:25
Sample	Cal.	W. List	
STD	Service	Results	

If there is no operation for more than 20 minutes, the instrument will enter into “standby” mode, the screen displays:

05-10-20
16:15:57

Wake up

 **Do not switch on instrument immediately after shut down, wait for 1minute.**

5.3 Sample measurement

5.3.1 Operations without auto sampler

Press “Sample” ; enter into sample measurement menu, the screen displays:

	Sample	ID	00000000 00000000
Num:	001	Get ID	Aspirate
			Exit

If the operator wants to change the sample number, then press the button

After Num, the screen displays:

Num:_____

1	2	3
4	5	6
7	8	9
./-	0	Cls
	Yes	Exit

Enter the patient number; press “Yes” to save.

Once the system date changes, the sample number will restart from 001 and increase until 999 (maximum) automatically.

Sample	ID
Num:	Aspirate
001	Get ID
	Exit

If the operator wants to change the patient ID number by barcode reader, then just scan the barcode on the sample tube. After being scanned, the ID will

Be displayed after “ID”

If the operator wants to change the patient ID number manually, and then press the button Get ID, the screen displays:

ID:_____

1

2

3

4

5

6

7

8

9

./-

0

Cls

Yes

Exit

Enter the ID number and press “Yes” to save.
Present the sample under the sample probe; press “ Aspirate” , the sample will be aspirated into the system. Remove the sample from the sample probe in time when the screen shows“Remove sample”and beep sound gives out. The results will be displayed within 60 seconds:

SampleID

Num:001

Get ID

Aspirate

Exit

K:5.09

pH:7.56

Na:145.5

Cl:105.3

Ca:1.31

And the results will also be printed out as below:

TIME: 2005-03-30 10:12

SAMPL-No: 001
PAT ID: 123456789012345678

K	5.09	mmol/L	3.5-5.2
Na	145.5	mmol/L	135-145H
Ca	1.31	mmol/L	1.1-1.4
Cl	105.3	mmol/L	98-108
TCa	2.55	mmol/L	2.2-2.9

Notes:
“H” indicates the result is higher than the normal range.
“L” indicates the result is lower than the normal range.
“?” indicates the slope is abnormal or the electrode has not been calibrated properly.

 **When the instrument gives out beep sound, the operator should remove the sample from the sample probe immediately!**

If there is no operation for more than 20 minutes, the screen will display “Wake up” , and the sample probe will come down. A few seconds later, the instrument will enter into standby mode. If the operator wants to measure sample again, just press “Wake up” to active the instrument. If the standby time is over 30 minutes, the instrument will do calibration automatically when it waked up. The electrodes will be maintained during the standby time.

5.3.2 Operations with auto sampler

Press “Sample” ; enter into sample measurement menu, the screen displays:

Sample

Tray Num01

QC 1

First Num01

QC 2

Last Num20

Eme. 1

Eme. 2

Start

Exit

Press the button after Tray Num and input the tray number. Input the first sample number and last sample number in the same way. The first number can be any number between 1 to 20, while the last number should be between first number to 20.

To measure the controls, press “QC 1” and/or “QC 2” the screen will show

“QC 1√” and/or “QC 2 √” . Then, before or after the test for the samples, the instrument will measure the controls placed on position “QC 1” or “QC 2” automatically. For example, if the operator presses “QC 1” only, then the instrument will measure the control on position “QC 1” before the tests for all samples. And if the operator presses “QC 2” only, then the instrument will measure the control on position “QC 2” after the tests for all samples.

During the regular measuring procedure, if emergency samples come, the operator should place them on position “E 1” or “E 2” of the sample tray. If there is only one emergency sample, then it must be placed on position “E 1” . Press “E 1” or “E 2” , it will show “E 1√” or “E 2√” . Then, after measuring the current sample,the instrument will turn to measure the emergency samples. When the measurement of the emergency samples finishes, “√” will disappear from the screen, the instrument will return to the measurement for the regular samples.

During the sample measuring procedure, the operator can press “Exit” to quit at any time. Then, after finish the measurement for the current sample, the instrument will return to the main menu.

In case the auto sampler fails, the operator can power off the instrument and disconnect the auto sampler from the main unit. When power on the instrument again, it will automatically switch to stand-alone working mode. Then the operator can continue to operate the instrument without the auto sampler.

5.4 Calibration

When systematic bias errors exist, the operator should calibrate the factors with control. Press “Cal” . In the main menu, the screen displays:

Target

K:

0.00

Na:

0.00

Cl:

0.00

Cal.

Exit

Press the button after K, the screen displays:

K:_____

1

2

3

4

5

6

7

8

9

./-

0

Cls

Yes

Exit

Enter the target value of K and press “Yes” to save. Enter Na and Cl target values in the same way. When all target values entered, press “Cal” , the screen displays:

Aspirate

Exit

Present the control under sample probe, press “Aspirate” , the instrument aspirates the control and tests it, after a few moments, the screen displays:

K

5.10

Cal.

Na

145.8

Cl

105.8

Exit

The values displays on the screen are calibrated values (calibrated value = actual measuring value * current factor). If necessary, press “Cal” to calibrate and obtain new factors, otherwise press “Exit” to quit.

After the calibration, the screen displays the new factors:

K	0.980	Cal.
Na	0.994	
Cl	0.992	Exit

And the new factors will also be printed out.

5.5 W. List

To input the work list, press “W. List” , the screen displays:

Sample Number		
Num	001	Num▲
ID00000000000000000000		Num▼
Exit		

The operator can press “Num▲” or “Num▼” to increase or decrease the sample number. The operator can also change the number by pressing the button after Num, if so, the screen displays:

Num:_____		
1	2	3
4	5	6
7	8	9
./-	0	Cls
Yes		Exit

Enter the sample number and press “Yes” to save.
If the operator wants to change the patient ID number by barcode reader, then just scan the barcode on the sample tube one by one. After being scanned, the ID will be displayed after “ID” , and the Num will be increased automatically.

If the operator wants to change the patient ID number manually, and then press the button Get ID, the screen displays:

ID:_____		
1	2	3
4	5	6
7	8	9
./-	0	Cls
Yes		Exit

Enter the ID number and press “Yes” to save.

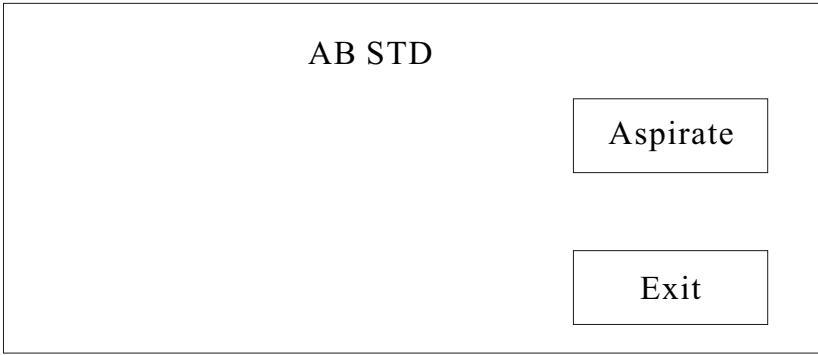
5.6 Measure STD

This program is to calibrate the slope of the electrode. The procedure is same as that of “section 4.2 Startup and self-test” .
Press “STD” the screen displays:

Sel. ISE
Sel. AB
Exit

Press “Sel.ISE” to calibrate the slope of K/Na/Cl/Ca electrode. The calibration procedure is same as that of “section 4.2 Startup and self-test” .

To calibrate the pressure sensor, press “Sel. AB” , the screen displays:



Present Standard AB under sample probe and press “Aspirate” to start the calibration. The procedure is similar as that of ISE calibration.
For auto sampler models, the operator should place Standard AB on position “QC1” of the sample tray.

After the calibration, if the result is good and stable, it will be printed out as following:
SLOPE:
AB 8.6 (5-30)

If the result is not stable, it will print out:
Error 7#
SLOPE:
AB 8.6 X

If the result is abnormal but stable, it will print out:
Error 6#
SLOPE:
AB 5.6 X

If the result is abnormal and not stable, it will print out:
Error 6#
Error 7#
SLOPE:
AB 5.6 X

-
- 1.After taking out the reagents from the refrigerator, and wait for a moment until they warm up to the room temperature. This is to prevent the possible damage of the electrodes.

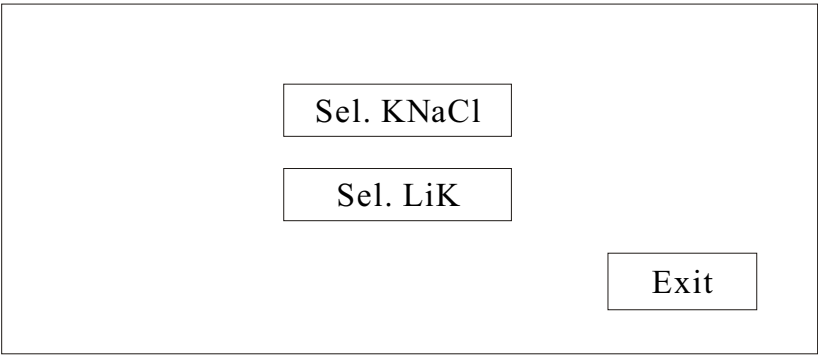
2.Rock the reagents properly before test, for best calibration result.

3.Screw up cap; keep solution away from air contact.

4.For AB and TCO₂ test: Blood must be completely sealed from air, during sample taking, centrifuging and transporting process.

XI-921ET model

Screen display:



Press Sel. KNaCl , to calibrate the slope of K/Na/Cl electrode. Printing format shows as self-test. Press Sel. LiK sample probe lift up, aspirate CSTD, up to 3 times, and then show as: LiK 0.008 , normal range of LiK: 0-0.028, the smaller slope the better.

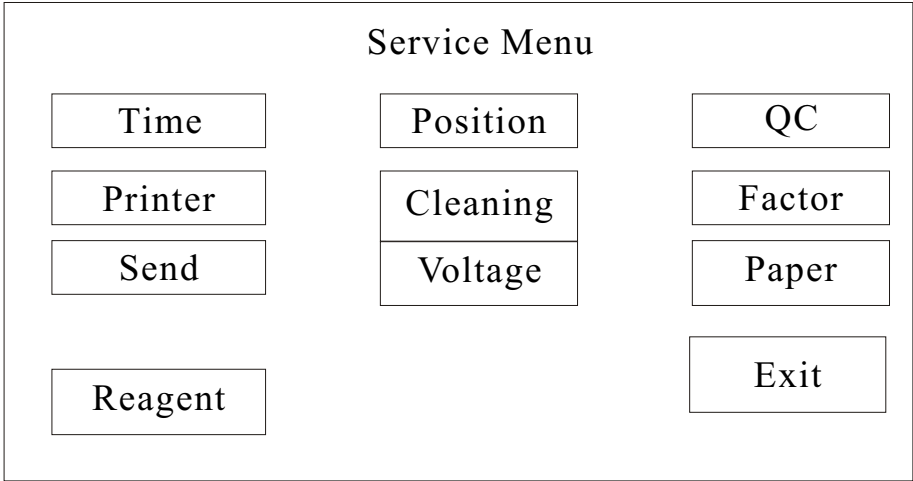
-
- ① LiK normally are stable, one calibration a day is enough.

② If variety of two LiK slope more than 0.002, recalibrate it.

③ Stop Li calibration, when Na electrode was failed.

5.7 Service

The instrument has comprehensive service programs.Press “Service” in the main menu, the screen displays:



5.7.1 Change time

Press “Time” the screen displays:

Year_____

1

2

3

4

5

6

7

8

9

./-

0

Cls

Yes

Exit

Enter the value of “Year” , press “Yes” to save. Set the month, date and time in the same way.

5.7.2 Position

This program is to setup the correct aspiration volume. Press “Position” , the instrument aspirates the liquid, the screen displays:

Position

Please position

Repeat

▲

▼

Exit

The operator should check if the liquid reaches the correct position: the liquid surface should be about 2cm away from the inlet of the electrode assembly. Press “▲” to increase the aspirating volume if the liquid does not reach that position, press “▼” to decrease the aspirating volume if the liquid exceeds the position.

It is suggested to run this position program after any services performed. The above operation can be skipped if the instrument has a positioner (fluid position sensor) installed. However, if the positioner is defective, the instrument will use the parameter that obtained from the above operations. For this reason, it is always suggested to run this program when installing a new instrument.

5.7.3 Quality Control

To run QC program, press “QC” , the screen displays:

Q C

Aspirate

Stat.

Lot No.

Exit

To enter a new Lot number, press “Lot No.” , the screen displays:

Lot No._____

1

2

3

4

5

6

7

8

9

./-

0

Cls

Yes

Exit

Enter the new lot number (8 digitals, such as 20050330); press “Yes” to save.

Note: All QC data stored in the instrument will be deleted automatically when a lot number entered!

Present control under sample probe, press “Aspirate” , the control will be aspirated into the system for measuring. (For auto sampler models, the control should be

placed to “QC1” position of the sample tray.) The result will be displayed and printed out within 60 seconds. When there exist 5 QC results or more (up to 220), a statistical report can be obtained. Press “Stat” , the screen displays:

By Day

By Month

Press “By Day” then the screen will show a statistical report including mean value (Mean), standard deviation (SD), coefficient variation (CV %).

	Mean	SD	CV
K	5.01	0.03	0.60
Na	145.2	0.51	0.41
Cl	105.5	0.35	0.30
Ca	1.31	0.03	0.29
Exit			

The report will also be printed out as below:
STATISTIC REPORT

TIME: 2005-03-30 10:00			STATISTIC REPORT			
QC			TIME: 2005-03-30 10:00			
Lot ID:00000000000000000000			Lot ID: 00000000000000000000			
K	5.09	mmol/L	Item	Mean	SD	CV(%)
Na	145.5	mmol/L	K	5.01	0.03	0.60
Cl	105.3	mmol/L	Na	145.2	0.51	0.41
Ca	1.31	mmol/L	Cl	105.5	0.35	0.30
AB	0.1	mmol/L	Ca	1.31	0.03	0.29
			AB	0.09	0.01	10.31
			N=10			

If press “By Month” it will print out a statistical report for all the last QC results of each day.

5.7.4 Printer

Press “Printer” , the screen displays:

Print ON

Print OFF

Press “Print ON” to enable the printer;press “Print OFF” to disable the printer.

5.7.5 Clean the electrode

Press “Cleaning” , the screen displays:

Cleaning

Deprotein.

Na Adjust

Exit

For auto sampler models, the operator should place the cleaning solution to the “Calib” position of the sample tray.

Press “Deprotein” Aspirate shows on the screen. Present the cleaning solution under sample probe. Press “Aspirate” to aspirate the cleaning solution into the instrument.After aspiration, Aspirate disappears and the percentage of the progress appears on the screen:

If any special reasons to suspend the program, press "Exit" directly to exit the program.

Cleaning

015%

Deprotein

Na Adjust

Exit

The whole process will take about 5 minutes.
Press “Na Adjust” , the screen displays Aspirate. Present the Na conditioner under sample probe. Press “Aspirate” to aspirate the Na conditioner into the instrument. After aspiration, Aspirate disappears and the percentage of the progress appears on the screen.
It takes about 1 minute to finish the “Na Adjust” program.

Note:
If Na slope more than 45, ignore “Na adjust” program

Factor
To change the calibration factors manually, press “Factor” , the screen displays:

Exit

a

b

K:

x1.000 +0.000

Na:

x1.000 +0.000

Cl:

x1.000 +0.000

Ca:

x1.000 +0.000

Note: a-slope, b-intercept

Select the item to be changed, for example K, then the screen displays:

K: a

1

2

3

4

5

6

7

8

9

./-

0

Cls

Yes

Exit

Enter the new slope value (a) and press “Yes” to save, then the screen displays:

K: b

1

2

3

4

5

6

7

8

9

./-

0

Cls

Yes

Exit

Enter the new intercept value (b). Press “Yes” to save.

5.7.6 Data transfer

Press “Send” the patient results will be transferred to the host computer.

5.7.7 Voltage

Press “Voltage” to check the potential of each electrode:

Voltage

Aspirate

Exit

Press “Aspirate” to aspirate a sample and check the voltages. For auto sampler models, the operator should place the sample to the “Calib” position of the sample tray.

The screen displays the voltages (in mV) every two seconds:

Voltage

K: 57.03

Na: 73.25

Cl: 61.30

Ca: 25.12

pH: 140.9

Phot.: 1510

Exit

Press “Exit” to quit.
The operator can check the performance of the electrodes by this program. For standard A or control, the normal values of K, Na and Cl should be about 50. If the values of K, Na and Cl are all smaller than 20, then most likely the reference filling solution or the reference membrane is getting aged and should be replaced.

5.7.8 Feed paper

Press “Paper” to feed the printing paper.

5.7.9 Reagent

To check the residual volume of the reagents, press “Reagent” , the screen displays:

Std A: 650 ml

Std B: 280 ml

Refill

Exit

The residual volume of the reagents will show on the screen. When replace a new reagent pack, the operator should press “Refill” to reset the values.

Note:

1. When icon  appears on the main menu screen, it indicates the remaining reagents can run about 150 samples.

2. When icon  appears on the main menu screen, it indicates the remaining reagents can run about 20 samples only.

3. When icon  appears on the main menu screen, it indicates the reagents are run out.

5.8 Result review

The instrument only stores one-day patient results for review.
Press “Results” the screen displays:

Results ID

000000000

000000000

K: 5.03

Na: 145.5

Cl: 105.2

Ca: 1.30

pH 7.56

Num001

▲

▼

Print

All

Exit

To review the result by sample number, press “Num 001” the screen displays:

Num_____

1

2

3

4

5

6

7

8

9

./-

0

Cls

Yes

Exit

Input the sample number, press “Yes” then the corresponding result will be displayed on the screen. The operator can also press “▲” or “▼” to change the sample number.

Press “Print” to print out the sample result.

Press “All” to print out all sample results. If there is no data stored, the screen will display “No data” .

Note: to print out the results, the printer should be enabled first. Refer to section 4.6

The printing format is as following:

001 PAT ID: 000000000000000000
5.09 145.3 105.3 1.31 7.56 0.1

002 PAT ID: 0000000000000000001
5.09 145.3 105.3 1.31 7.56 0.1

003 PAT ID: 0000000000000000002
5.09 145.3 105.3 1.31 7.56 0.1

.....

Chapter 6 Precautions

6.1 Operation precautions

1. The analyzer is designed to work continuously for 24 hours a day. No need to shut down the machine everyday.
2. Do not use the standard solutions for flame luminosity. They include strong acid and other supplements that may damage the electrodes.
3. Not all commercial controls are suitable for ISE measurement. Some of them contain too much chemical additives that may interfere in the measurement.
4. The bubbles should be excluded during the sample aspiration; otherwise the results will be unreliable.
5. When the sample reaches the checking point, make sure there are no bubbles inside; otherwise the sample should be measured again.
6. If the ambient temperature fluctuates for more than 10degree, the instrument should be calibrated again.
7. The pH value of the standard solutions and the samples should be within 6-9, otherwise it will interfere in the measurement of sodium ions.
8. Discard the reagent if mildew or deposition found.
9. Perform the routine maintenance according to the instructions.
10. Test sample as soon as possible after collection, to minimize measuring deviation, especially pH.

6.2 Safety precautions

1. The electric voltage inside the instrument may be harmful to human body. Do not open the instrument before disconnect it from the power supply.
2. Because the samples may have pathogenesis bacterium or viruses, all replaced tubes, electrodes and waste containers should be discarded according to the safe laboratory procedures and government regulations.
3. The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
4. The reagents are harmful to human body. If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go to see a doctor.

If the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go to see a doctor.

6.3 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 sensor.

Chapter 7 Maintenance

7.1 Daily maintenance

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

7.2 Weekly maintenance

- 1. Check each electrode; see as if the internal filling solution is sufficient. Refill the filling solution if it is less than 2/3 of the total volume.
- 2. Check if there is salty crystal on the electrode, if so, clean it with wet tampon.
- 3. Check if the sample aspiration volume is correct (sample reaches the checking point), if necessary, adjust the pump according to section 4.7.2.
- 4. Run cleaning program in service menu once a week if more than 25 samples measured every day. If less than 20 samples measured every day, then the user just need to run the cleaning program every 2-3 weeks. Please refer to section 4.7.5.
- 5. Run “Na adjust” program if the slope of Na electrode is less than 45. Please refer to section 4.7.5.
- 6. Check the voltage of each electrode. If necessary, replace the reference filling solution or reference membrane. Please refer to section 4.7.8.

7.3 Spare parts replacement

Check the following parts periodically:

- 1. Pump tube
- 2. Aspirating tube
- 3. Connecting tubes
- 4. Valve
- 5. Internal electrodes

If necessary, replace the aged part.

7.4 Check the tubing system

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

- 1. Run the calibration program.
- 2. Check the flow inside the electrode assembly.
- 3. Check the flow inside the tubing system.
- 4. The normal condition is a long section of air followed by a long section of liquid.
- 5. If the tubing connection loose, then bubbles can be found near the connector. Connect the tubing again.

6. If somewhere between the electrodes leaks, then disassemble the electrodes and check the gasket.
7. If the tubes are being tightly connected, then check if there is any blockage.
8. Replace the pump tube if it is seriously distorted, otherwise the aspiration volume will not be sufficient.

7.5 Replace the electrode

1. Pull out all electrode wires from the plugs. Remove the tubes from the inlet and outlet of the electrode assembly.
2. Loose the fixing nuts of the electrode assembly.
3. Disassemble the whole electrode assembly.
4. Discard the electrode to be replaced.
5. Take a new electrode and add the filling solution.
6. Assemble the electrodes in correct order. Make sure that the rubber gaskets are in right position.
7. Tighten the fixing nuts of the electrode assembly.
8. Connect the tubing. Insert the electrode wires back to the plugs.
9. Calibrating the instrument.

7.6 Replace the reference membrane

1. Pull out all electrode wires from the plugs. Remove the tubes from the inlet and outlet of the electrode assembly.
2. Loose the fixing nuts of the electrode assembly.
3. Disassemble the whole electrode assembly.
4. Loose the screw cap, take out the internal electrode, remove the filling solution, O-ring and old reference membrane (see figure 7 and figure 8).
5. Soak the new reference membrane in distilled water, and then place it evenly on the internal interface and put on the O-ring.
6. Refill the reference filling solution and tighten the screw cap
7. Clean and dry the electrode.
8. Assemble the electrodes in correct order. Make sure that the rubber gaskets are in right position.
9. Connect the tubing. Insert the electrode wires back to the plugs.
10. Calibrating the instrument.

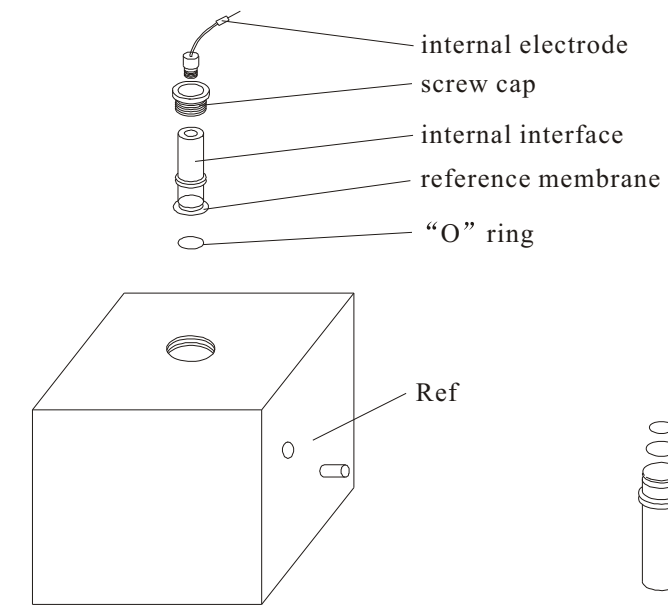


Figure 7

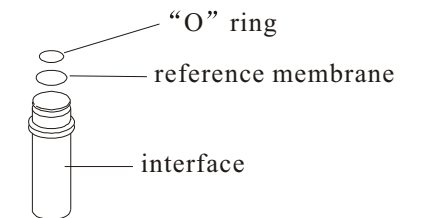


Figure 8

Chapter 8Error code

8.1Printed error code

Code	Description
Error 0#	Liquid positioning failed
Error 1#	Liquid detecting failed
Warn 2#	Bubbles detected
Error 3#	Too much or less sample aspirated
Error 4#	Slope abnormal
Error 5#	Slope unstable
Error 6#	AB Slope abnormal
Error 7#	AB Slope unstable

8.2Displayed error code

Code	Description
1#	Liquid distribution valve failed
2#	Elevator switch failed
3#	Optical coupler for the sample tray origin failed
4#	Optical coupler for the sample tray cup failed
AB pressure over limit	Pressure too high due to tubing blockage or sensor damaged

Chapter 9Troubleshooting

9.1Slope unstable

Cause	Recommended Solution
Unreliable grounding	Check the connection of the grounding wire
No standard A or standard B aspirated	Check and replace Standard A or B; Check the tubing connection
Incorrect positioning	Adjust positioning again
The reference filling solution or reference membrane not working	Replace when necessary
The internal electrode turns gray	Replace when necessary
Poor connection of the electrode wire	Check and connect again
Electrode membrane leaks	Replace when necessary
Power supply voltage fluctuates	Use UPS or power stabilizer
Humidity too high	Lower the humidity or move the instrument to a dry place
Bubbles inside the tubing	Check the tubing system
Liquid leakage inside the valve	Replace gasket or valve when necessary
The electrode is not activated or the activating time is insufficient	Activate the electrode first

9.2Slope abnormal

Cause	Recommended Solution
Too many organic deposits on the electrode membrane	Wash it with de-protein solution
Reagent contaminated	Replace the reagent
Insufficient filling solution	Refill the filling solution
Electrode does not work	Replace the failed electrode
Dust or moisture around the electrode or plug	Clean and dry the electrode and plug

9.3Aspiration abnormal

Cause	Recommended Solution
Aspirating tube loose or broken	Connect again or replace it
Pump tube sticks	Restore the tube
Pump tube broken	Replace the tube

Pump tube blocked	Clear the blockage
The gasket between the electrodes does not placed properly or missing	Place the gasket properly
The electrode assembly leaks	Tighten the assembly again
Dust on the localizer or localizer damaged	Clean or replace

Chapter 10 Specifications

Principle: Direct measurement by Ion Selective Electrode (ISE)

Sample: whole blood, serum, plasma, diluted urine
Sample Volume: 150 μl

	Measuring	RangePrecision (CV %)
K ⁺	0.50-15.00 mmol/L	≤1.0%
Na ⁺	30.0-200.0 mmol/L	≤1.0%
Cl ⁻	30.0-200.0 mmol/L	≤1.0%
Ca ²⁺	0.10-5.00 mmol/L	≤2.0%
Li ⁺	0.20-3.00 mmol/L	≤3.0%
pH	4.00-9.00 unit	≤1.0%

Throughput:	up to 60 samples /hour
Data Storage:	up to 200 patient results
Calibration:	Automatic or On-demand
Input:	Touch-screen, barcode reader
Display:	Large LCD with backlight
Output:	Internal thermal recorder, RS-232 serial port

Ambient Conditions:
Temperature: 15 - 32℃
Relative humidity: ≤85%, non-condensing environment

Input Voltage: AC 220V / 110V ± 10%, 50/60Hz
Power consumption: 60W

Dimensions: 360mm*270mm * 500mm (H*W*D)
Weight: Main unit -- 10kg
Auto Sampler (option) -- 1.5kg