



Electrolyte Analyzer

Operating/Technical Manual



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Chapter 1 Safety

1.1 Safety Information

This chapter lists all warnings, Attentions, and basic safety information when using Electrolyte Analyzer. Similar or related and other safety information can be found in appropriate chapters.

Danger

- Indicates immediate danger. If not dealt with, it can cause death, serious injuries, or property damage.

Warning

- Indicates potential danger or unsafe operation. If not dealt with, it can cause death, serious injuries, or property damage.

Caution

- Indicates potential danger or unsafe operation. If not avoidance, it can cause personal injuries, product malfunction,, damage, or property damage.

Attention

- Emphasis on Attention with explanation on how to better use the product.

1.1.1 Danger

There is no safety information on levels of danger.

1.1.2 Warning

Warning

- Only professional doctors and nurses can use this analyzer for clinical under certain conditions.
- Before using this analyzer, users must check the device and its accessories to ensure its proper function and safety.
- Reagent should be disposed according to the regulations of the hospital.
- Do not use this analyzer in an environment where flammable substances are present to prevent fire and explosion.
- Do not open the analyzer case. Otherwise it may cause electric shock. Any services, upgrades should be conducted by authorized personnel.
- The packaging material should be disposed according to local regulations and should be kept in a place where no children can reach.
- Connect this analyzer only to a power outlet with protective grounding. Do not use any power outlets without grounding.



1.1.3 Caution



-
- The waste container holds human body fluids which may be potentially infectious; handle with appropriate care to avoid skin contact or ingestion.
 - Dispose the analyzer according to local regulations when their valid time period is expiring. If there is any doubt, contact manufacturer.
 - Magnetic fields can affect the performance of the analyzer. Any equipment in use near the analyzer must be in compliance with EMC Standards. Cell phones, X-ray, or MRI devices are possible interference sources, as they emit high electro-magnetism radiation.
 - Before connecting the analyzer to power, make sure the voltage and frequency are in accordance with the requirements on the label or in the manual.
 - Install and transport the analyzer properly to prevent any damages by dropping, impact, shakes, or other mechanical forces.

1.1.4 Attention



-
- Place this manual next to the monitor for convenience when needed.
 - Place the analyzer where easy observation, operation, and maintenance can be obtained.



Chapter 2 Overview

The purpose of this manual is to provide operating, maintenance, and repair information to users. This manual illustrates detailed performance indexes, routine installation, operation and maintenance procedures, and important safety information. To ensure safety standards and performance functions carefully read this manual prior to using the analyzer.

2.1 Brief introduction

Electrolyte Analyzer is based on advanced Ion-Selective Electrode (ISE) technology and sensor technology. With the advantages of easy operation and accurate measurement, it is a fast, accurate, convenient and practical clinical instrument.

The instrument is intended use in hospitals to measure K^+ 、 Na^+ 、 Cl^- 、 Ca^{2+} 、Li ions and TCO₂ as well as pH values, AG in samples of whole blood, serum, plasma, urine solution(diluted).

This product has multi-parameter functions which can be selected, combined and configured by the user according to his/her requirements. The instrument has 7 combination types:

Type A: K^+ Na^+ Cl^-
Type B: K^+ Na^+ Cl^- TCO₂
Type C: K^+ Na^+ Cl^- iCa nCa TCa pH
Type D: K^+ Na^+ Cl^- iCa nCa TCa pH TCO₂ AG
Type F: K^+ Na^+ Cl^- Li^+
Type H: K^+ Na^+ Cl^- iCa nCa TCa pH Li^+
Type I: K^+ Na^+ Cl^- iCa nCa TCa pH Li^+ TCO₂ AG

2.2 Electrode working principles

Ion selective electrode is a kind of electrochemical sensor (also called electrode), the activity changes of specific ion could be converted into the electrical potential changes of electrode, the relation accord with Nernst equation.

“Ion-selective electrode” means that each electrode is only sensitive to one type of ions. For example, the Na electrode is only sensitive to Na^+ , but not sensitive to other ions.

The key component of electrode is the ion-selective membrane. The two sides of membrane get contact with sample and internal solution respectively. The side touching with sample is responding to the ion concentrations change. The other side touch with internal filling solution, the conversion from ion conduction to electron conduction is carried out by Ag/AgCl inner electrode.

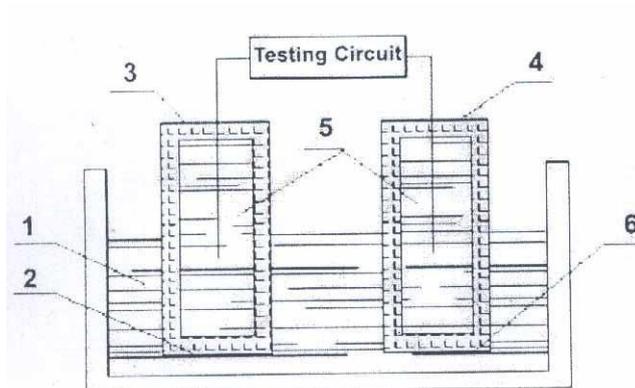
The reference electrode provides the reference potential to complete the measuring circuit. This electric potential does not change along with ion concentration, therefore providing a standard



reference for measuring potential difference.

2.3 Measuring principles

The instrument applies ISE to measure the ion concentrations in the sample. Refer to the following figure for the working principles of ISE.



1. Measured solution
2. Conjunction point
3. Reference electrode
4. Ion selective electrode
5. Internal filling solution
6. Ion selective membrane

ISE is sensitive to the ion activity in the sample. When the ion concentration in the sample is below 10^{-4}M and activity coefficient is close to 1, the difference between ion activity and concentration can be ignored (when concentration goes over 10^{-4}M , the activity coefficient decreases, and the difference increases.)

When ISE gets contact with the measured solution, the measured ion in the sample goes to ISE membrane due to the diffusion effects of the concentration difference, which creates a potential between measure electrode and reference electrode. The potential than an ideal ISE creates for the "X" ion can be described by the Nernst formula:

$$E = E_0 + \frac{2.3026RT}{ZF} \log_{10} a(x)$$

E_0 : Electrode standard potential

R: Gas constant

T: Absolute temperature

F: Faraday constant

Z: Ion valence

$a(x)$: Ion activity

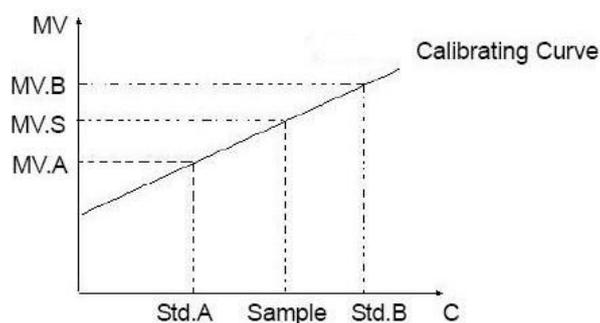
When the activity coefficient is 1 and temperature is 25°C (298°K), the electrode potential is



proportional to the logarithm of ion concentration “C”, which can be described as the following formula:

$$E = E_0 + \frac{59.12}{Z} \log_{10} C(x)$$

It is manifested that before applying ISE to perform the measurement, the values of potential (E_0) and slope ($59.12/Z$ is the theoretical value) must be determined first through the two-point calibration by using two Calibration Solutions. Moreover, the ion activities in the Calibration Solution and the testing sample must be kept close enough in order to ensure the accuracy of measurement. The following figure shows the measurement principle:



2.4 Warranty

The Analyzer is covered by a one year limited warranty from date of the purchase. The electrodes carry a one year limited warranty. Consumables are excluded from this warranty.

The following situations are not included in the warranty:

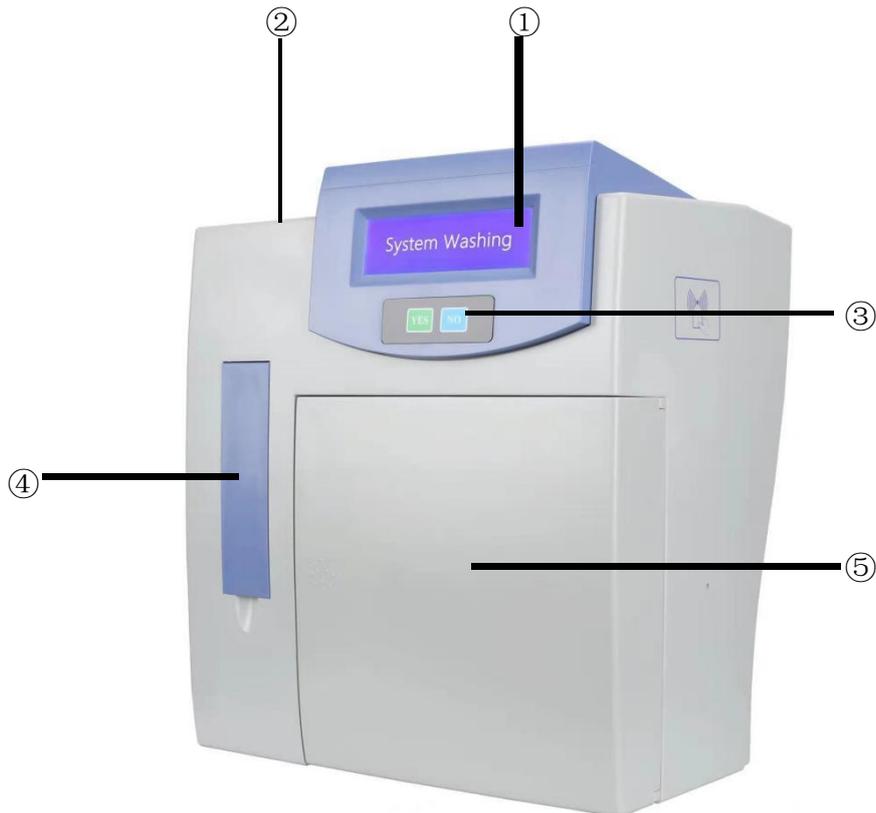
1. The serial number of the analyzer or electrode is missing or unreadable;
2. The analyzer or electrode is damaged due to improper connection with other equipment;
3. The analyzer or electrode is accidentally damaged;
4. The analyzer or electrode has been modified without written authorization from the manufacturer.



Chapter 3 Description of Analyzer

3.1 Description of external features

3.1.1 Front panel



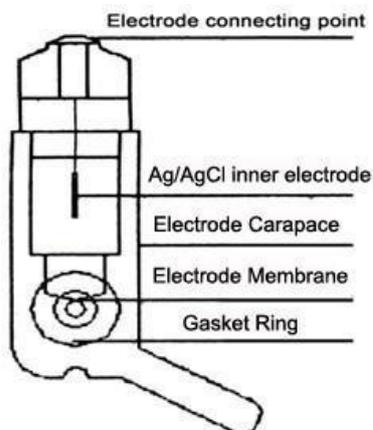
- ① Display: LCD screen to displays test results and prompts.
- ② Printer: built-in printer to print test results and other data.
- ③ Keyboard: YES、 NO keys for operation.
- ④ Sample door: Sample probe inside for aspirating liquid
- ⑤ Main door: Measuring system inside including electrodes, tubes etc.

3.1.2 Rear panel



- ① LIS interface: connect to the PC
- ② Power button: Start up or close the Analyzer.
- ③ AC socket

3.2 Description of electrode





3.3 Description of reagent

Calibration Solution A:	For calibration of sodium, potassium, chloride, ionized calcium and lithium in the electrolyte analyzer.
Calibration Solution B:	For calibration of sodium, potassium, chloride, ionized calcium and lithium in the electrolyte analyzer.
Reference Electrode Internal Solution:	A salt bridge for calibration and measurement in the electrolyte analyzer.
Electrode Internal Solution:	A bridge for measurement in the electrolyte analyzer.
Cleaning Solution:	For cleaning the analyzer measuring system before power off.
Activating Solution:	For activation of sodium, potassium, chloride, ionized calcium and lithium electrodes in the electrolyte analyzer.
QC Solution:	For correction of sodium, potassium, chloride, ionized calcium and lithium in the electrolyte analyzer.
Electrode Washing Solution: (Protein Enzyme and Diluent)	For deproteinization of sodium, potassium, chloride, ionized calcium and lithium in the electrolyte analyzer.
CO2 Acidic Washing Solution:	A reaction liquid for measurement of TCO2.
CO2 Calibration Solution 1:	For calibration of CO2 sensor in the electrolyte analyzer.
CO2 Calibration Solution 2:	For calibration of CO2 sensor in the electrolyte analyzer.

Attention:



The storage temperature is 10°C-30°C. The reagents are allowed to be refrigerated, but must be recovered to room temperature before using. Frozen is forbidden.



The reagents are used for in-vitro diagnostics ONLY.



A waste container is provided with the IMS-972 which, when used, holds human body fluids which may be potentially infectious; handle with appropriate care to avoid skin contact or ingestion.



Chapter 4 The equipment installation

4.1 Preparation work

4.1.1 Installation and operating environment

- Placement

The installation place should be suitable for the size of the analyzer.

Analyzer should be placed on a stable surface at an appropriate height for its use. Secure analyzer so it will not fall and cause injury.

There should be power with ground line within reach of the analyzer power cable.

Attention:



The instrument must have good grounding by special grounding cable.

- Operating conditions

Environment temperature: (10 ~ 30)°C

Relative humidity range: ≤ 70 %

Atmosphere pressure: (86 ~ 106) kPa

Power Voltage: AC 220V/110V±10%

Power Frequency: 50Hz/60Hz

- Influence on other equipment

If installed or used not according to the instruction of the manual, it may cause interference to nearby equipment. If unstable readings, interruption of operation without obvious reasons, or malfunction of the analyzer occur, it may be due to such interference. Keep the analyzer away from high efficiency equipments such as X-ray device to avoid interference.

4.1.2 Inspection

Open the package according to the marks on the box. Carefully remove the analyzer and its accessories.

- Count the accessories according to the packing list.
- Check the analyzer and accessories for any physical damage.

If there are any problems, contact the distributor immediately.

Friendly reminder: The packaging material should be saved for future transportation and storage.

4.1.3 Connecting AC power



- Confirm the AC power source conforms to the requirements of this equipment: AC 220V±22V, 50Hz±1Hz
- If the power voltage is unstable, UPS or high quality manostat is strong recommended.
- Connect the analyzer to AC power.
- Connections to external equipment should conform to the requirements specified in this manual.
- Electric balancing terminal should be connected to the grounding end of the public power grid or properly connected to the other protective grounding ends.

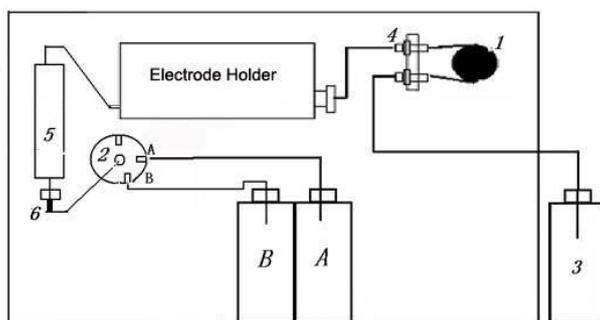
Attention:



The analyzer power cable must be connected to a suitable receptacle designated for hospital use.

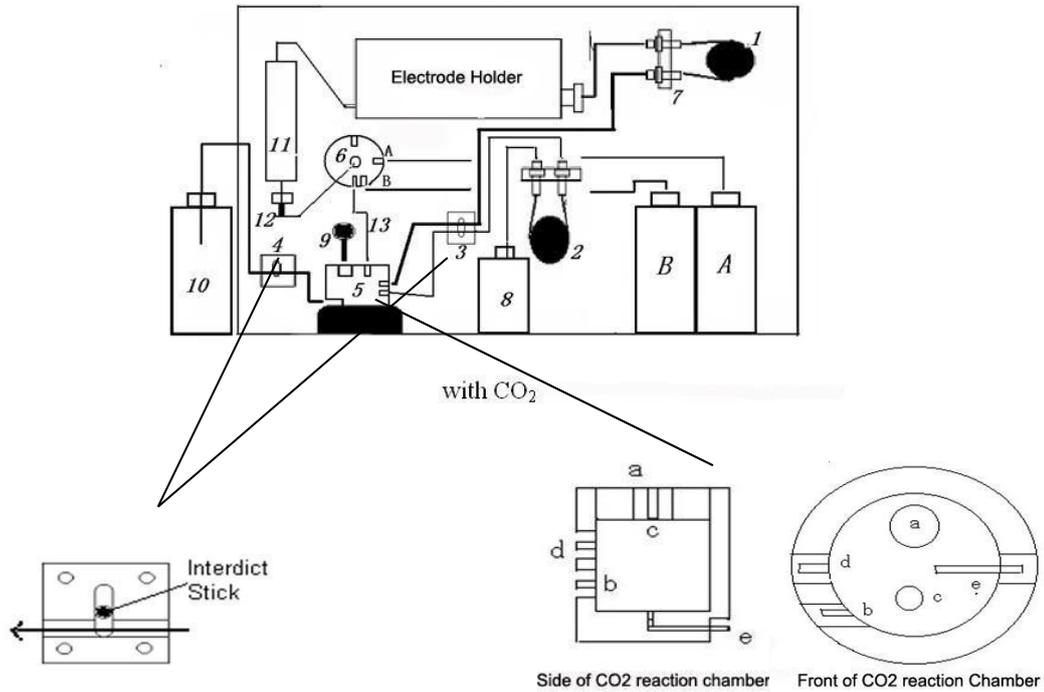
4.2 Reagent and tube installation

- (1) Fix the tubes according to the signs on the distribution valve. (The Standard A tube on the right of distribution valve, the Standard B tube on the below);
- (2) Clip the pump tube to the bracket. (The “up” side should be placed on the top of the bracket, otherwise the sample can’t be aspirated.)
- (3) Take Standard A, Standard B, and CO₂ reaction solution (if available), after changing to the special bottle caps with hole, put them inside the instrument. The order from left to right is: Calibration Solution A, Calibration Solution B, CO₂ reaction solution (optional).
- (4) Insert the tube signed “A” into Standard A, and the tube signed “B” into Standard B through the hole on the caps. Put the waste container on the right outside of the instrument, then insert the waste tube.



without CO₂

1. Sample pump head
2. Distribution valve
3. Waste container
4. Pump tube holder
5. Sample probe
6. Gasket ring



1. Sample pump head
2. CO₂ reaction solution pump head
3. Air orifice/sample interdict switch
4. Waste liquid interdict switch
5. Reaction chamber
6. Distribution valve
7. Pump tube holder
8. CO₂ reaction solution
9. CO₂ sensor
10. Waste container
11. Sample probe
12. Gasket ring
13. Vent-tube

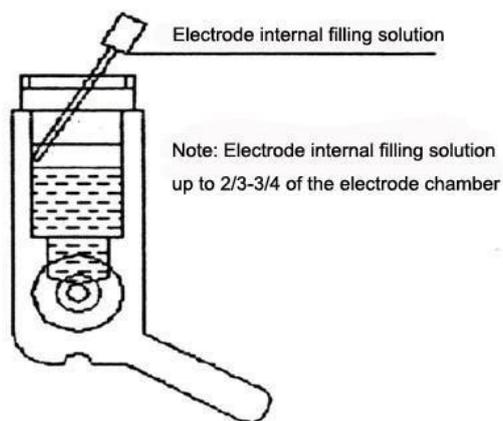
Attention:



Make sure the tubes are inserted into the correct reagent bottles according to the signs on distribution valve.

4.3 Electrodes installation

- (1) Rotate to open the head of electrode. Use clean syringe aspirate filling solution, then inject into electrode chamber. The filling solution should be up to 2/3-3/4 of the electrode chamber.



Attention:

- ⚠ The length of syringe probe should be 8-10mm. The probe should not enter the electrode for avoiding damage the electrode membrane.
- ⚠ The Ag/AgCl inner electrode must be immersed in reference filling solution always.
- ⚠ Add internal solution to reference electrode from the orifice on top right corner.

(2) Cover the head, then install the electrodes on the electrode base, beginning on the left and working to the left (the reference electrode will be installed last). The sequence of electrodes from left to right is as following:

Type A, B: K^+ Na^+ Cl^- Ref

Type C, D: K^+ Na^+ Ca^{2+} pH Cl^- Ref

Type F: K^+ Na^+ Cl^- Li^+ Ref

Type H, I: K^+ Na^+ Ca^{2+} Li^+ pH Cl^- Ref

Attention:

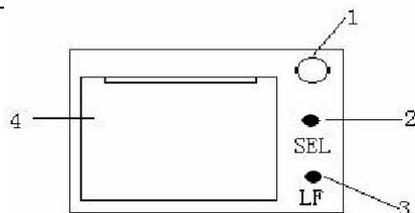
- ⚠ Flick the electrode bottom repeatedly. Make sure no air bubbles close to the electrode membrane.
- ⚠ Do not use expired, mildewed or corrupt reagent.
- ⚠ Immediately seal the reagent bottle after take out the requested reagent. Do not open the reagent bottle for long time.

(3) Finally, clockwise rotate the knob on the right of measuring chamber to fix the electrodes.

Attention:

- ⚠ Check electrode regularly to make sure the internal solution up to 2/3-3/4 of the electrode chamber and the Ag/AgCl inner electrode is immersed to internal solution always.
- ⚠ Keep the orifice on the top right corner of reference electrode be clean, avoid clog by crystallization salt.

4.4 Printer paper installation



1. Open/Close button
2. SEL button
3. LF button
4. Cover

- (1) Press the Open/Close button, then open the cover.
- (2) Place a new roll into the chamber and thread it into the feeder (make the thermal side face down), then close the cover.
- (3) Press the SEL button to make indicator off, press LF button until the paper completely through the feeder for 10 cm.

Attention:



DO NOT pull paper backwards.

4.5 Sample tray installation (Optional)

Place the sample tray gap under the sample probe, then place the socket at the bottom of sample tray to the BNC connector plugs on the turntable, push and fix it.

4.6 Sample collection and handling

Safety

Universal precautions must be observed when collecting blood specimens. It is recommend that all blood specimens be handled as potentially infectious specimens capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV), or other bloodborne pathogens. Proper blood collection technique must be followed in order to minimize risk to the laboratory staff. Gloves should always be worn when handling blood and other body fluids.

1. Whole blood samples

Whole blood samples should be analyzed as soon as possible within one hour after collecting the sample. If a brief storage is required, do not cool the sample as the erythrocytes could burst and release the intracellular potassium, creating an inaccurate value of potassium in the sample.

2. Plasma samples

Plasma can be stored longer than whole blood samples. If storage is required, plasma samples should be capped and placed in the refrigerator. Prior to analysis, always allow sample to warm to room temperature.

Attention:



For whole blood and plasma samples, the proper amount of anticoagulant must be used to prevent the sample from clotting. DO NOT use anticoagulants such as EDTA, citrate, oxalate, etc.



Lithium heparin may be used, if lithium is not installed.

3. Serum sample

Serum can be stored longer than whole blood, though preferably capped and placed in the refrigerator. Prior to analysis, always allow sample to warm to room temperature.

Attention:



For serum samples, DO NOT use any surfactant, anticoagulants, etc., otherwise will cause incorrect results, or even destroy the sensor.

4. Urine:

1. Dilute the urine sample as 1:9 with diluent prior to analysis.
2. Boracic acid is recommended as urine aseptic, other aseptic may affect the measurement.

Chapter 5 Operation

5.1 Turning on the unit

Turn on the power switch. The distribution valve starts running.

The instrument begins initialization. The microcomputer checks power, memorizer and printer, preheat the inner hardware circuitry until stable. Then, the pump begins to run.

During the pump running, if the system demonstration is as follows:

Detector Fail

The pump will run one more circle automatically. If the same prompt appears, the instrument will stop running. Please refer to Troubleshooting Sheet to resolve the problem.

5.2 System Flushing

After initialization completed, the screen displays:

System Flushing

The instrument automatically aspirate Calibration Solution B and A to clean the liquid flow path. Operator can observe the liquid flow to check if any tube blockage or air leakage.

5.3 Activation

After system flushing completed, the system demonstration to be as follows:

Activating

Press "NO" to next step. Press "YES" to start activating. The instrument provides two patterns as follows:

5.3.1 Type without Sample tray

When the screen displays:

Introduce Activating Solution

Press YES to continue

Press NO to quit

Insert the sample probe to activating solution, then press "YES" to start aspirating. The system sounds "bee" to prompt the aspirating completed, meanwhile the screen displays:

Remove

Remove the activating solution and close the probe, the screen displays:

Activating

The instrument is performing activation automatically.

Attention:



Make sure the probe tip be immersed in solution always and no air aspirated during aspirating.

5.3.2 Type with Sample tray

After press “YES”, the instrument automatically aspirates Calibration Solution A to activate. The screen displays:

Activating

Attention:



The default activation time is 30 minutes. Press YES or NO to stop activating; system will go to next step.



For new electrode, or unused for long time (e.g. one week), or electrode not stable, operator must activate the instrument by activating solution or fresh serum for at least 2 hours. Method: Aspirate activating solution or fresh serum, turn off machine for 2 hours for activation.



Activation could make the electrodes stable and prolong the electrode life. The recommended activation time for daily use is 15 minutes.

5.4 Calibration and Self-checking

The instrument can obtain and store the electrodes slope data by calibration, also could evaluate the electrode stability by comparing electrodes' mv values during calibration.

5.4.1 Calibration

When performing calibration, the instrument automatically aspirates the Calibration Solution A & B to perform calibration. The screen displays:

	A	B	A	B
K	AA.A	BB.B	AA.A	BB.B
Na	AA.A	BB.B	AA.A	BB.B
Cl	AA.A	BB.B	AA.A	BB.B

AA.A and BB.B denote the electrodes' mv values after calibration.

Operator could compare the electrodes' mv values to evaluate the stability of electrodes.

Attention:



Calibrate the instrument after every 10-15 sample testing.



Calibrate the instrument before measuring if the instrument has not been used for long

time.



It's very important that the main door is closed during calibration, since it provides shielding from sources of electromagnetic interference.

5.4.2 Self-check

After calibration completed, the screen displays:

Please Wait

The instrument aspirates Calibration Solution A to perform self-checking automatically. The screen displays:

Self-checking

If passed self-check, the instrument will go to next step automatically. If fail, the instrument will automatically self-check again. If fail again, the system sounds "bee" for alarm, meanwhile the screen displays:

XX Electrode slop abnormal! Recalibrate?

Press "YES" to recalibrate automatically. If still electrode drifts, check the instrument and electrodes refer to Troubleshooting sheet.

Press "NO" to stop calibrating and go to next step.

5.4.3 CO₂ Calibration (Optional)

After self-checking completed, the instrument displays:

Calibrate TCO₂

Press "NO" to next step. Press "YES" to start calibrating, the screen displays:

Insert CO₂ Calibration Solution 1

Press YES to continue

Press NO to quit

Insert the sample probe to CO₂ solution 1, then press "YES" to start aspirating. The system sounds "bee" to prompt the aspirating completed, meanwhile the screen displays:

Remove

Remove the CO₂ solution 1 and close the probe. The system analyzes the aspirated solution automatically. About 30 seconds later, the instrument displays the ion concentrations as following:

Analyze Sample		
K	4.05	mmol/L
Na	140.2	mmol/L
Cl	100	mmol/L
CO ₂	100	mmol/L

Then the screen displays:

0.00

Then the screen displays:

Insert CO₂ Calibration Solution 2
Press YES to continue
Press NO to quit

The process is the same as calibration of CO₂ Calibration Solution 1.

Attention:



It's necessary to calibrate TCO₂ sensor before measuring CO₂.



Calibrate TCO₂ every 2-3 days according to sample quantity during CO₂ measurement.

5.5 Analyze Sample

After self-checking or CO₂ calibration completed, system will automatically perform flushing. When it finish, the screen displays:

Analyze Sample

Press "YES" to start analyzing, press "NO" to next step.

Attention:



The sample temperature should be 10°C~30°C.



5.5.1 Type without sample tray

(1) When press "YES" key, the pump start running. The screen displays:

Please Wait

When the screen displays:

Introduce Sample
Press YES to continue
Press NO to quit

Lift the sample door, insert sample probe to the sample, then press "YES" to start aspirating.

Attention:



Make sure the probe tip been immersed in solution always. Do not aspirate cruor or air during aspirating.

- (2) The system sounds “bee” to prompt the aspirating completed, meanwhile the screen displays:

Remove

Remove the sample and close the probe. The system analyzes the aspirated sample automatically. About 60 seconds later, the instrument displays the ion concentrations as following:

Analyze Sample		
K	4.05	mmol/L
Na	140.2	mmol/L
Cl	100	mmol/L

- (3) The instrument automatically washes the electrodes, meanwhile prints the measuring result as following:

Date	07-02-20		
Time	16:30:59		
PAT-ID	1		Normal(mM)
K	4.05	mmol/L	(3.5-----5.2)
Na	140.2	mmol/L	(136-----150)
Cl	100	mmol/L	(96-----109)

- (4) The screen displays “Sample Analyze” again. Press “YES” to test another sample. Press “NO” to return to main Menu.

5.5.2 Type with sample tray

Press “YES” key, the screen displays:

Sample Quantity

Input the sample quantity, then press “YES” for confirmation. The screen displays:

Start Position

Operator can select any position as the start position. After inputting the start position, place the samples in sample tray. Press “YES” to start sample analyzing automatically. Press “NO” to return to “Analyze sample” mode.

Attention:



The sample quantity and start position should be the figure between 1~30, and the sum must be less than 31. For example, if sample quantity is 20, the start position should be a number between 1~11.



When screen displays “analyze sample”, if don’t operate in certain period, the instrument go to standby mode automatically. The instrument calibrate automatically at regular intervals. If emergency analysis requested, press “YES” to calibrate automatically and then start sample analyzing.

5.6 Analyze QC

Press “NO” to service menu. Press “YES” key, the screen displays:

Introduce Sample
Press YES to continue
Press NO to quit

Lift the sample door, insert sample probe to the sample, then press “YES” to start aspirating.

Attention:



Make sure the probe tip been immersed in solution always. Do not aspirate cruor or air during aspirating.

(2) The system sounds “bee” to prompt the aspirating completed, meanwhile the screen displays:

Remove

Remove the sample and close the probe. The system analyzes the aspirated sample automatically. About 60 seconds later, the instrument displays the ion concentrations as following:

Analyze Sample		
K	4.05	mmol/L
Na	140.2	mmol/L
Cl	100	mmol/L

Chapter 6 Service program

6.1 Perform Daily Cleaning

Press "NO" to next step. Press "YES" to perform daily cleaning. After finished, the system returns to main menu.

6.2 Calibrate TCO₂ (Optional)

Press "NO" to next step. Press "YES" to calibrate CO₂, the process is the same as 5.4.3 CO₂ Calibration.

6.3 CO₂ Correction (Optional)

Press "NO" to next step. Press "YES", the screen displays:

Input CO₂ Correction Factor
1.00
Correct Y/N?

Press "YES" to move cursor, press "NO" to change the number. When input finished, press "YES" to save the correction factor, the system returns to main menu. Press "NO" to reset the correction factor.

6.4 Electrode Deproteinization

Electrode Deproteinization could thoroughly clean the instrument to avoid precipitating of protein, curor or salt in the tubes or electrodes.

6.4.1 Type without sample tray

(1) Press "NO" to next step. Press "YES", the screen displays:

Electrode Deproteinization
Press YES to continue
Press NO to quit

Lift the sample door, insert sample probe to the sample, then press "YES" to start aspirating.

Attention:



Make sure the probe tip been immersed in solution always. Do not aspirate cruor or air during aspirating.

(2) The system sounds "bee" to prompt the aspirating completed, meanwhile the screen displays:

Remove

Remove the sample and close the probe. The system performs Electrode Deproteinization, and the screen displays:

Electrode Deproteinization

- (3) Press “YES”, the system automatically performs SYSTEM FLUSHING to clean tubes and electrodes, and then perform activation for 2 hours to make the electrodes stable.

6.4.2 Type with sample tray

Put electrode wash solution (with enzyme and diluent) at sample tray position 1, put activating solution/QC solution/fresh blood at position 2. Press “YES” to start protein-removing and activation automatically. Activation for 2 hours is recommended. Press “YES” during activation, the system will stop activation and return to main menu.

Attention:



Do electrode deproteinization at least once a week. For the hospital with quantity samples, deproteinization every 2-3 days is recommended.



If need to measure sample after electrode deproteinization, it's necessary to activation for 2 hours and recalibrate before measurement.

6.5 Recalibration

Press “NO” to next step. Press “YES” to recalibrate, the process is the same as “5.4 Calibration and Self-checking”.

Attention:



If measuring intervals more than 3 minutes, or measured sample more than 15, recalibrate the instrument.

6.6 One-point Correction

Correction is intended for quality control. Before correction, Calibrate repeatedly until the electrode stable. Operator could use one-point correction or two-point correction as follows.

6.6.1 Type without sample tray

- (1) Press “NO” to next step. Press “YES”, the system automatically performs “SYSTEM FLUSHING”. When finished, the screen displays:

Please Input the QC 1 Default Value

K	000.00
Na	000.00
Cl	000.00

Input target value according to default value of QC solution 1. Press “YES” to move cursor, press “NO” to change number. When input completed, on screen button will display:

Correct Y/N?

Attention:



Don't change the default value of the ion which no need to be corrected. If the target value is 000.00, this ion won't be corrected (or remain the previous correction factor).

(2) Press “NO” to reset the target value. Press “YES” to save the data, and the screen displays:

**Insert QC solution 1
Press YES to continue
Press NO to quit**

Lift the sample door, insert sample probe to the sample, then press “YES” to start aspirating.

Attention:



Make sure the probe tip been immersed in solution always. Do not aspirate cuor or air during aspirating.

(3) The system sounds “bee” to prompt the aspirating completed, meanwhile the screen displays:

Remove

Remove the sample and close the probe. The system analyzes the aspirated solution automatically. About 60 seconds later, the instrument displays the ion concentrations as following:

Analyze Sample		
K	4.05	mmol/L
Na	140.2	mmol/L
Cl	100	mmol/L

Attention:



This measuring result won't be print out.

6.6.2 Type with sample tray

Put the QC solution 1 at position 35. Then operate same as above.

6.7 Two-point Correction

6.7.1 Type without sample tray

Press “NO” to next step. Press “YES” to perform two-point correction by using QC solution 1 and solution 2, the process is the same as one-point correction. The instrument automatically

calculate correction factor (slope and intercept) by two-point correction.

Attention:

 **The QC solution 2 should be made by the same manufacturer but in different batch, and the target value difference should be as big as possible.**

 **Do not use same QC solution to make two-point correction, otherwise the measuring results of all the samples will be the same and meaningless. In this case, clear the calibration factor.**

 **The bigger the target value difference is, the better correction result will be.**

6.7.2 Type with sample tray

Put the QC solution 1 and QC solution 2 in related position. Then operate same as above.

Attention:

 **Calibrate repeatedly until the electrode stable before correction.**

 **Use one-point correction if only slope requested, use two-point correction if both slope and intercept requested.**

 **Do not use the flame photometer Calibration Solution. The strong acid and other additive in it will make electrode poisoning.**

 **Do correction again if the temperature changes greater than 10°C.**

 **Check correction factor after complete correction.**

6.8 Set Date

Press "NO" to next step. Press "YES" to set data and time, the screen displays:

Please Input Data and Time

- ## - ## - # - ## - ## -

It means year、month、day、week、hour、minute、second. Press "YES" to move the cursor, press "NO" to change the number. When input finished, on the screen bottom will display:

Correct Y/N?

Press "NO" to reset. Press "YES" to save the date and time.

6.9 Display Slop

Press "NO" to next step. Press "YES" to display the slope as follows:

Display Slope	
K	XX.X
Na	XX.X
Cl	XX.X

A few seconds later, the system returns to main menu automatically.

Attention:



Slope is an important parameter to evaluate electrode status. Refer to Appendix A to find the normal slope range.

6.10 Review Result

Press "NO" to next step. Press "YES" to review the specified result, the screen displays:

Enter PAT-ID
001

Press "YES" to move cursor, press "NO" to change number. Input any number between 0~999, on the screen bottom will display:

Correct Y/N?

Press "NO" to reset the sample ID. Press "YES" to continue, the system demonstration to be as follows:

	Yes to Print or No to Quit		
K	X.XX		mmol/L
Na	XXX.X		mmol/L
Cl	XX.X		mmol/L

Press "YES" to print, press "NO" to return to main menu.

6.11 Check QC Correction Factor

Press "NO" to next step. Press "YES" to display the correction factor as below:

Correction Factor	
K	1.00
Na	1.00
Cl	1.00

A few seconds later, the system returns to main menu automatically.

6.12 Clear QC Correction Factor

Press "NO" to next step. Press "YES" to clear all the correction factors to be 1, then the system return to main menu.

6.13 Delete QC Data

Press "NO" to next step. Press "YES" to delete the QC data, then the system return to main menu.

6.14 Display QC Result

Press "NO" to next step. Press "YES" to display the QC result.

6.15 Change PAT ID

Press "NO" to next step. Press "YES", the screen displays:

Enter PAT-ID
001

Press "YES" to move cursor, press "NO" to change the number. Set the ID number of next sample, on the screen bottom will display:

Correct Y/N?

Press "NO" to reset the sample ID. Press "YES" to save the sample ID, and the system return to main menu.

6.16 Change Measure Parameter

Press "NO" to next step. Press "YES", the screen displays:

State	Change
K	ON
Na	ON
Cl	ON
pH	ON
CO2	ON

Press "YES" to move cursor, press "NO" to change the ON/OFF status. When finished, on the bottom right corner of screen displays:

YES/NO?

Press "NO" to reset. Press "YES" to save the status, and the system return to main menu.

6.17 Li Correction (Optional)

This is used to modify the selective coefficient of Li⁺ electrode. Input any number between 0.20-0.50, the larger number inputted, the lower measuring result will be. when displaying Li⁺ concentration in the sample without Li⁺, input the Li⁺ values larger (increase 0.05 each time), directly measure without calibration until the Li⁺ result is 0, QC solution's result is 0.8-1.1.

The procedure is used to modify interferences to Li⁺ from other ions, different from one-point calibration, when the Li⁺ electrode is not stable, it's better to use the QC solution or fresh serum to activate for one hour.

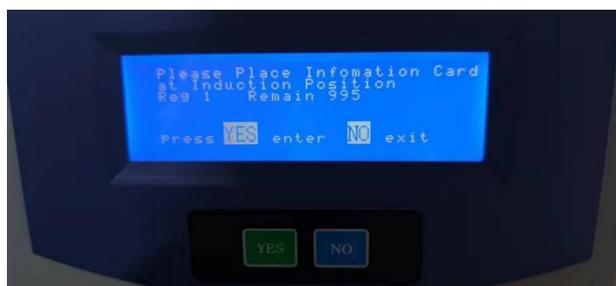
6.18 REPLACE REAGENT

This interface is set up for the user to identify the reagent information card easily. Select the interface and press “yes” to display it.



- | | |
|---------------------------|-----------------------------|
| 1. Replace Reagent | 2. Auto Locate |
| 3. User Setting | 4. Maintenance Check |

At this time, please put the information card into the designated area and press “yes” to complete the reading, as shown in the pictures below:



Chapter 7 Maintenance

7.1 Inspection

Before using the monitor, do the following inspection:

- Check any mechanical damage.
- Inspect thoroughly the wire, cables, and accessories.
- Inspect all the functions to be used on patients. Make sure the analyzer is in good working condition.

If any signs of damage found and evidenced, the analyzer should not be used for any measurement. Contact the service department or a local representative.

Inspect the analyzer's functions and safety every 6-12 months or after each service by authorized personnel.

All safety and maintenance inspection should be done by qualified maintenance personnel. Contact the service department or a local representative. information on local maintenance/service centers.

Warning:



If any inspection finds the equipment abnormal or its performance changed due to environment changes, replace related spare parts immediately. Any changes in performance will result in incorrectly measured data or system down.



If the hospital/institution does not implement a satisfactory maintenance plan, it will result in equipment malfunction.



When the equipment is dampened accidentally, do not turn it on. Ask qualified service personnel to open the monitor and let it air dry immediately.



Dispose spare parts (including batteries) in accordance with local government's regulations.

7.2 Daily maintenance

- (1) Before power off, the instrument must aspirate Cleaning Solution (C) to rinse the measuring system.
- (2) After power off, unload the pump tube to avoid tube sticking to the pump. No need to unload the pump tube if keep the instrument 24 hrs on.
- (3) Check the Calibration Solution A, B and CO2 reaction solution volume frequently.
- (4) Check the internal solution in each electrode.

- (5) Check tubes and liquid flow system to makes sure the liquid path unobstructed.
- (6) Clean the waste container every day.
- (7) Perform activation every day.

Attention:

Notice: Electrode serial number is the proof of warranty; please keep electrode and package well for maintenance guarantee.

7.3 Weekly maintenance

- (1) Check and clean CO2 reaction chamber.
- (2) Check the reference solution volume, make sure inner electrode is immersed into reference internal solution always. When necessary, add internal solution from orifice by syringe. Make sure the orifice is unobstructed.
- (3) Use electrode wash solution (with protein enzyme and diluent) to perform electrode deproteinization every week.

7.4 Maintenance of key components

- (1) Take out all tubes and immerse into distilled water for cleaning at least every 2 months.
- (2) Replace internal solution when it's turbid, replace electrode if necessary.
- (3) If electrode is polluted, use protein-removing solution to clean pollution adhered on electrode membrane. If polluted seriously, use a cotton thread to pull come-and-go through electrode orifice to clean the pollution (It is forbidden to poke electrode with hard things).
- (4) If tube or electrode clogs, lift down the tube, absorb distilled water with injector (remove the injector head and replace a soft tube) and cleanout it. Allow distilled water effuse from sample probe. It is forbidden to punch through the electrode membrane with injector head.
- (5) If disuse of the electrodes for a long time, clean residue in the electrode membrane tube with distilled water, airproof it for storage.

Chapter 8 Consumables and Purchase information

8.1 Electrode

Description	Unit
K Electrode	1
Na Electrode	1
Cl Electrode	1
Ca Electrode	1
pH Electrode	1
Li Electrode	1
Reference Electrode	1

8.2 Reagent

Description	Unit	Volume
Calibration Solution A	1 bottle	350ml
Calibration Solution B	1 bottle	350ml
Reference Electrode Internal Solution	2 bottles	10ml
Test Electrode Internal Solution	1 bottle	3ml
Cleaning Solution	1bottle	110ml
Activating Solution	1 bottle	110ml
QC Solution	1 bottle	110ml
Electrode Wash Solution	Protein Enzyme	5 bottles
	Diluent	5 bottles
CO2 Acidic Washing Solution	1 bottle	110ml
CO2 Calibration Solution 1	1 bottle	110ml
CO2 Calibration Solution 2	1 bottle	110ml

Attention:



Not all sold QC serums are suitable for ion-selective electrode measurement. Some QC serum will interfere the electrode because of additive.

Appendix A: Technical Specifications

B.1 Basic parameters

K Na Cl iCa nCa TCa PH Li Mg TCO₂ AG

B.2 Normal working environment

- Temperature Range: (10 ~ 30) °C;
- Relative Humidity: ≤ 70 %;
- Atmospheric pressure: (86~106) kPa;
- Power voltage AC: 100-240V
- Power frequency: 50Hz-60Hz

B.3 Measuring range and measuring precision

Items	Measuring Range	Resolution	Measuring Precision (CV%)
K	0.5-15.0 mmol/L	0.01 mmol/L	≤1.5%
Na	30.0-200.0 mmol/L	0.1 mmol/L	≤1.5%
Cl	20.0-200.0 mmol/L	0.1 mmol/L	≤1.5%
Ca	0.10-6.00 mmol/L	0.01 mmol/L	≤2.0%
Li	0.10-6.00 mmol/L	0.01 mmol/L	≤3.0%
Mg	0.10-6.00 mmol/L	0.01 mmol/L	≤3.0%
PH	4.00-9.00 mmol/L	0.1 mmol/L	≤2.0%
TCO ₂	5.0-70.0 mmol/L	0.1 mmol/L	≤3.5%

B.4 Clinical electrolyte range

Items	Serum	Urine
K	3.5-5.2 mmol/L	50-100 mmol/L
Na	136-145 mmol/L	130-217 mmol/L
Cl	96-106 mmol/L	170-250 mmol/L
Ca	1.09-1.35 mmol/L	
Mg	0.7-1.15 mmol/L	
TCO ₂	20-33 mmol/L	(Adult)

Items	Slope range
K	40-70 mv/10 times concentration
Na	40-70 mv/10 times concentration
Cl	40-70 mv/10 times concentration
Ca	20-40 mv/10 times concentration
Li	40-70 mv/10 times concentration
Mg	20-40 mv/10 times concentration
PH	40-70 mv/10 times concentration

B.6 Dimensions and weight

Model	Dimensions (mm)L*W*H	Net weight (kg)	Gross weight (kg)
/	380*270*400	8	10

B.8 Packaging

■ Packaging

Place the analyzer in a plastic bag. Place it in a corrugated carton filled with the buffer or other fillers. Seal the carton.

Appendix B: Ca and pH Instruction

The serum composition is very complex, the protein and Citrate in serum could combined with calcium ion becoming to complexation calcium which does not have physiological activity. The standard of calcium balance in human body is the ionized calcium but not total calcium. But due to limit of measuring method, the traditional method of titration method and colorimetric method are used to measure total calcium. After ion-selective electrode emerged, the ion-selective electrode technology could measure ionized calcium more conveniently and accurately.

The relationship between nCa, TCa and complexation calcium is as below:

$$\text{TCa} = \text{nCa} + \text{Complexation calcium}$$

(When pH = 7.40, TCa \approx 2·nCa)

The electrolyte Analyzer measure ion concentration by analyzing serume sample. After serume separated, due to centrifugal role and time extend, contact with ambient air will cause a loose of CO₂ in the sample and the subsequent rise in pH will cause a reduction in ionized calcium. In this case, the iCa value in measuring result is meaningless in clinic.

The pH value displayed on screen is on the high side because of CO₂ emission. Based on this actual pH value, the instrument works out the nCa value (equal to ionized calcium in human body) according to specific formula. The nCa value.is the main basis for clinical diagnosis.

During sample analyzing, the system displays only nCa on screen, but print out iCa, nCa and TCa in measuring result, therein nCa is used for clinic diagnosis, iCa and TCa only for reference.

The pH value in printed measuring result is the value has been corrected by the instrument, which is different from the pH value displayed on screen. Because CO₂ emission is irregular, the pH value is only for reference in serum analyzing, it mainly works to correct calcium ion.

If use aqueous QC solution or other samples (except serum) which has no CO₂ emission, the iCa and displayed pH value on screen should be the basis for clinical diagnosis.

Appendix C: Program Flow Chart

