

H900 Electrolyte Analyzer

Operating/Technical Manual

MR International Healthcare Technology Co.,Ltd.

Product information

Product model: H900
Product name: Electrolyte Analyzer

Version information

This version is subject to change or upgrade without notice.

Version: _____

Issue date: _____

Declaration

MR International Healthcare Technology Co.,Ltd. reserves the right to change the product described in this Operating Manual.

All information contained in this Operating Manual is subject to change without prior notice.

Manufacturer's Responsibility

Most Reliable is responsible for the safety, reliability and performance of the device under the following conditions:

- (1) Operating this device following this Manual.
- (2) Assembling, upgrading, resetting, and repairing are performed by Most Reliable's authorized personnel.
- (3) Product storing environment, operating environment, and electrical environment are as described in this manual.
- (4) Product serial number and labels are intact to verify the product identity as manufactured by MR International Healthcare Technology Co.,Ltd.
- (5) Damages not by miss-use or accidental dropping.

Free services apply to those products with applicable items within warranty period. For those beyond the description of warranty conditions, Most Reliable Medical will charge for service. Any returned goods to Most Reliable Medical for service, customers should pay for the transportation and any applicable customs fees.

Return Procedures

If return is necessary, take the following steps:

- 1、Obtain return merchandise authorization from Most Reliable Customer Service Department. Inform Most Reliable of the serial number and mark this serial number on the cartons. If the serial number can not be recognized, the return can not be accepted. Describe briefly reasons for return.
- 2、Freight Charge: customer is responsible for freight charges (including customs) for any returns.

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Chapter 1 Safety

1.1 Safety Information

This chapter lists all warnings, attentions and basic safety information when using H900 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



-
- Use of calibration solutions or electrodes not manufactured by Most Reliable could void the warranty.
 - 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

H900 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、Li、Mg 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 11 combination types:

Instrument Type	Parameters
Type A	K、Na、Cl
Type B	K、Na、Cl、TCO ₂
Type C	K、Na、Cl、iCa、nCa、TCa、PH
Type D	K、Na、Cl、iCa、nCa、TCa、PH、TCO ₂ 、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、TCO ₂ 、AG
Type J	K、Na、Cl、Mg
Type K	K、Na、Cl、iCa、nCa、TCa、PH、Mg
Type L	K、Na、Cl、iCa、nCa、TCa、PH、Mg、TCO ₂ 、AG
Type M	K、Na、Cl、iCa、nCa、TCa、PH、Li、Mg、TCO ₂ 、AG

2.2 Electrode working principle

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.

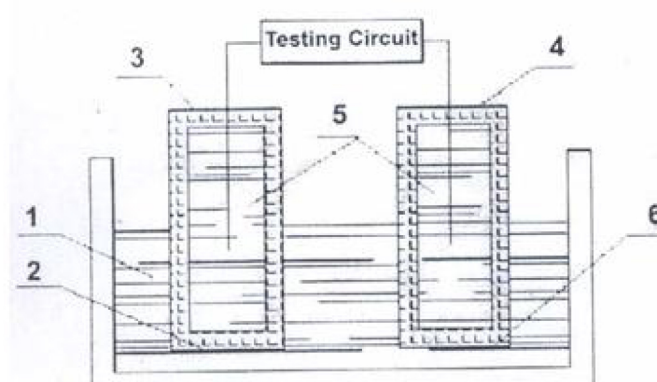
The key component of electrode is the ion-selective membrane. The two sides of membrane get contact with sample and internal Electrode Internal Solution respectively. The side touching with

sample is responding to the ion concentrations change. The other side touch with internal Electrode Internal 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 principle

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. Conjunctive point
3. Reference electrode
4. Ion selective electrode
5. Internal Electrode Internal 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

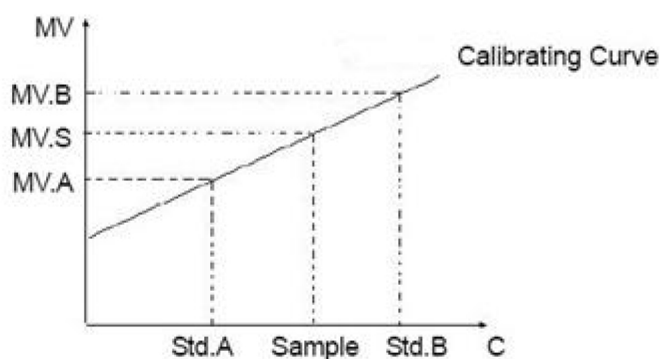
R: Gas constant

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 standard solutions. Moreover, the ion activities in the standard 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

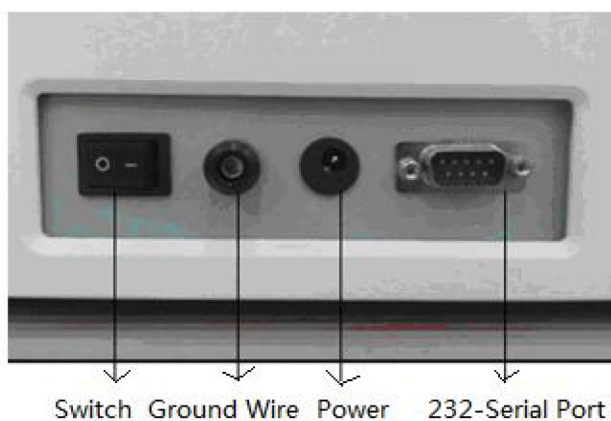
3.1 Description of external features

3.1.1 Front panel

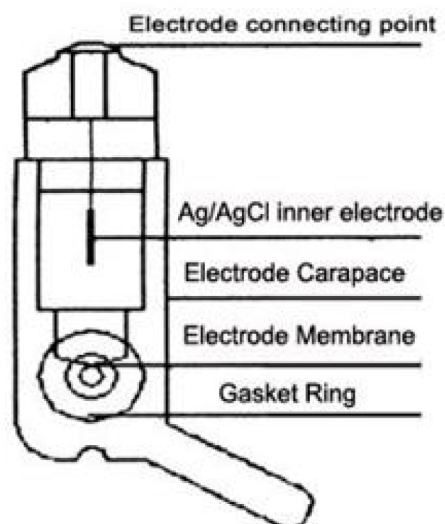


- ① Display: LCD screen to displays test results and prompts.
- ② Printer: built-in printer to print test results and other data.
- ③ Reagent pack
- ④ Main door: Measuring system inside including electrodes, tubes etc.
- ⑤ Sample door: Sample probe inside for aspirating liquid
- ⑥ Sample Tray

3.1.2 Rear Cover



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 (C)	For cleaning the analyzer measuring system before power off.
Activating Solution (D)	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 & 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 TCO ₂ .

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:

Use of calibration solutions or electrodes not manufactured by Most Reliable could void the warranty.



The storage temperature is 18°C-25°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 H900 which, when used, holds human body fluids which may be potentially infectious; handle with appropriate care to avoid skin contact or ingestion.

Chapter4 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, or 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: $\leq 70\%$

Atmosphere pressure: (86 ~ 106) kPa

Power Voltage: AC 100-240V

Power Frequency: 50Hz \pm 1Hz

- 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 100-240V, 50Hz \pm 1Hz
- If the power voltage is unstable, UPS or high quality Manos that is strong recommended.
- Connect the analyzer to AC power.

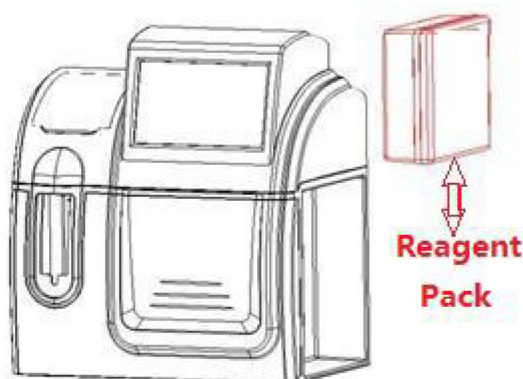
- Connections to external equipment should conform to the requirements specified in this manual.
- Electric balancing terminal should be connected to the grounding end of the public power grid or properly connected to the other protective grounding ends.

Attention:

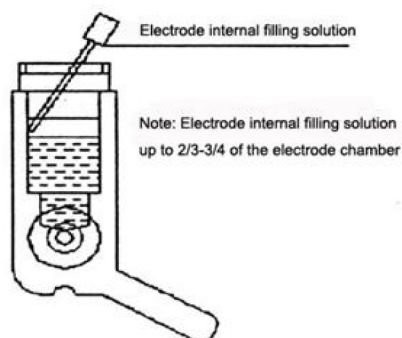
The analyzer power cable must be connected to a suitable receptacle designated for hospital use.

4.2 Reagents and tube installation

- (1) Fix the tubes according to the signs on the distribution valve. (The Calibration Solution A tube is on the below, the Calibration Solution B tube is on the right of distribution valve.)
- (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) Turn on the analyzer, enter “Maintenance” menu and choose “Replace Reagent Pack”, put the reagent pack at the slot, push and fix it.

**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 filling 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:

Instrument Type	Sequences of electrodes
Type A、B	K、Na、Cl、Ref
Type C、D	K、Na、Ca、PH、Cl、Ref
Type F	K、Na、Cl、Li、Ref
Type H、I	K、Na、Ca、Li、PH、Cl、Ref
Type J、K、L	K、Na、Ca、Mg、PH、Cl、Ref
Type M	K、Na、Ca、Mg、Li、PH、Cl、Ref

Attention:

Flick the electrode bottom repeatedly to make sure no air bubbles are close to the electrode membrane.



Do not use expired, mildewed or corrupt reagent.



Immediately seal the reagent pack before using. Do not open the reagent pack for long time.

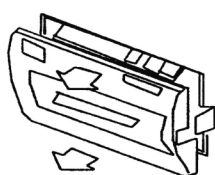
- (3) Finally, clockwise rotate the knob on the right of measuring chamber to fix the electrodes.

Attention:

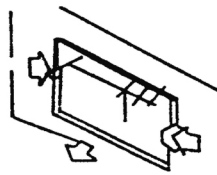
Check electrode regularly to make sure the internal filling solution up to 2/3-3/4 of the electrode chamber and the Ag/AgCl inner electrode is immersed to internal filling solution always.



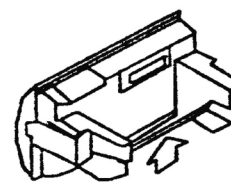
Keep the orifice on the top right corner of reference electrode be clean, avoid clog by crystallization salt.

4.4 Printer paper installation

1-1



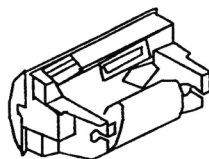
1-2



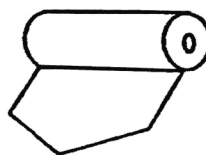
1-3

- 1) Lift down the front plate of printer according to chart 1-1

- 2) Turn off the instrument, and then lift down the printer from the instrument carefully according to chart 1-2.
- 3) Lift down the paper reel from printer according to chart 1-3.



1-4



1-5

- 4) Place a new paper to the paper reel, and fix the paper reel firmly according to chart 1-4 (make the thermal side inward).
- 5) Scissor the paper as chart 1-5 pattern.
- 6) Turn on the instrument, press the SEL button to turn off the indicator light, and then press the LF button to deliver paper. After the paper comes out with certain length, press the LF button or the SEL button. Turn off the instrument, cover the front plate of printer, and let paper pass through the paper exit.
- 7) Place the printer to the instrument.

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:

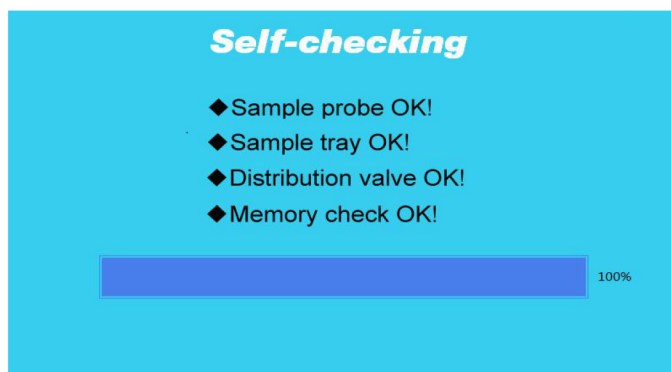
1. Dilute the urine sample as 1:9 with diluent prior to analysis.
2. Boracic acid is recommended as urine aseptic, other aseptic may affect the measurement.

Chapter 5 Operation

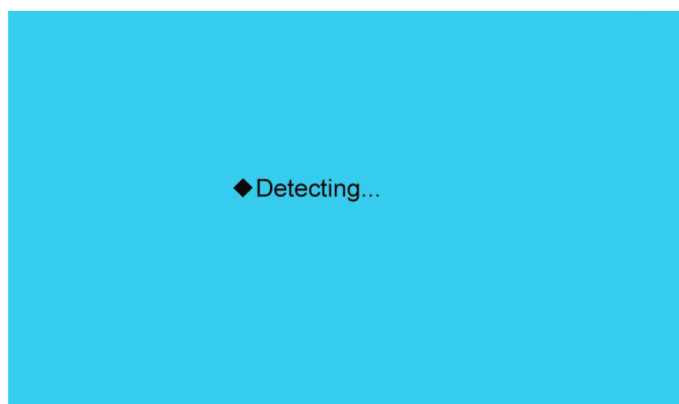
5.1 Turning on the unit

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

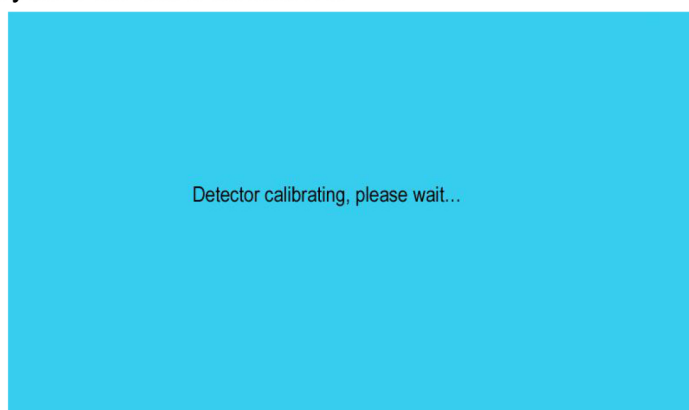
The instrument begins initialization.



The microcomputer checks power, memorizer and printer, preheat the inner hardware circuitry until stable. Then, the peristaltic pump begins to run. The system displays the checking result as follows:



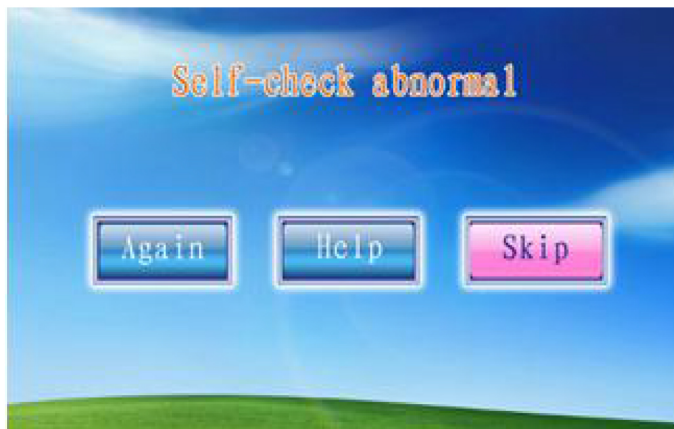
After detecting, the system will show as follows:



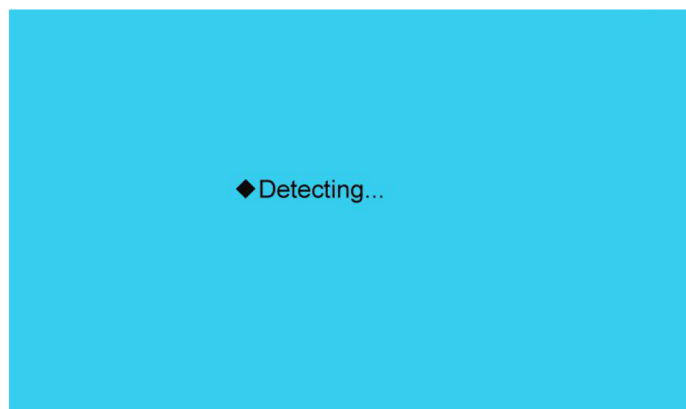
If "Detector Fail", the pump will run one more circle automatically. If the same prompt appears, the instrument will stop running. Please refer to Service Manual to resolve the problem.

If "Sample probe Fail", turn off the analyzer, then grab the sample probe (match with sample tray) lightly and slide it up to down.

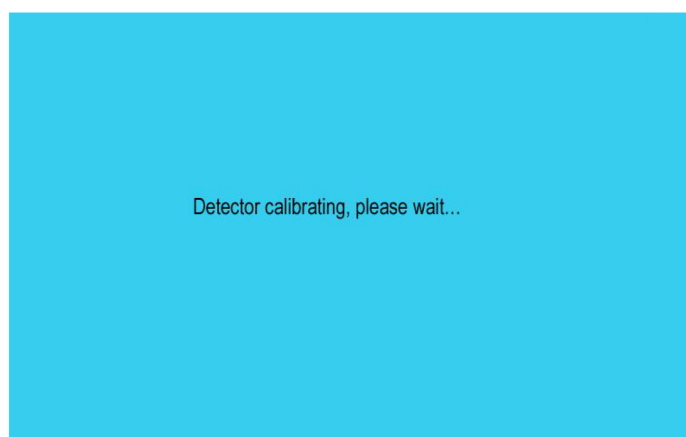
If “Sample tray Fail”, turn off the analyzer, and reinstall the sample tray.



Press “Again”, the system performs system checking again. If self-check pass or click “Skip”, the screen displays:



Next, the screen displays:

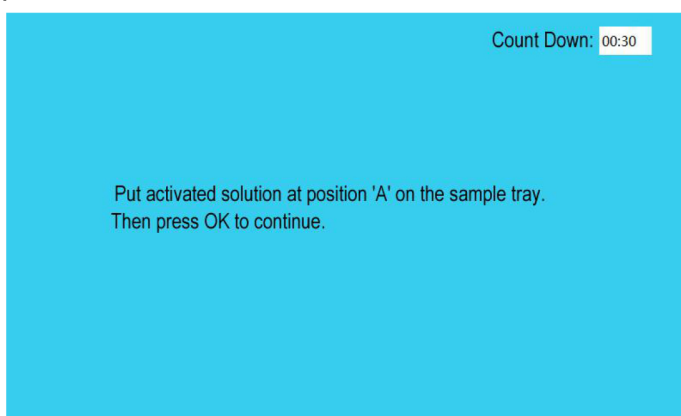


5.2 Activation

After liquid pipe checking finished, the screen displays:



Press “NO” or wait for 30 seconds, the system will go to next step. Press “YES” to start activating. The screen displays:



The instrument automatically detects the activated cup and aspirates solution to activate.

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 activation the instrument by QC serum or fresh serum for at least 2 hours. Method: Aspirate QC serum or fresh serum, turn off machine for 2 hours for activation.



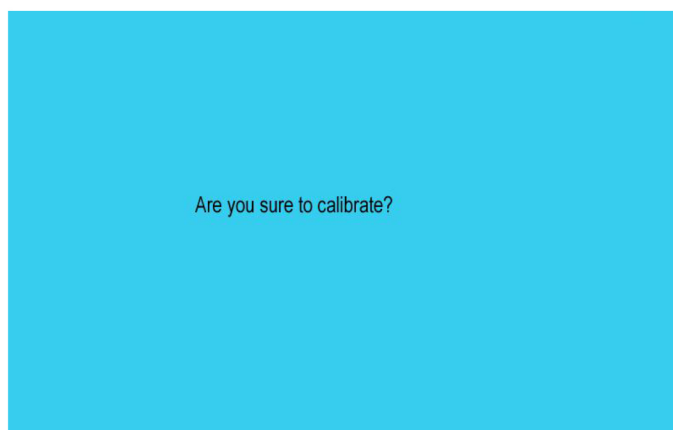
Activation could make the electrodes stable and prolong the electrode life. The recommended activation time for daily use is 15 minutes.

5.3 Calibration

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.

5.3.1 Calibration

After the activation, the system will show as follows:



When performing calibration, the instrument automatically aspirates the standard solution A & B to perform calibration. If you press “OK”, the screen displays:

	ISE Calibrating...						
	K	Na	Cl	Ca	PH	Li	Mg
A1:	AAA	AAA	AAA	AAA	AAA	AAA	AAA
B1:	BB.B	BB.B	BB.B	BB.B	BB.B	BB.B	BB.B
A2:	AAA	AAA	AAA	AAA	AAA	AAA	AAA
B2:	BB.B	BB.B	BB.B	BB.B	BB.B	BB.B	BB.B
S:	SS.S	SS.S	SS.S	SS.S	SS.S	SS.S	SS.S
X:	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

1.The old software version

	Calibración ISE OK						
	K	Na	Cl	Ca	pH	Li	Mg
A1:	55.1	74.6	91.4	81.3	107.0	—	75.4
B1:	72.2	68.4	99.7	71.4	73.2	—	65.5
A2:	55.1	74.7	91.5	81.2	106.8	—	75.3
B2:	72.2	68.4	99.7	71.3	73.0	—	65.3
S :	66.8	60.0	62.9	33.0	61.4	—	33.2

2.The new software version

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 10-30 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 eletromagnetic interference.



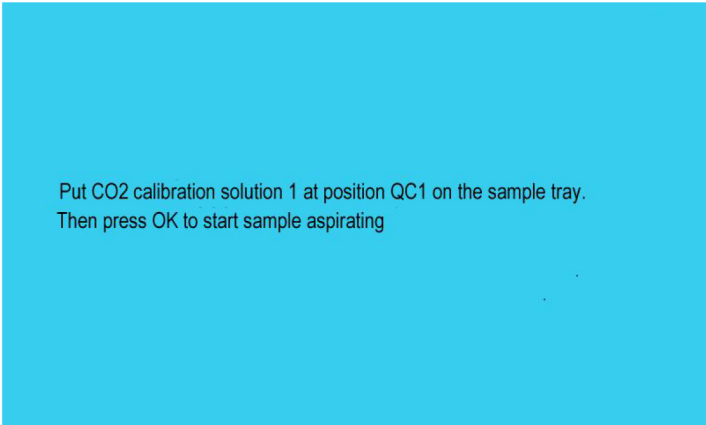
The S in picture 1 stand for slope, X in picture 1 is the concentration of calibration solution A. We removed the X in the new software version, because after a long inquiry we find that it will be better to evaluate the calibrate results only by the slope, so that is why we remove the X inside the

5.3.2 CO₂ Calibration

After ISE calibration completed, the system performs CO₂ calibration automatically depending your choice. If you press “ok”, the screen displays:



After the system finishes checking the pipeline, the screen will show:



Put CO2 calibration solution 1 at position QC1 on the sample tray.
Then press OK to start sample aspirating

Press OK, the screen displays:



Sample aspirating, please wait...

The instrument automatically aspirates reagents to perform CO₂ calibration.



CO2 calibrating...

When finished, the system goes to the Main Menu.



Chapter 6 Main Menu

The instrument including six menus: Calibration, QC analysis, Sample analysis, System setting, Maintenance, Other services. After calibration completed, the screen displays as below:



6.1 Calibration

Select "Calibration" and then the screen displays as below:



6.1.1 ISE Calibration

The process is same as ISE Calibration in 5.3.1.

6.1.2 CO₂ Calibration

The process is same as ISE Calibration in 5.3.2.

Attention:



It's necessary to calibrate CO₂ before measuring CO₂.



Calibrate CO₂ every 1-2 days according to sample quantity.

6.2 QC Analysis



6.2.1 Quality Test

Operate this menu when operator needs to do “QC Statistics”. The screen displays as below:

 The image shows the 'Quality test' input screen. It has a light blue background. The title 'Quality test' is at the top. Below it is a table for inputting data:

	Lot No.	K	Na	Cl	Ca	Li	Co2
QC1:							
QC2:							
QC3:							

 To the right of the table are three buttons: 'Start Test' (blue), 'Save Target' (blue), and 'Quit' (orange). At the bottom is a numeric keypad with buttons for digits 1-9, 0, a decimal point, and a back arrow. There are also 'NO' and 'YES' buttons.

Input target value of QC solution, then press “Start Test”. The screen displays:

 The image shows the 'Result of QC test' screen. It has a light blue background. The title 'Result of QC test' is at the top. Below it, the results are displayed:

QC: 1	Lot No.: 000001
K:	4.5 mmol/L
Na:	142.43 mmol/L
Cl:	96.3 mmol/L
Ca:	1.23 mmol/L

 Below the results is the text 'Save Data?' and two buttons: 'YES' (blue) and 'NO' (pink).

Compare the QC results with the target value inputted. If the results are ok, press YES to return to the previous menu.

6.2.2 Correction Factor

Input correction factor which the operator calculated when the screen displays:

	<i>Slope</i>	<i>Intercept</i>	<i>Coef</i>
K	1.00	+0.00	+0.00
Na	1.00	+0.0	+0.00
Cl	1.00	+0.0	+0.00
Ca	1.00	+0.00	+0.00
Li	1.00	+0.00	+0.00
Mg	1.00	+0.00	+0.00
pH	1.00	+0.00	+0.00
CO ₂	1.00	+0.00	+0.00

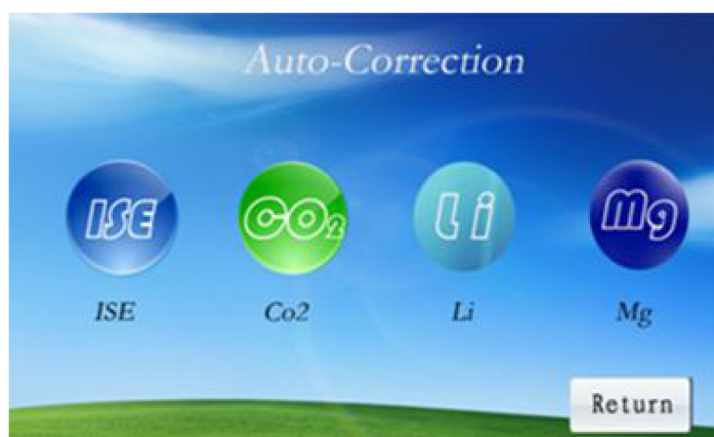
1 2 3 ±
4 5 6 .
7 8 9 0

OK Cancel

Press OK to save and return to previous menu.

6.2.3 Auto-correction

Select "Auto-correction", the screen displays as below:



6.2.3.1 ISE Correction

Click "ISE Correction", the screen displays as below:



Operate could choose “One-point Correction” or “Two-point Correction” according to need. Input target value of QC solution, then press “Start Test” to perform correction.

6.2.3.2 CO₂ Correction

Input CO₂ calibration 1 target value as 30, then press “Start Test” to perform correction.



6.2.4 QC Statistics

Users should perform “Quality Test” every day, after 5 days, the machine will calculate M、SD、CV value automatically. If stored results are less than 5, the machine can't display any value.

When the screen displays:



Click any one to review the corresponding QC statistics as below:

QC Statistics			
QC1	MEAN	SD	CV
K :	4.76	0.34	0.26
Na :	140.03	0.50	0.30
Cl :	97.06	0.68	0.39
Ca :	1.33	0.71	0.89
Li :	1.01	0.51	0.98

6.3 Sample Analysis

Select “Sample Analysis” in the main menu to enter sample test program. The screen displays as below

Sample Analysis

Cup Type: ☒ T&K ☐ OC ☐ BC ☐ BL

Input Tray No.: (1-201)

Cup Detection Method: ☐ Manual ☐ Automatic

6.3.1 Automatic

Click “Automatic” to test the whole Sample Tray. The screen displays as below:

If you choose “manual” mode, the screen displays as below:

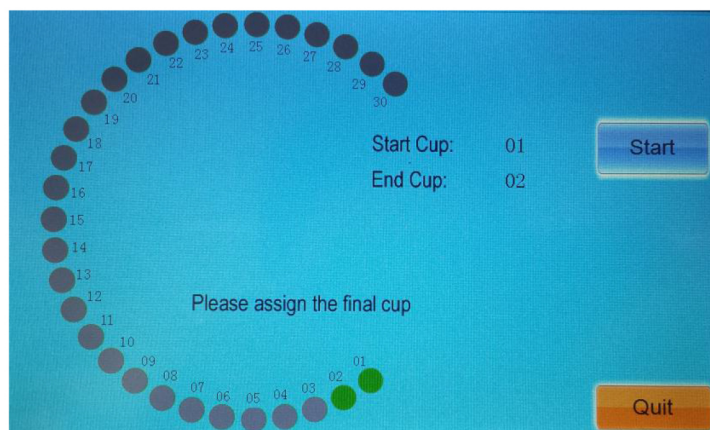
Sample Analysis

Cup Type: ☒ T&K ☐ OC ☐ BC ☐ BL

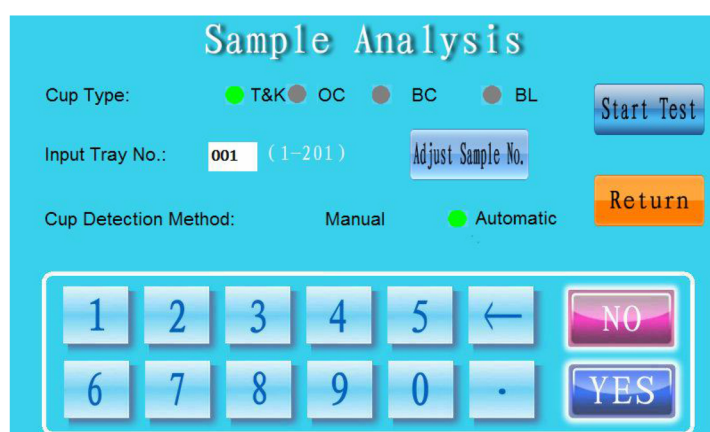
Input Tray No.: (1-201)

Cup Detection Method: ☒ Manual ☐ Automatic

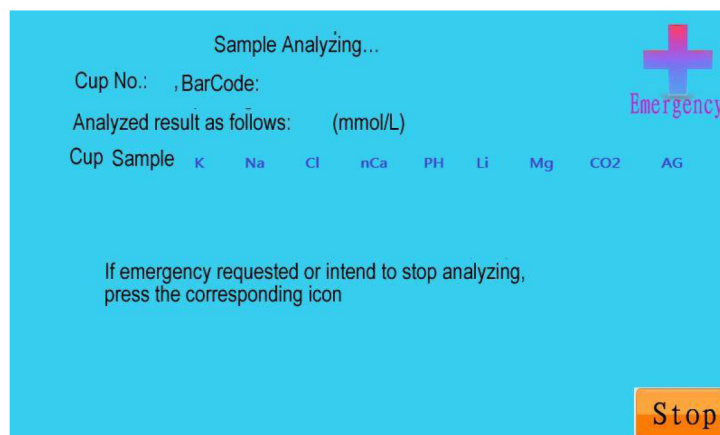
Assign the Sample cup NO. (No.1、2) and then press “Start Test”



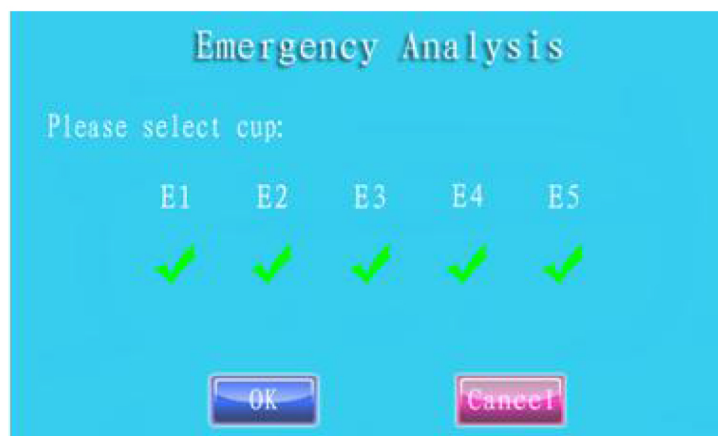
If you choose “automatic” mode, the screen will show as below:



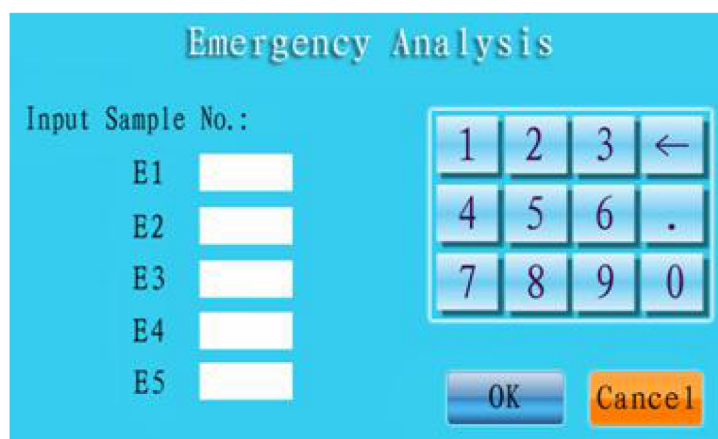
For each mode of testing, when testing finished, the instrument displays the test results as below:



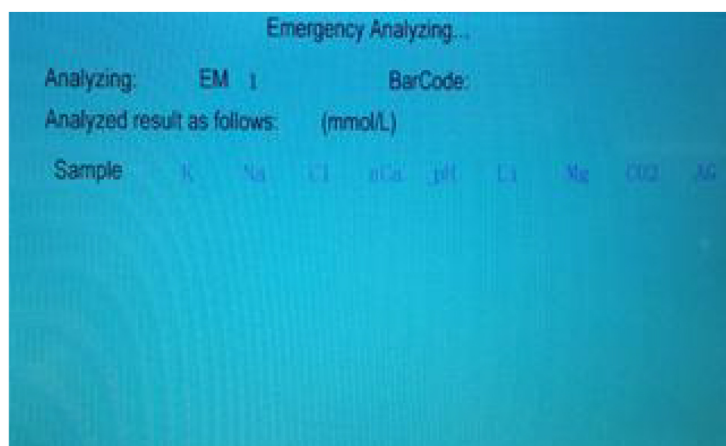
Press “Emergency” whenever emergency testing is requested, the instrument will perform emergency testing in next testing cycle. The screen displays:



Tick the cups which need be tested and then the screen will show as follows:.

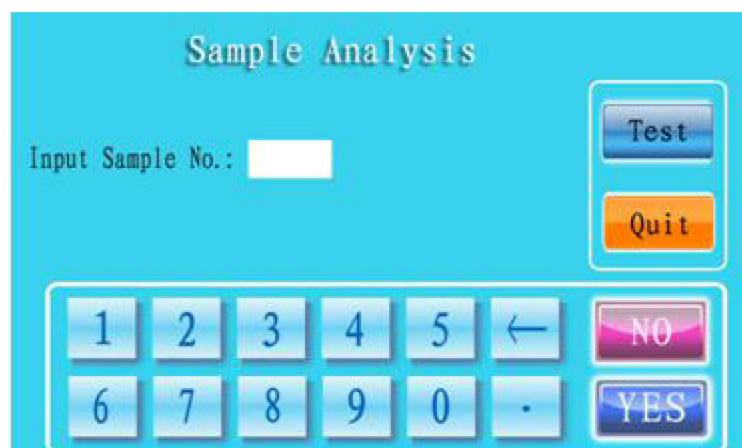


Input sample no., press OK and the screen displays:



6.3.2 Manual

Click "Manual" to test the specified sample in the Sample Tray. The screen displays as below:



Input sample no. and press "Test" to start testing.

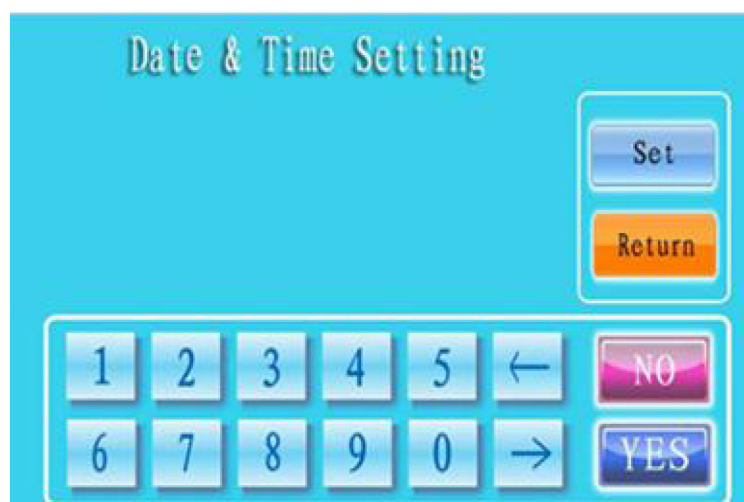
6.4 System Setting

Choose "System setting" in the main menu to set up date, time, parameter, printer, test speed or tracing frequency.



6.4.1 Date and Time

Input the date and time, then press "YES" to save.



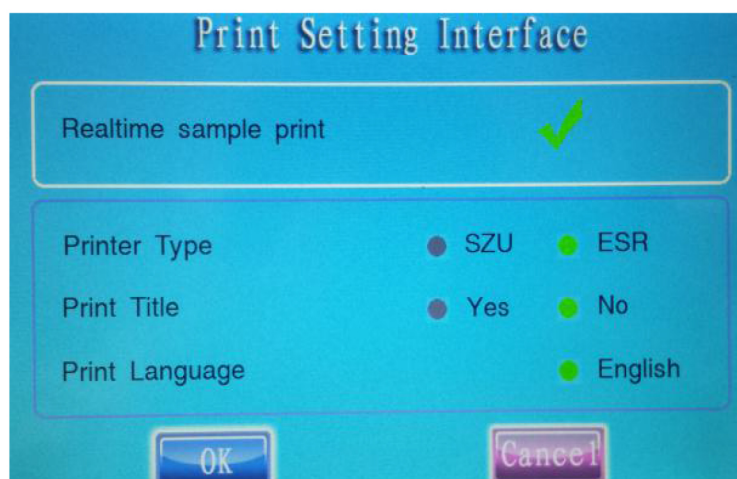
6.4.2 Item Select

Select parameters by ticking the items.



6.4.3 Print Setup

Open / close the printer function by change the status as below:



6.4.4 Normal Value

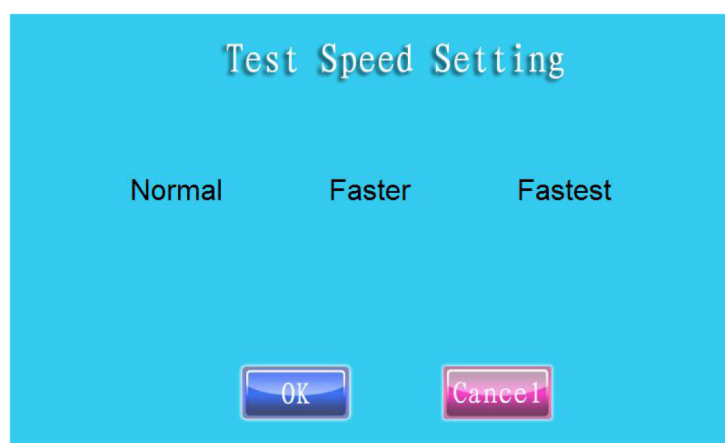
Input the default value, press OK to save.



The screen is titled "Normal Value Range Setting". It features a list of chemical elements on the left: K, Na, Cl, Ca, Mg, Li, CO2, and AG. Each element has a corresponding input field with a minus sign and a plus sign. To the right of these fields is a numeric keypad with buttons for digits 1-9, 0, a decimal point, and a left arrow. At the bottom right, there are two buttons: "OK" and "Cancel".

6.4.5 Test Speed

User could change the test speed in this menu.

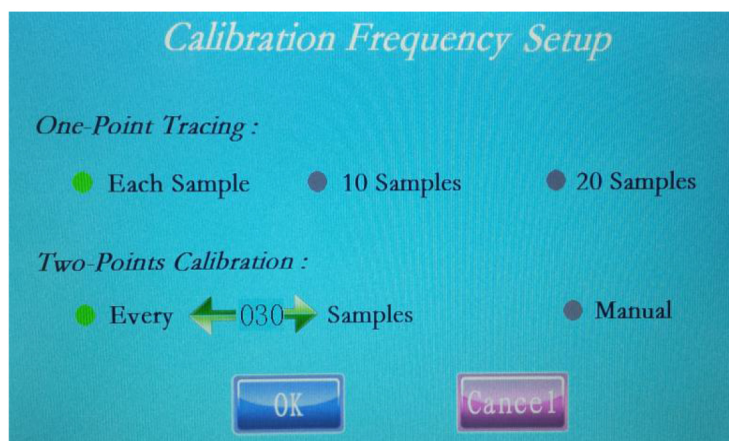


The screen is titled "Test Speed Setting". It displays three options: "Normal", "Faster", and "Fastest". At the bottom, there are two buttons: "OK" and "Cancel".

6.4.6 Tracing Frequency

The instrument default is performing calibration after each sample analysis. User could change the frequency for every 10 or 20 sample.

If you change the one-point calibration to "10 samples", it means the system will perform one-point calibration each 10 samples.



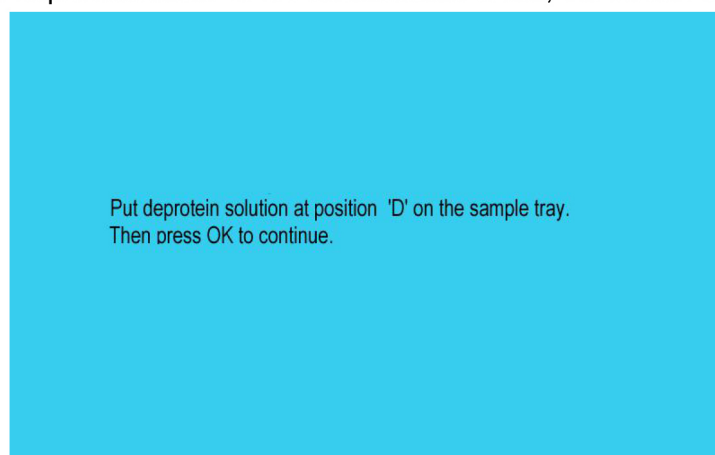
6.5 Maintenance

The instrument has four system service programs as below:



6.5.1 Deproteinize

Choose "Electrode deproteinization" in the maintenance menu, the screen displays as below:

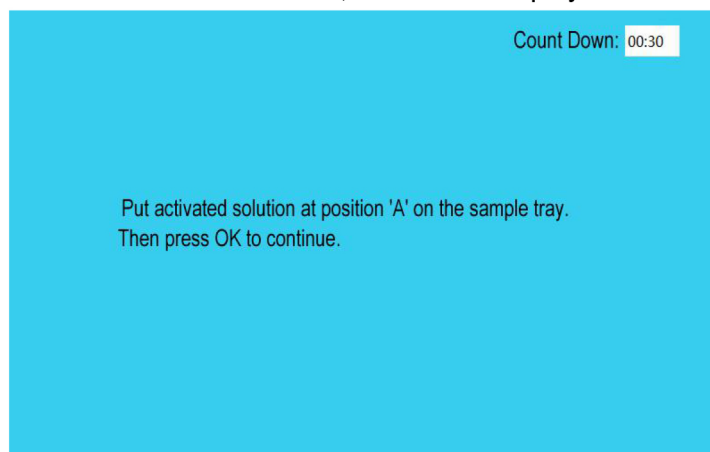


Press OK to start deproteinization.

Normally after 100 testing finished the system will remained you to perform deproteinization function.

6.5.2 Activate electrode

Choose “Activation” in the maintenance menu, the screen displays as below:



Press OK to start activating.

Attention:



The default activation time is 30 minutes.



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



Activation could make the electrodes stable and prolong the electrode life.

6.5.3 Flushing

Choose “Flushing” after finish testing a number of samples. The instrument aspirates distilled water or Calibration Solution A to perform flushing automatically.



6.5.4 Replace Reagent pack

Choose “Replace reagent” if the instrument prompt “lack of reagent”. The procedure is the same as installation of reagent.

6.6 Other services



6.6.1 Review Sample Data

Input date to query the measuring records in the specified date.

Input sample ID to query the specified sample.

6.6.2 Upload Data

Connect the analyzer to computer, and then click “Data Transmission” to copy the measuring records to PC.

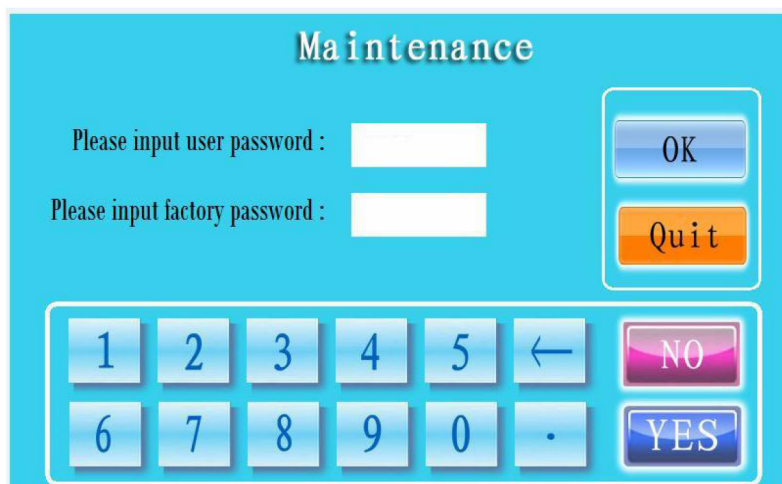
6.6.3 Calibration Data

Click on the icon to review the ISE calibration data or CO2 calibration data.



6.6.4 Advanced setup

Maintenance for user is available by inputting password:123456. But for factory part, it is just for manufacturer.



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 MR International Healthcare Technology Co.,Ltd for 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

- 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.
- Check the standard solution A, B and CO₂ reaction solution volume frequently.
- Check the internal filling solution in each electrode.
- Check tubes and liquid flow system to makes sure the liquid path unobstructed.
- Clean the waste container every day.
- 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 solution always. When necessary, add internal filling solution from orifice by syringe. Make sure

the orifice is unobstructed.

- (3) Use deprotein solution (with enzyme) 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 filling 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

Description	Unit
K Electrode	1
Na Electrode	1

8.1 Electrode

Cl Electrode	1
Ca Electrode	1
PH Electrode	1
Li Electrode	1
Mg Electrode	1
Reference Electrode	1

8.2 Reagent**8.2.1 Without CO₂ Measurement**

Description		Unit	Volume
Reagent Pack (Calibration Solution A & B)		1 pack	430ml/70ml
Reference Electrode Internal Solution		2 bottles	10ml
Electrode Internal Solution		1 bottle	3ml
Activating Solution		1 bottle	110ml
Cleaning Solution		1 bottle	110ml
QC Solution		1 bottle	110ml
Electrode Washing Solution	Protein Enzyme	5 bottles	25mg
	Diluent	5 bottles	1ml

8.2.2 With CO₂ Measurement

Description		Unit	Volume
Reagent Pack (Calibration Solution A & B)		1 pack	430ml/110ml
CO2 Acidic Washing Solution		1 bottle	110ml
Reference Electrode Internal Solution		2 bottles	10ml
Electrode Internal Solution		1 bottle	3ml
Activating Solution		1 bottle	110ml
QC Solution		1 bottle	110ml
Cleaning Solution		1 bottle	110ml
Electrode Washing Solution	Protein Enzyme	5 bottles	25mg
	Diluent	5 bottles	1ml
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

- a) Temperature Range: (10 ~ 30) °C;
- b) Relative Humidity: ≤ 70 %;
- c) Atmospheric pressure: (86~106) kPa;
- d) Power voltage AC: 100-240V
- e) 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%
TCO2	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	
TCO2	20-33 mmol/L	(Adult)

B.5 Slope range

Items	Slope range
K	40-75 mv/10 times concentration
Na	40-75 mv/10 times concentration
Cl	40-75 mv/10 times concentration
Ca	25-40 mv/10 times concentration
Li	40-75 mv/10 times concentration
Mg	25-40 mv/10 times concentration
PH	40-75 mv/10 times concentration

B.6 Dimensions and weight

Model	Dimensions (mm)L*W*H	Net weight (kg)	Gross weight (kg)
H900	340*200*380	6	8

B.7 Packaging, transportation and storage**■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.