Electrolyte Analyzer

Operation Manual

Models:IMS-972Plus-3、IMS-972Plus-5、IMS-972Plus-F

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Preface

Dear User: Thank you for choosing the Electrolyte Analyzer,, a product of Dezhou Guoke Medical Technology Co., Ltd(hereinafter referred to as "Guoke Medical"). This user manual applies to the following models: IMS-972Plus.

Copyright

Declarations

■ This manual contains the latest information available at the time of printing. Sinseng Company reserves the right to modify the content without prior notice.

■ Some images in this manual are schematic diagrams for reference only. If there is any discrepancy between the images and the actual product, the actual product shall prevail.

■ This manual stipulates the agreements regarding the establishment and termination of rights and obligations between Sinseng Company and the user concerning product quality assurance responsibilities and after-sales services.

■ Users must carefully study this manual before using the product and strictly follow the operational guidelines provided herein.

■ Failure by the user responsible for operating this instrument to implement a satisfactory maintenance plan may result in instrument failure.

■ Guoke Medical makes no implied warranties of merchantability or fitness for any particular purpose regarding the instrument.

■ The service life of this instrument is eight years.

■ Production Date: Please refer to the label on the instrument nameplate.

Quality Assurance and After-Sales Service Commitment

Sinseng Company provides a one-year quality guarantee and warranty service from the date of instrument shipment for malfunctions caused by manufacturing processes or material defects under normal use. The company commits to arranging a response within 24 hours after receiving a user's repair request.

Sinseng Company's obligation under this guarantee is limited to free repair, covering labor and material costs incurred for warranty maintenance, and does not include losses or additional expenses resulting from instrument downtime.

Sinseng Company shall not be liable for direct, indirect, or consequential damages and delays caused by the following circumstances:

■ Improper use

■ Failure to maintain the instrument as specified

■ Use of accessories or reagents not provided by Sinseng Company

■ Repairs or modifications performed by personnel not authorized by Sinseng Company

■ Losses or damages caused by external factors, such as lightning strikes, earthquakes, theft, etc.

Should any issues arise with the product, please contact us promptly and provide the device model, serial number, purchase date, and nature of the problem. Contact information can be found on the cover.

Safety Precautions

To ensure operational safety and long-term stability of equipment performance, please read this manual carefully and fully understand the equipment's functions, operation, and maintenance knowledge before operating the device. To remind operators of potential hazards and dangerous conditions, different warning and caution symbols are provided based on the severity of the risk. Particular attention must be paid to the "WARNING," "CAUTION," and "NOTE" sections in the user manual. Improper operation or failure to follow the instructions of the manufacturer or its agents may result in equipment damage or personal injury.

WARNING

Failure to follow the operating procedures may cause significant harm to the operator, the environment, or both.

CAUTION

Emphasizes operating procedures that must be followed to avoid potential hazards, damage to the instrument, or possible erroneous test results.

NOTE

Highlights important information.

Safety Symbols:

 Biohazard Symbol |  Caution! Refer to Accompanying Documents |  In Vitro Diagnostic Device

■ Preventing Electric Shock

Do not open the instrument while the power is on unless you are an authorized service personnel.

If liquid enters the instrument or if the instrument is leaking liquid, immediately turn off the power and contact Sinseng Company's After-Sales Service Department or the local service representative promptly. Improper handling of liquids may cause electric shock hazards and damage the machine.

■ Protection Against Biochemical Hazards

Improper handling of samples may lead to risk of infection.

Do not directly touch samples, reagents, or waste liquids with bare hands. Always wear protective gloves during operation to prevent infection.

If a sample comes into contact with the skin, immediately take remedial measures according to the user's workplace standards or consult a physician.

Handle reagents with care to prevent direct contact with hands or clothing.

If reagents come into contact with hands or clothing, immediately and thoroughly rinse with soap and water.

If reagents accidentally get into the eyes, immediately rinse with plenty of clean water and consult a physician for further treatment.

■ Waste Liquid Disposal

Some substances in reagents and samples are regulated by contamination control regulations and discharge standards. Dispose of waste liquids in accordance with the "Medical Waste Management Measures" or follow local discharge regulations and consult Sinseng Company's After-Sales Service Department or the local service representative.

■ Prevention of Fire and Explosion

Do not use flammable hazardous materials around the instrument.

Usage Precautions

To ensure safe and reliable use of this instrument, strictly adhere to the following precautions:

■ Intended Use

Adhere to the declared intended use of this instrument. Do not use it beyond its specified scope.

■ Operating Environment

The instrument must be installed in the environment and under the conditions specified in this manual. Installation or use outside the specified conditions may yield unreliable results and could lead to instrument damage.

If changes to the instrument's status are required, contact Sinseng Company's After-Sales Service Department or the local service representative.

■ Operators

This instrument is strictly for use by personnel trained and authorized by the manufacturer.

The equipment is calibrated for optimal performance at the factory. Do not adjust any parameters in the equipment system maintenance except as specified in the user manual.

Do not disassemble the equipment. If necessary, request service from Sinseng Company's After-Sales Service Department or the local service representative.

■ Use, Maintenance, and After-Sales Service

Strictly follow the requirements in this manual for daily use, maintenance, and care.

All spare parts used for this instrument must be inspected and provided exclusively by Sinseng Company or its designated authorized agencies.

■ Other

If this instrument needs to be connected to electronic or mechanical devices from other companies, contact Sinseng Company's After-Sales Service Department or the local service representative before making any connections.

If the instrument needs to be returned to the factory for repair, pack the main unit with shock-absorbing foam (without any reagents inside). The transport environment should be between 0–40°C with relative humidity below 80%. Handle with care during transportation and do not invert the instrument.

If the instrument is to be stored idle for an extended period or requires transportation, thoroughly disinfect and clean the instrument casing and other parts before storage or transport.

WARNING

Strictly follow the methods specified in this manual for instrument operation. Failure to do so may compromise the protection provided by the instrument.

Chapter 1 Overview

Electrolyte analyzer is an automated analytical instrument that utilizes ion selective electrode measurement technology and sensor technology, and is controlled by a microcomputer for analysis. It is a fast, accurate, convenient, and practical clinical laboratory equipment.

K, Na, Cl, and Ca are the main components of electrolytes in the human body. Rapid and accurate measurement of their electrolyte content can provide significant assistance for clinical diagnosis.

The ion-selective electrode method does not require dilution of the sample (except for urine), which shortens the analysis time. The results can reflect the activity and changes of the electrolyte. Additionally, it also eliminates the risk of gas polluting the laboratory environment and of accidents occurring.

The electrolyte analyzer is a new-generation product developed by Sinseng Company through the exclusive introduction of advanced foreign technology and production processes. Intended Use: Used in conjunction with specialized reagents to measure the concentrations of K^+, Na^+, Cl^-, Ca^{2+}, pH, Li^+, Mg^{2+}, and total carbon dioxide (TCO_2) in human blood, as well as the concentrations ofK^+, Na^+, and Cl^- in human urine.

Contraindications: None.

Section 1 Working Principle

1. Electrode principle

Ion selective electrode is an electrochemical sensor (also known as electrode) that can convert the activity changes of specific ions in a solution into changes in electrode potential, and its relationship conforms to the Nernst equation.

The so-called "selection" in "ion selective electrodes" refers to a sensor that is only sensitive to a specific ion.

For example, the Na electrode is only sensitive to Na ions in the solution and not sensitive to other ions. Similarly, by combining various electrodes, the concentration of various ions in a sample can be measured simultaneously.

There are 11 combinations of electrolyte analyzers (see Table 1):

Table 1

Model	Testing items
A	K^+ Na^+ Cl^-
B	K^+ Na^+ Cl^- TCO_2 AG
C	K^+ Na^+ Cl^- iCa^{2+} nCa^{2+} TCa^{2+} pH
D	K^+ Na^+ Cl^- iCa^{2+} nCa^{2+} TCa^{2+} pH TCO_2 AG
F	K^+ Na^+ Cl^- Li^+
H	K^+ Na^+ Cl^- iCa^{2+} nCa^{2+} TCa^{2+} pH Li^+
I	K^+ Na^+ Cl^- iCa^{2+} nCa^{2+} TCa^{2+} pH Li^+ TCO_2 AG

K	K^+ Na^+ Cl^- iCa^{2+} nCa^{2+} TCa^{2+} pH Mg^{2+}
L	K^+ Na^+ Cl^- iCa^{2+} nCa^{2+} TCa^{2+} pH Mg^{2+} TCO_2 AG
M	K^+ Na^+ Cl^- iCa^{2+} nCa^{2+} TCa^{2+} pH Mg^{2+} Li^+ TCO_2 AG
N	K^+ Na^+ Cl^- iCa^{2+} nCa^{2+} TCa^{2+} pH Mg^{2+} Li^+

The key part of the electrode is the ion selective membrane, which is in contact with the sample on one side and responds to changes in electrolyte concentration in the sample, while on the other side it is in contact with the electrode internal solution. The transition from ion conduction to electron conduction is achieved through a silver rod coated with silver chloride, which is called an internally conductive electrode. In addition, there is a reference electrode used to provide a reference potential, thereby forming a complete measurement circuit. When the electrolyte concentration in the solution changes, the potential of the reference electrode remains unchanged, providing a reference point for measuring the potential difference.

2. Method principle

The measurement principle of electrolyte analyzer is based on the Nernst response of ion selective electrode. The relationship between the measured ion activity (concentration) and electrode potential can be expressed by the Nernst formula:

E=E0+(RT/NF)LNAX

In the formula: E=potential of ion selective electrode in measuring solution

E0=Standard electrode potential of ion selective electrode

R=gas constant

T=absolute temperature

F=Faraday constant

AX=Activity of the measured ion in the solution

N=the number of charges ofthe measured ion

From the Nernst formula, it can be seen that under certain experimental conditions, the electrode potential is linearly related to the logarithm of the measured ion activity. Therefore, the activity of the measured ion can be determined by measuring the electrode potential.

Section 2 Main parameters and Characteristics

1. Measurement Range and Accuracy

Electrode	Measurement Range	Measurement Accuracy
K	0.50-20.00 mmol/L	1.5(CV%)
Na	15.0-200.0 mmol/L	1.5(CV%)
Cl	15.0-200.0 mmol/L	1.5(CV%)
Ca	0.10-6.00 mmol/L	2.0(CV%)
pH	4.00-9.00pH	2.0(CV%)
CO_2	2.0-70.0 mmol/L	3.5(CV%)
Li	0.10-6.00 mmol/L	3.0(CV%)
Mg	0.10-4.00 mmol/L	3.5(CV%)

2. Display Resolution

K^+	0.01 mmol/L
Na^+	0.1 mmol/L
Cl^-	0.1 mmol/L
Ca^{2+}	0.01 mmol/L
pH	0.01pH
CO_2	0.1 mmol/L
Li^+	0.01 mmol/L
Mg^{2+}	0.01 mmol/L

3. Other

Power Supply： AC220V±22V
Input Power： 120W
Insurance Specifications: 2.0A

4. Normal Reference Range for Clinical Electrolytes

Electrolyte	Serum	Urine
K	3.5-5.5mmol/L	50-100mmol/L
Na	135-145mmol/L	130-217mmol/L
Cl	98-106mmol/L	170-250mmol/L
Ca	1.09-1.35mmol/L	
Mg	0.60-1.10mmol/L	
CO_2	20-33mmol/L (Adult)	
	12-23mmol/L (Young Children)	

5. Normal Range of Slope

Electrode	Slope (S) within Normal Range	
K	20-70	mv/10 × concentration
Na	20-70	mv/10 × concentration
Cl	20-70	mv/10 × concentration
Ca	15-50	mv/10 × concentration
pH	20-70	mv/10 × concentration
Li	20-70	mv/10 × concentration
Mg	15-50	mv/10 × concentration

Section 3 Product Structure

The electrolyte analyzer consists of a microprocessor, an automatic sampling system, an ion detection electrode, a carbon dioxide detection system, and a fully automatic sampling tray (optional). All operations are carried out through human-machine dialogue.

Display: LCD screen displays results and prompts for operation information.

Printer: Use a micro printer to print sample measurement results and other data.

Detection system: Ion-selective electrodes for potassium, sodium, chlorine, calcium, pH, lithium, and magnesium are adopted as measuring electrodes. Use an Ag/AgCl reference electrode.

Electrode: The ion selective electrode consists of an ion selective membrane, an electrode housing, an Ag/AgCl internal reference electrode, an internal filling solution, and a sealing ring (see Figure 1).

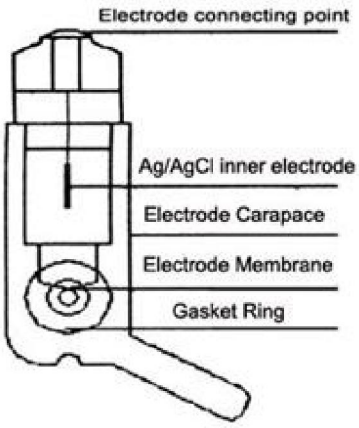


Figure 1 Schematic Diagram of Electrode Structure

Reagents: The electrolyte analyzer is mainly calibrated using two calibration solutions: Drift Calibration Solution A and Slope Calibration Solution B. Additionally, several other reagents are used for flushing and maintenance the electrodes, including reference electrode internal solution, electrode internal solution (for ordinary electrodes), cleaning solution, activating solution, electrode Washing solution (Enzyme), and QC solution (for instrument calibration), For models equipped with a CO_2 module, the following are also required: CO_2 Drift Calibrator (CO_2 Standard 1), CO_2 Slope Calibrator (CO_2 Standard 2), and CO_2 Cleaning Solution.

The reagents for the electrolyte analyzer are for *in vitro* diagnostics use only. Reagents

should generally be stored at room temperature (18℃~25℃). Refrigeratited is acceptable,,but freezing is strictly prohibited. If refrigerated, allow the reagents to equilibrate to room temperature for at least 30 minutes after removal from the refrigerator before use. All reagents should be used within their validity period.

The electrolyte analyzer determines the slope of the potassium, sodium, chlorine, calcium, pH, and lithium electrodes by measuring the potential values of the two calibrators (A and B), and automatically established a calibration curve internally.

Chapter 2 Installation and Operation Steps of IMS-972 Plus Electrolyte Analyzer

Section 1 Installation Steps

1. Open the instrument packaging and check the packing list to ensure all components are present and undamaged. Inspect all parts for any damage that may have occurred during transit. If any damage is found, notify the supplier immediately.

Warning: DO NOT OPERATE THE DEVICE. For safety reasons, operation is prohibited if any damage is detected during the unboxing inspection.

2. After verifying the inventory is complete, carefully remove the instrument and place the main unit on a stable and flat workbench.

3. Installation of reagents and tubing. This instrument can be configured with either a distribution valve or a pressure tube valve. The manual uses the distribution valve installation as an example (refer to Figure 2 and Figure 3);

Tubing: When facing the front of the liquid flow distribution valve, identify the port of the calibration solution according to the markings on the valve;

Pump head: This is the injection pump head (for models equipped with a CO_2 module, an additional pump head for the carbon dioxide (CO_2) cleaning solution is located beneath it);

Pump tube: Clamp the pump tube directly onto the bracket.

Take out one bottle each of Drift Calibration Solution A, Slope Calibration Solution B, and CO2 Cleaning Solution. Replace the original caps with the dedicated perforated caps and tighten them. Place this bottles into the instrument (refer to Figure 2). Then, insert the tubing labeled “A” and “B” into the bottles of Drift Calibration Solution A and Slope Calibration Solution B, respectively. Next, take out the waste container and position it on the right side of the instrument's exterior. Finally, insert the waste tubing into this container.

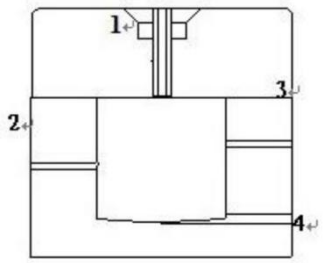


Figure 2 Reaction Tank Tubing

1. Pore
2. Reaction liquid port
3. Injection Port
4. Waste liquid outlet

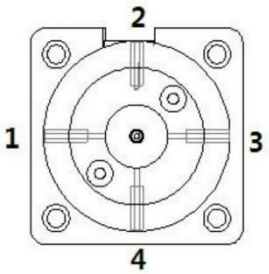


Figure 3 Schematic Diagram of Front Interface of Distribution Valve

1. Air Valve
2. Zero position hole
3. B Standard hole
4. A Standard hole

4. Electrodes Installation

Firstly, the electrode must be filled with electrode internal solution before use. When filling, use a dedicated syringe needle (with a metal needle length of 8-10mm to avoid puncturing the electrode membrane). The filling volume of the electrode internal solution should be 2/3~3/4 of the electrode cavity (see Figure 4). Then tighten the internal conductive electrode, and ensuring no air bubbles remain between the electrode internal solution and the electrode membrane (please refer to User Troubleshooting 3 for specific troubleshooting methods). Wipe the electrode surface and place the electrodes neatly on the electrode holder in left- to- right order, following the markings on the instrument's electrode holder.

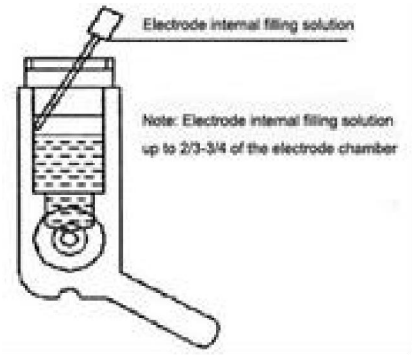


Figure 4 Schematic Diagram of Internal Solution Injection

Secondly, when installing the reference electrode, please use a clean syringe to aspirate the internal solution and inject it into the reference electrode, ensuring that there are no bubbles are present at the reference membrane below the reference electrode chamber. During subsequent use, the reference filling solution should be replaced regularly must remain free of turbidity. If the reference filling solution is insufficient, add it promptly (filling the chamber to 2/3~3/4 of the cavity). The filling hole at the upper right corner of the reference electrode must be kept unobstructed to prevent blocked by crystalline salt.

Finally, after all electrodes are connected correctly in the above order, tighten the knob on the right side of the electrode holder to secure the electrodes in place.

The above items need to be checked regularly; otherwise, electrode drift may occur.

Warning Newly installed electrodes must be activated with fresh quality control serum or fresh serum for at least 2 hours.

During use, electrodes may become contaminated, poisoned, or experience a reduction in internal filling solution. These conditions manifest as electrode drift and abnormal electrode response, including irregularities in electrode mV readings and abnormal mV differences. In cases of electrode contamination, a deproteinizing cleaning solution can be drawn into the electrode to remove contaminants adhering to the electrode membrane. For severe contamination, a cotton thread may be passed through the electrode orifice and moved back and forth to clear adhered deposits (note: hard objects must never be used to probe any electrode!). If the internal filling solution is depleted, the original solution should be expelled and the electrode refilled.

Abnormal electrode mV readings (including conditions requiring electrode deproteinization or regeneration, as the use of acidic substances may also cause such abnormalities) can be addressed by activating the electrode with fresh quality control serum or fresh serum for more over 2 hours until stabilization is achieved.

Attention The electrode can be stored for a long time at room temperature, but it should be protected from direct sunlight and freezing is strictly prohibited.

The electrode serial number is one of the warranty certificates for the electrode. Please keep the electrodes and their original packaging properly for future inquiry.

6. Connect the power supply:

Before powering on, keep the instrument power switch in the off position.

Connect the instrument to the power socket with a power cord, ensuring it is not loose.

7. Installation of automatic sample tray (applicable to models with sample tray):

Align the notch on the injection tray with the suction nozzle under the injection needle, then align the socket under the injection system with the insertion hole on the injection tray, and push it in and fix it.

Section 2 Installation Acceptance

1.After the power switch is turned on, the instrument passes the self-test and then enters standby mode.

2. Follow the operating procedures in the instruction manual to access and operate each menu. If all operations are fully normal, the instrument can be determined to be functioning properly.

3. Take quality control samples for actual testing. If the test results meet the requirements, print them out. Thus, the instrument’s.performance can be deemed qualified.

4.After the above acceptance steps are completed, the on-site sales and service engineer shall fill out the user acceptance form and warranty card, and must also provide comprehensive training to the user.

Section 3 Basic Operating Procedures

Subsection 3.1 Power On and System Self-Test

After the power switch is turned to the "ON" position, the instrument will automatically execute the system self-test procedure. During this process, the system will inspect key components (including sample needles, sample tray, distribution valves, and memory) and

preheat internal circuits to achieve a thermally stable state. Subsequently, the peristaltic pump will start operating and the fluid distribution valve will begin working.

For models equipped with a sample tray, the system will check components such as the sample needle, sample tray, distribution valve, and memory; In contrast, for models without a sample tray, functions related to the sample needle and sample tray will not be checked. Using a model with a sample tray as an example, the following describes possible scenarios of self-test failure and the corresponding troubleshooting methods.

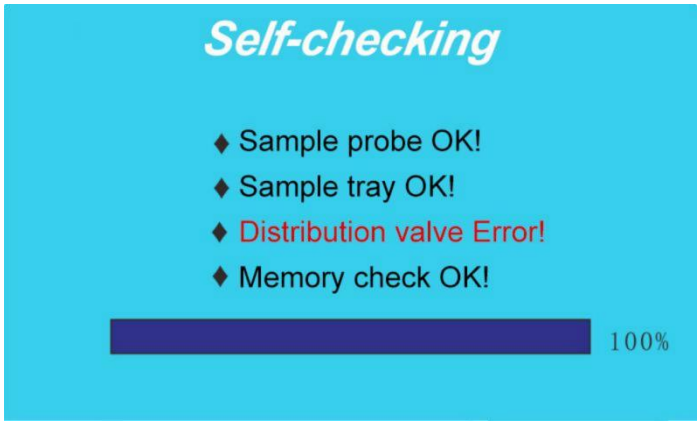


Figure 5 Example of a Failed System Self-Test

If the screen displays “Distribution Valve Detection Abnormal” during the self check process, the system will rotate the valve for an additional cycle. If the prompt persists (models with an automatic sample tray may also show "Sample Tray Detection Abnormal" or "Sample Needle Detection Abnormal"), the instrument will halt operation. In this case, refer to the first item in the "User Troubleshooting" section or directly press the "View Help" button to access a solution.

If the prompt reads "Sample Needle Detection Abnormal", turn off the power, manually lift and lower the sample needle to slide it freely, and then restart the test.

If the prompt reads “Sample Tray Detection Abnormal”, turn off the power, reset the sample tray by disconnecting and reconnecting it, and then restart the instrument.

If a fault occurs during the self-check process, the system will display the interface shown below:

Figure 6 Diagram of Abnormal Self-Test Results

Recheck: Execute the complete self-check procedure;

Skip self-test: Ignore the current issue and proceed directly to the main menu;

View Help: Display system help information.

Subsection 3.2 Login Interface

After the instrument completes the self-test, it will proceed to the login Interface (Figure 7). Users can access the main interface with corresponding permissions by entering different passwords: entering "123456" leads to the Standard User Main Interface (Figure 8), while entering "45679" leads to the Advanced User Main Interface (Figure 9).

The Standard User Main Interface provides three core functional modules: "System Calibration", "Sample Analysis", and "Other Services". Advanced Users have access to all the modules available to Standard Users, plus additional modules including “System Settings”, “Quality Control Analysis”, and “Maintenance”.

Since the Advanced User interface encompasses and extends all the Standard User functions, the following descriptions will primarily be based on the Advanced User interface. Standard User functions can be understood by referring to the corresponding sections.

Figure 7 Login Interface

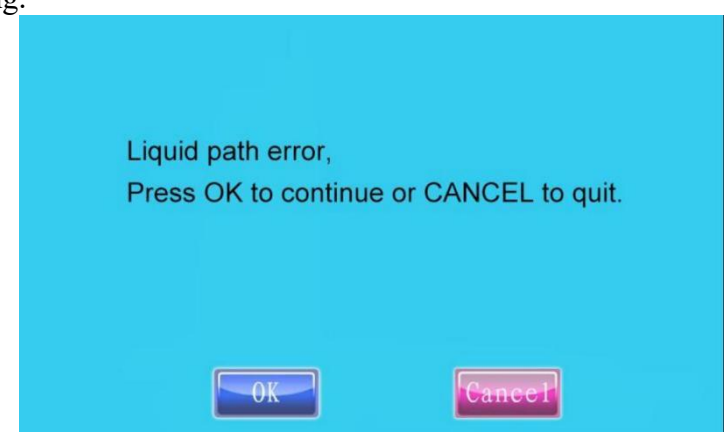
Figure 8: Standard User Main Interface

Figure 9: Advanced User Main Interface

Subsection 3.3 Detector Calibration and Liquid Circuit Inspection

The screen displays as follows:

This indicates that the instrument is aspirating reagents and calibrating the quantitative detector to more accurately position the aspirated reagents or samples. If the detector is abnormal or fails to aspirate the sample at this point, the system will directly return to the Main Menu to allow for troubleshooting. If the detector functions normally, the process proceeds to the next step: liquid circuit inspection. Should any issue be detection in the liquid circuit, the screen will display the following:



This indicates a possible blockage or air leak in the instrument's tubing. Please carefully inspect all tubing sections (refer to Item 2 in the User Troubleshooting Guide), resolve any issues found, and then press OK to resume detector calibration. Alternatively, press Cancel to proceed to the next step.

Subsection 3.4 System Calibration

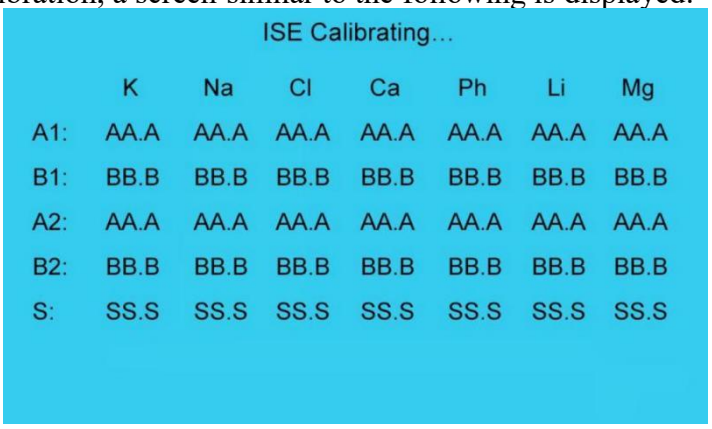
System calibration calculates the slope for the potassium, sodium, chloride, calcium, pH, lithium, and magnesium electrodes based on tests performed with standard solutions. It then automatically established several calibration curves within the instrument. These curves are used to calculate the corresponding electrolyte parameters in actual patient samples. Therefore, system calibration is a crucial step for ensuring accurate instrument measurements.

Stability assessment of each electrode is performed by comparing their millivolt readings via a two-point calibration procedure. In this procedure, Calibration A1 and A2 serve as the

baseline points, while Calibrators B1 and B2 serve as the slope points. The A1 and B1 values displayed on the screen represent the last recorded millivolt readings from the previous calibration. This methodology will be illustrated with a concrete example in the following section.

1. Measurement of Calibration A and B

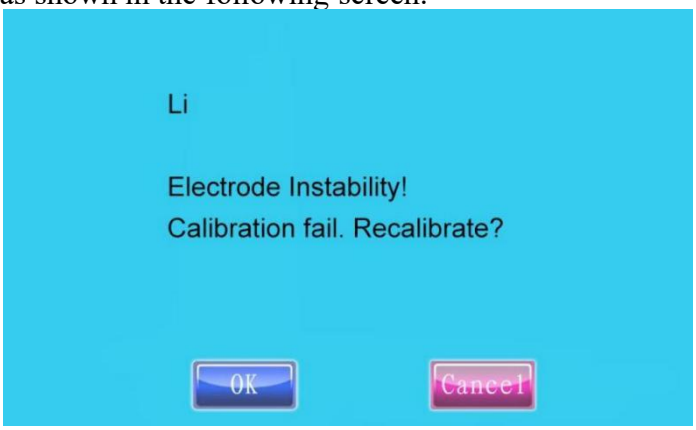
During system calibration, a screen similar to the following is displayed:



Among them, A1 and A2 are the values obtained in the current calibration cycle. If A1 is very close to A2, the system automatically determines a “Pass” status for that parameter. The same logic applies to B1 ad B2.

AA. A and BB. B indicate the millivolt readings of each electrode during measurement of Calibrator A and Calibrator B, respectively. SS. S represents the slope value calculated from the calibration.

If system calibration is successful, the instrument automatically proceeds to the next measurement program. If calibration is fails, the screen will display indicate which specific electrodes are unstable, as shown in the following screen:



The menu prompts the user whether to perform recalibration. If required, press the OK button to initiate an automatic recalibration cycle. If the system still reports an electrode calibration failure, inspect the instrument and electrodes to identify and resolve the cause (refer to Item 3 in the User Troubleshooting Guide for detailed instructions). Upon successful calibration, for models equipped with a CO2 sensor, the system will prompt the operator to perform "CO2 Calibration". For models without CO2, it will automatically return to the Main Menu.

Subsection 3.5 CO_2 Calibration

For models equipped with a CO_2 analysis module, the operator can calibrate the sensor using the "CO_2 Calibration Program" before analyzing the sample. Calibration is recommended every 1 to 2 days, depending on daily workload.

The operation steps are as follows:

1. Press the "System Calibration" button and select "CO_2 Calibration" to enter the calibration process.

2. For models with sample trays, the system will prompt to place Calibrator 1 for CO_2 in the QC1 cup position; For models without a sample tray, follow the on-screen instructions to lift the probe and perform manual aspirate of the calibrator.

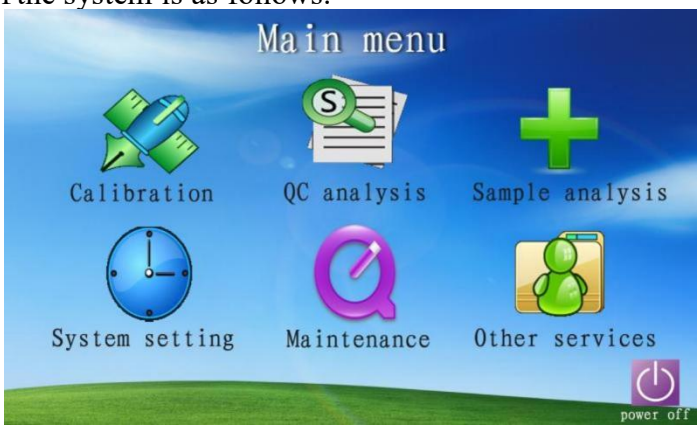
3. During calibration, the system performs two measurements by aspirating Calibrator 1 for CO_2 and automatically calculates the average of the two results. The average value is usually about 160mV (if Calibrator 2 for CO_2 is used, the average value is about 100mV).

4. Monitor the deviation between the two test results. Under normal operating conditions, this deviation should not exceed 10mV.

After the calibration is completed, the system will automatically return to the Main Menu.

Subsection 3.6 Sample Measurement

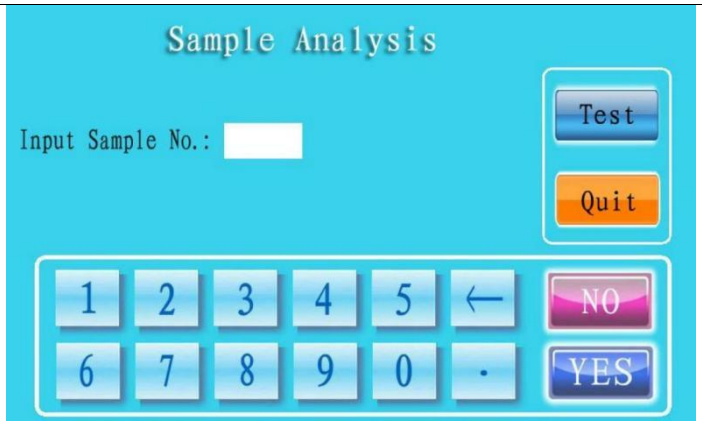
The Main Menu of the system is as follows:



The software version number is displayed at the bottom of the screen. To analyze a patient samples, click "Sample Analysis" directly.

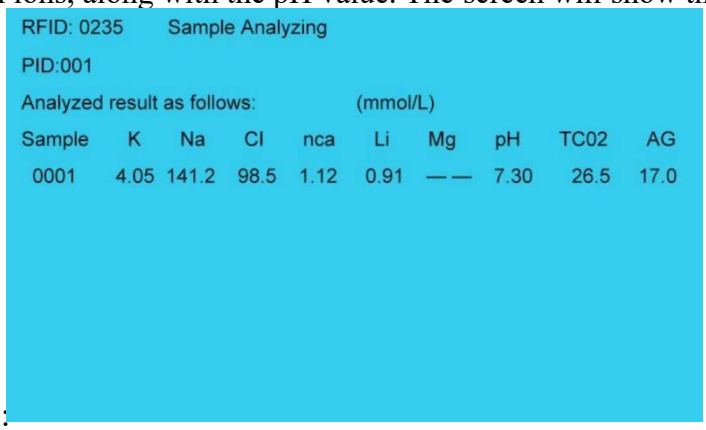
1. Models without a Sample Tray:

To analyze serum samples, press the "Sample Analysis" button (Note: The sample temperature at aspiration should be between 10℃ and 30℃). The screen will display the following:



To change the sample ID at this time, click on the "0001" filed, The cursor will begin to flash. Use the numeric keypad below to enter the new sample ID, then press the “Start Test” button. At this point, lift the sample probe, insert it into the blood sample, and ensure it is not placed within a clotted portion. The instrument will then automatically aspirate the sample. Upon completion of aspiration, an audible beep will prompt you to remove the sample.

Testing now begins. After about 40 seconds (or approximately 80 seconds for models with CO_2 capability), the instrument displays the measured concentrations of potassium, sodium, chlorine, and calcium ions, along with the pH value. The screen will show the following



:

Once testing is complete, the system automatically perform tubing rinse and initiates the printer. The printer outputs the measured results for potassium, sodium, chlorine, calcium, and pH (for models with CO_2 capability, CO_2 and AG are also printed). The printout format is as follows:

Electrolyte Analysis Report			
Time		16-07-01 15:44:37	
Info		1-1-0-0-2-27	
Sample		Serum	
Medical Record	0001	mmol/L	Normal Range Value
K		3.35	(3.5——5.2)↓
Na		140.2	(136——145)
Cl		100	(96——108)
iCa		1.35	
nCa		1.32	(1.1——1.3)↑
TCa		2.64	(2.1——2.6)↑
TCO_2		26.4	(10—— 33)
AG		20	(7—— 16) ↑
pH		7.34	

This indicates the measurement of the sample concentration, performed on July 1, 2016, at

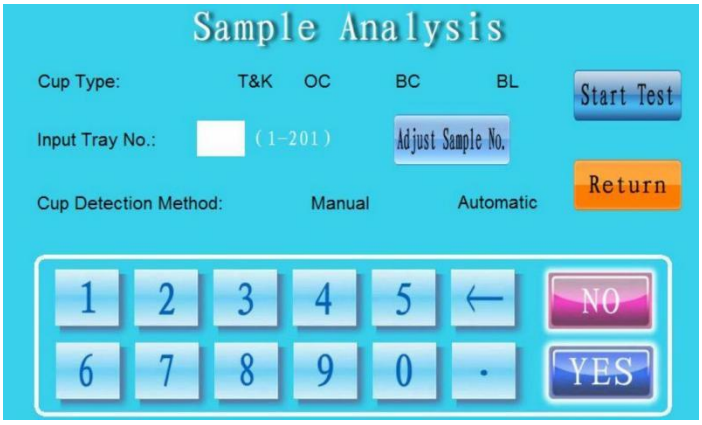
15:44:37.

For an explanation of measured ionized calcium (iCa, also known as free ionized calcium), standard ionized calcium (nCa), and total calcium (TCa), please refer to the User Troubleshooting Guide.

Upon completion of the system rinse cycle, the instrument automatically prepares for the next blood sample measurement. To exit the measurement procedure, press the "Cancel" button.

2. Models with a Sample Tray:

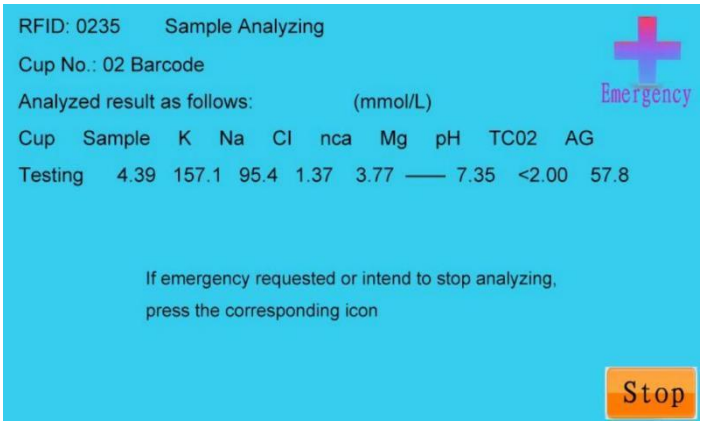
To analyze serum samples, press the "Sample Analysis" button (Note: The sample temperature at aspiration should be between 10℃ and 30℃). The screen will display the following:



Each sample tray can hold 30 samples. Place any additional samples on a subsequent tray. If a second tray is required and still insufficient, use a third disk. Cup positions on the first tray are numbered 1 through 30. Cup positions on the second tray continue the sequence from 31 through 60, on those on a third tray from 61 through 90. To begin testing the entire tray, press the “Start Test” button.

The tray number increments cumulatively throughout the day. After the Nth tray is tested, the system will automatically display tray number **N+1**. At the start of a new day, the tray numbering resets and begins again from **1**.

Attention: Avoid exposing the sample tray to strong light, at this may cause the detection cups to malfunction!



Emergency Testing: If an emergency test is required during a full-tray test run, press the Emergency button in the top-right corner of the screen and enter the designed emergency cup position. The first 5 cup positions on the sample tray are reserved for emergency use. Upon completion of the emergency analysis, the system automatically returns to the sample test

screen and resumes testing of the original tray from where it was interrupted. If testing had progressed to the Nth sample prior to the emergency, it will resume from sample N+1.

Aborting the Measurement. To halt the analysis of remaining samples during a full tray test run, press the "Exit" button at the bottom located right of the screen. The system will wait for the current sample to complete testing and then prompt you to confirm aborting the test. Selecting “Confirm” will exit the procedure and return to the Main Menu.

Subsection 3.7 Quality Control Analysis

This routine is specifically designed for users to run quality control materials with assigned target ranges. Prior to analyzing patient samples, the operator can use this routine to perform two or three quality control runs, observe if the results fall within their respective target ranges, and then proceed to analyze samples in the "Sample Analysis" section. This process ensured the accuracy of patient sample results.

When switching to a quality control material with a different assigned target value (i.e. different batch number), the operator must access the parameter settings by clicking on QC1, QC2, or QC3 within the Quality Control Analysis module. The target values for the new quality control must be entered and saved for the respective channel. To run a different QC material subsequently, simply select the corresponding QC channel (e.g. QC1) and press “Start Test” button.

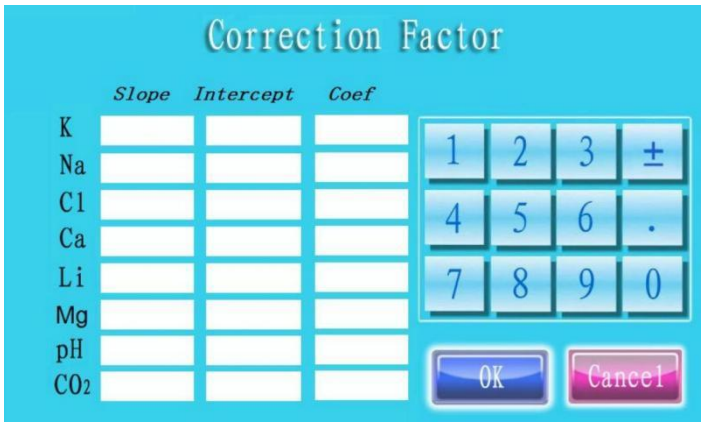
Following quality control analysis, the system will prompt the user to save the current quality control results for monthly statistical purpose. It is recommended to perform and store one quality control solution run per day for each lot of QC material. Please note: For any given lot of quality control material, regardless of how many times quality control analysis is performed on the same day, the system will retain only the result from the most recent test for that specific lot.

The "QC Statistics" function in the menu automatically calculates the mean (M), standard deviation (SD), and coefficient of variation (CV) of the most recent QC runs performed in the “Quality Control Analysis” module. To print this statistical report, click the "Print" button. The data is automatically saved upon shutdown. Users can retrieve and review this monthly quality control data at the end of the month (e.g., to print quality control charts) to monitor instrument and electrode performance.

1. Input factors

The input factor correction method can be applied when a deviation is observed between

the quality control result and its assigned target value. The input factor is calculated by dividing the target value by the actual measured value. To apply it, click the “Input Factor” button and enter the calculated value. For Li and Mg assays, it is not necessary to adjust the factor if a deviation occurs. Instead, adjust the calibration coefficient. Navigate to the Automatic Calibration menu, then select "Li Coefficient" or "Mg Coefficient" for correction. The instrument will automatically calculate the correct coefficient.



2. Single Point Calibration

If a measurement deviation is observed, press the "Single Point Calibration" button to perform calibration. Upon selecting “Automatic Calibration”, the following screen will be displayed:

- To calibrate the ISE electrode, press the "ISE Automatic Calibration" button;
- To calibrate CO_2, Li or Mg parameters, click their respective icons.

After initiating ISE Automatic Calibration, the screen will display the following:

Using "ISE Automatic Calibration" as an example: after pressing the button, the screen will prompt for the entry of quality control target value. Enter the respective values sequentially, then

click “Start Calibration”.

- For models with sample trays, place the calibration solution in the QC1 cup position beforehand.
- For models without a sample tray, the system will instruct you to lift the probe and manually aspirate the calibration solution.

During calibration, the instrument performs measurements. The results are not printed, but the system will automatically performs internal calculations to generate a calibration factors for each electrode. After completion, an "Input Correction Factor" window pops up on the screen, displaying various calibration parameters, including the slope.

The operational procedures for CO_2 Single Point Calibration, Li Coefficient calibration, and Mg Coefficient calibration are similar.

3. Two Point Calibration

When two quality control materials with different concentration levels are available, the two-point calibration method can be selected. Compared to Single-Point Calibration, this requires entering one additional target value and performing one additional measurement. Upon completion of the test, the system will similarly calculate the correction factors automatically, the "Input Correction Factor" window will then pop up, displaying the slope and intercept of the calibration parameters for each electrode. Two Point calibration is not applicable for CO_2.

Attention: Do not enter the same target value for both points in a Two-Point Calibration. Doing so will cause the instrument to report results identical to the input value, rendering the measurement invalid.

Section 4 Main Functions and Parameter Settings

Subsection 4.1 Time and Date

To set the time and date, enter this screen and click the "Settings" button.

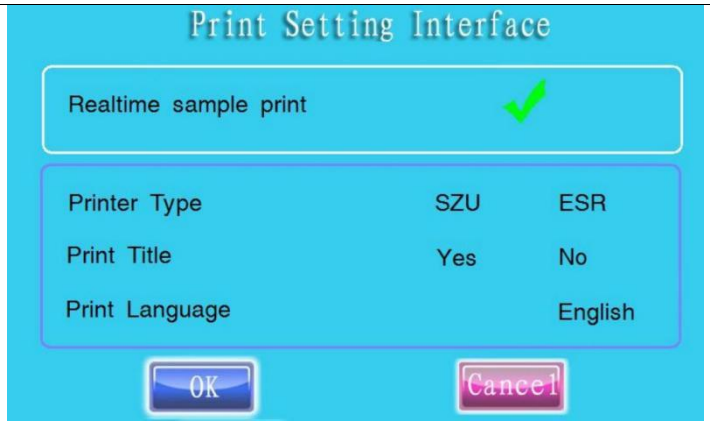
Attention: If the system date is displayed as 2096, this usually indicates that the display backup battery is depleted. Please contact an after-sales service engineer for replacement.

Subsection 4.2 Parameter Settings

If you do not need to display or print measurement results for a specific parameter, make the selection on this interface. After entering the interface, click the unneeded parameter--the "√" will change to "×", and the parameter will no longer be tested. If you switch "×" back to "√", it means that the parameter needs to be displayed and printed. Parameters not set for printing will show "---". However, if the instrument itself is not equipped with the corresponding module, such as magnesium ion parameters, clicking the "×" for magnesium ion will not switch it to "√".

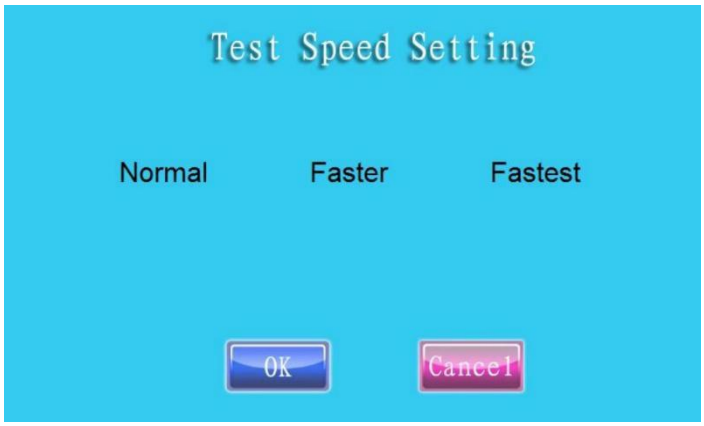
Subsection 4.3 Print Settings

In the "Print Settings" menu, you can configure whether test results are printed and select the report language (Chinese or English). After entering the menu, click the "√" next to Print Status to switch it to "×", and the printing function will be disabled. Select the printer model and choose between Chinese and English for the report..However, regardless of whether the printing function is enable or disable, the emergency test results will be printed automatically after the test.is completed.



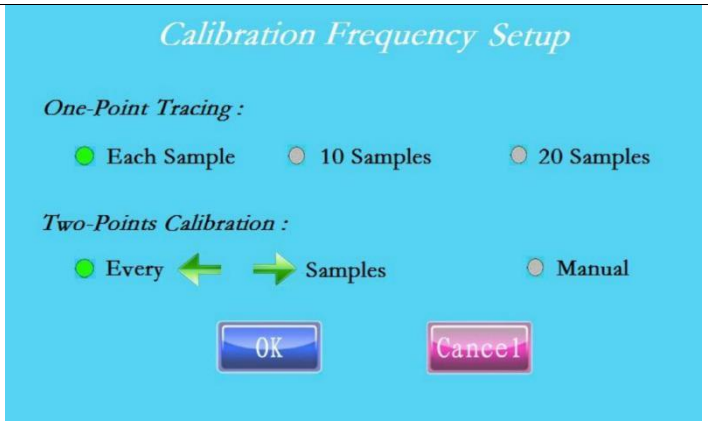
Subsection 4.4 Test Speed

This instrument offers three testing speeds modes: Normal, Fast, and Express. User may select the appropriate mode based on their operational needs.Although the Normal mode is the slowest, it provides the most stable and accurate results.



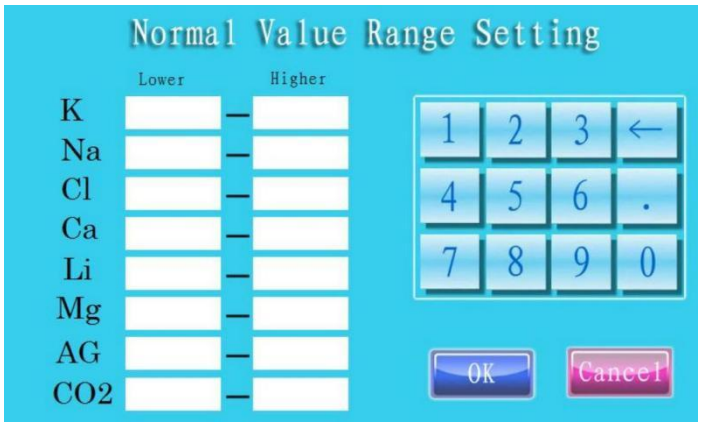
Subsection 4.5 Single-Point Tracking Settings

Single-Point Tracking means testing the sample alongside the calibration standard solution to calibrate the sample results. This makes the measurement results more reliable and can more accurately reflect the actual performance of the electrodes, but the testing speed for each sample will be slightly slower. The system defaults to performing Single-Point Tracking for each sample. In this menu, you can choose to perform Single-Point Tracking for every sample, every 10 samples tested, or every 20 samples tested. Users can also configure the calibration frequency in this menu. The system defaults to a maximum of one two-point calibration every 30 samples and a minimum of one every 5 samples. Press the arrows in the menu to make adjustments, or select Manual Calibration. If Manual Calibration is selected, automatic calibration will be disabled permanently. If calibration after every N samples is selected, a mandatory two-point calibration will be triggered upon completion of the Nth sample.



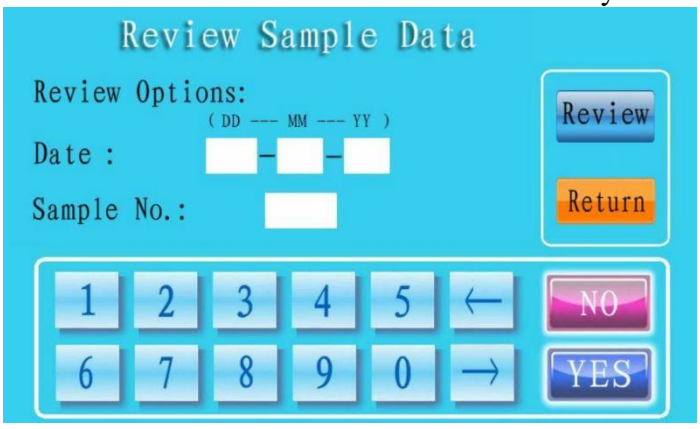
Subsection 4.6 Normal Value Range Settings

Each test parameter has a normal range. If different test subjects are selected, such as cats, dogs, rabbits, and other animals,, the normal range of the parameters may differ from those of human serum and urine. These normal ranges will be printed alongside with the measurement results.



Subsection 4.7 Sample Data Query

After entering this function item, you can enter a date or sample number to query historical test results. When querying by date, the first sample tested on the entered date will be displayed, and you can navigate forward or backward to view the results one by one.

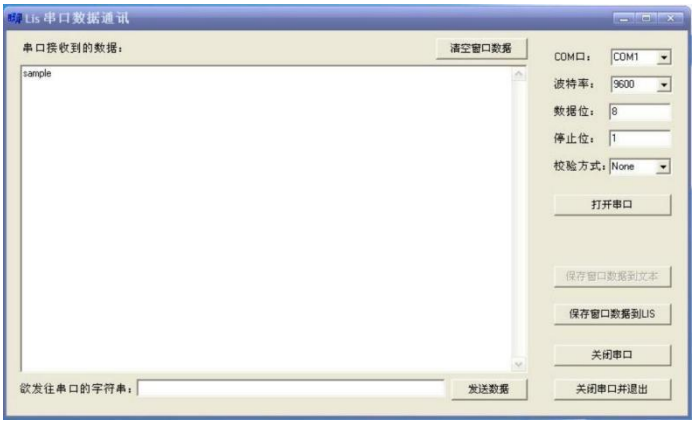


Subsection 4.8 Data Transmission

The analyzer communicates with a host computer via an RS232 interface. Set the serial

port baud rate on the computer to 9600bps. After testing each sample, the instrument automatically sends the test results to the computer's serial port in real time. Once testing is completed, you can also transmit all data recorded that day to the computer via [Other Services] → [Data Transmission].

On the host computer, run Liscom.exe and click the "Open Serial Port" button. Once data transmitted from the instrument appears in the receiving window on the computer, click the "Save Window Data to LIS" button to save the on-screen data to disk. The figure below shows the interface of the electrolyte analysis system data transmission software (PC version) provided by our company.



Run the company's LIS software to import the test results from the data file generated in the previous step to a specific patient and print the corresponding report.

The figure below shows the operating software (PC version) of the electrolyte analysis system provided by the company.

Users may contact the manufacturer to obtain the relevant data transmission and operation software.

For instruments equipped with original sample tube sampling, it is important to noted that if barcode scanning is used, the current version does not support simultaneous testing and transmission. During testing, the RS232 cable connected to the computer must be unplugged, otherwise the barcode scanner will fail to read the barcode. After all samples are tested, reconnect the RS232 cable to transmit all test results ofthe day to the host computer, then import the test data and associate it with the corresponding patient to print the test report.

Subsection 4.9 Calibration Data Query

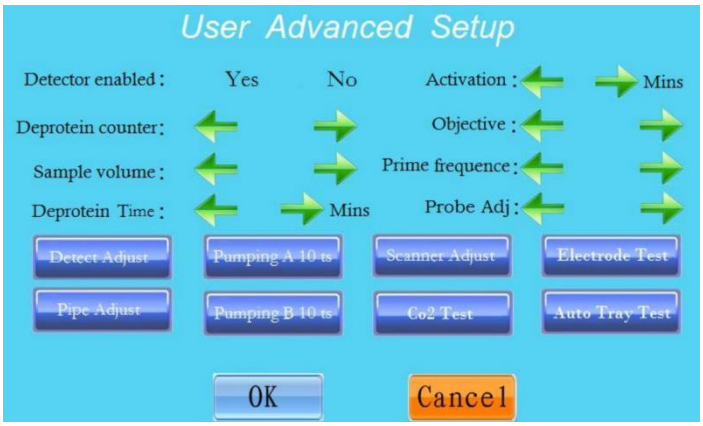
To view the result of the last successful calibration, select this function item. The displayed

result can also be printed from this menu.

Subsection 4.10 Manufacturer Maintenance

This function is an exclusive maintenance function for the manufacturer and is not accessible users. It includes menus such as “Model Selection”, “Detector Adjustment”, “Pump Volume Setting”, “Potential Stabilization Test”, “CO_2 Module Test”, “Advanced Settings”, “Automatic Cup Position Detection”, “Liquid Level Detection”, “Screen Calibration”, etc. Engineers may refer to the Maintenance Manual.

1. User Settings



The password for user settings is 123456. After entering the menu, the following functions as available:

"Use Quantitative Detector": If the quantitative detector in the liquid circuit malfunctions or is damaged, you must disable the automatic positioning function in the software.

"Activation Time": This setting is used to define the duration of activation. If a samples needs to be tested while activation is in progress, the activation process can be stopped at any time.

"Protein Removal Count "is used to set the number of samples (N) after which the user is prompted to perform a protein removal procedure. When the preset number N is reached, the system will automatically prompt the user to carry out electrode protein removal.

"Test Subject" refers to the type of human or animal sample being tested. Currently, the instrument supports 9 sample types: human serum, human urine, dog, cat, monkey, rabbit, rat, mouse, and guinea pig. The normal ranges vary among different sample types and can be displayed on the printed results. When testing human urine, a 1:9 urine diluent must be added.

"Sample Aspiration Volume" refers to the amount of sample aspirated during sampling, offering three selectable levels: MAX, MEAN, and MIN.

"Interval Time " refers to the periodic automatic flushing performed by the instrument while in standby mode, which helps keep the electrodes moist and stable. Users can adjust the interval duration using the arrow keys as needed, with the maximum setting being once every 5 hours.

"Deproteinization Time" is used to set the duration of the deproteinization process. If a sample needs to be tested while deproteinization is in progress, the process can be stopped at any time.

"Sampling Needle Adjustment "is used to adjust the depth to which the automatic sampling needle enters the test cup. Use the arrow keys to modify the setting:. a higher value corresponds to a shallower insertion depth, and a lower value to a deeper insertion.

"Aspirate Calibrators A and B 10 Cycles "is a relatively fast method designed to promptly aspirate Calibrators A and B to the distribution valve after a liquid path malfunction has been resolved.

“Potential Stability Test” is used to indicate whether the electrode potential is stable.

“Automatic Turntable Test” provides users with a tool to verify the accuracy of the cup position optocoupler judgment for the automatic turntable.

2. Detector Adjustment

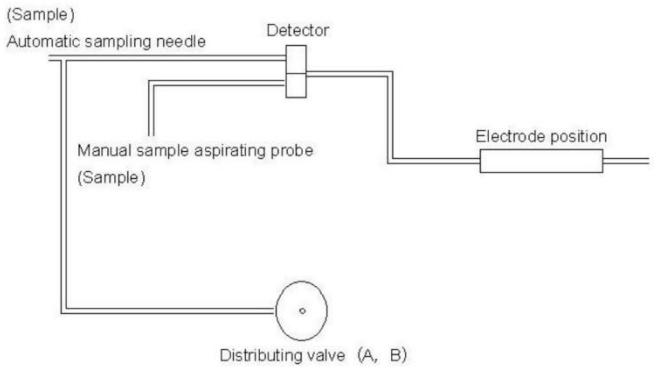
The detector is a key component for liquid circuit control in an electrolyte analyzer. When liquid flows through the detector, the detector generates a voltage value that differs from that when no liquid is flowing.

After clicking the "Detector Adjustment" button in the "User Settings" menu, the instrument will automatically begin testing the detector voltage. Observe the test results closely to ensure the voltage difference with and without liquid flow exceeds 300mV.. Specifically, the difference between the voltage with no liquid flow (V1) and the voltage with liquid flow (V2) must be greater than 300mV, i.e., V1 - V2 > 300mV. If the difference is less than 300mV, the detector should be repaired first (refer to Section 6.10.7 for details). If the detector cannot be repaired and the instrument must remain in use, the four pipeline parameters must be manually configured.

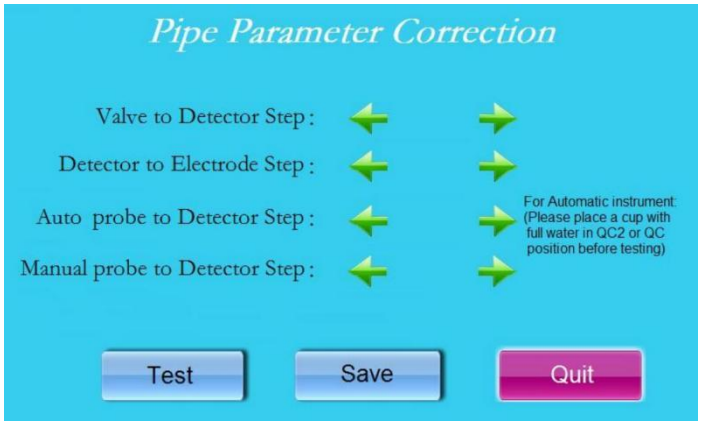
The AVG value displayed on the screen is the result of the previous test, specifically the average of the last measured V1 and V2. Once the test confirms that the difference exceeds 300mV, you must click "Save the Result" before you can exit.

3. Pipeline Parameter Adjustment

The pipeline parameters determine the step numbers for the stepper motors connecting the main control components in the liquid circuit. By setting these parameters, it is possible to fully control the movement and dwell time of liquid in the pipeline as needed. The diagram of the liquid circuit is shown below:



Click on "Pipeline Parameter Adjustment" in the "User Settings" menu to enter the following screen:



Four parameters need to be set:

The " Number of Steps from Distribution Valve to Detector" can be automatically measured, with a typical value of approximately 1800 steps.

The "Number of Steps from Automatic Sampling Needle to Detector "can be automatically measured. However, a cup filled with liquid must first be placed in the QC2 cup position (for the instrument that add samples directly to original test tubes, this refers to the QC cup position), with a typical value of approximately 1100 steps.

The "Detector Continues Advancement Step" refers to the number of steps that the liquid continues to move towards the electrode after reaching the detector,. This value requires manual input, with a typical setting of approximately 700 steps.

The "Number of Steps from manual Sampling Needle to Detector" applies to the semi-automatic mode without sample tray. It requires manual entry, with a typical value of approximately 1000 steps.

The purpose of adjusting pipeline parameters is to ensure that the liquid accurately stays at the electrode position.

Although the detector is the key component of the analyzer's liquid circuit control, it is not indispensable. In practical use, if the detector malfunctions or the voltage difference is insufficient, the instrument can still be used normally without the detector- provide that the four pipeline parameters are correctly entered. However, a software setting is required, and the procedure is as follows:

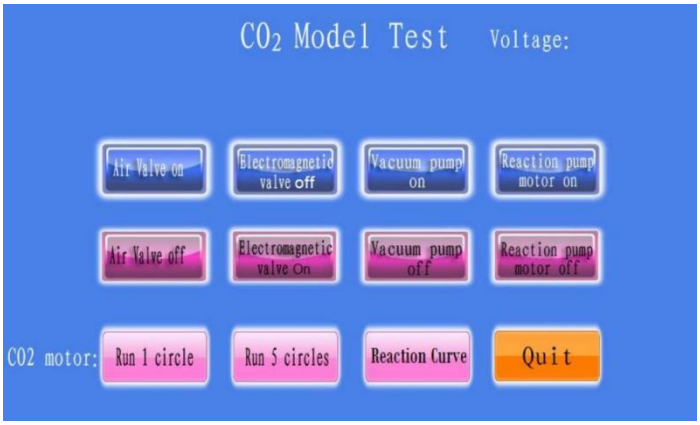
In the “User Settings” menu, users can configure the "Quantitative Detector" option to either “Present” or “Absent”. If the detector malfunctions but the instrument must remain in use,

this setting must be switched to “Absent”..

Generally, even after the pipeline ages from extended use, normal instrument operation can still be ensured by appropriately adjusting the aforementioned four parameters.

4. CO_2 Testing

For instruments equipped with CO_2 modules, the system specifically provides maintenance methods for the CO_2 module:



CO_2 module testing provides a range of tools to detect faults in the CO_2 module:

"Air Valve Open" refers to opening the air valve, at which point the pipeline at the air valve position remains unobstructed.

"Air Valve Closed" refers to closing the air valve, at which point the pipeline at the air valve is blocked and the air path is disconnected..

"Electromagnetic Valve Closed" refers to closing the electromagnetic valve, at which point the pipeline at the electromagnetic valve position is blocked and the gas path is disconnected..

"Electromagnetic Valve Open" refers to opening the electromagnetic valve, at which point the pipeline at the electromagnetic valve position remains unobstructed.

"Vacuum Pump Running "means the vacuum pump starts operating, generating air pressure, at which point the sound of the motor working will be heard.

"Vacuum Pump Stopped " means the vacuum pump stops working, and the motor will also stop working.

"Mixing Motor Running" refers to starting the mixing motor, at which point the sound of the mixing motor rotating will be heard.

"Mixing Motor Stopped” refers to turning off the mixing motor, and the sound of the mixing motor rotation will cease.

"CO_2 Motor Rotates Once "refers to pumping one revolution’s worth of CO_2 reaction solution into the reaction cell.

"CO_2 Motor Rotates 5 Turns " refers to pumping five revolution’s worth of CO_2 reaction solution into the reaction cell.

"Reaction Curve" refers to accessing the CO_2 reaction test curve display screen, which is used to test the performance of the instrument. Users generally do not need to use this function.

The voltage value displayed in the upper right corner of the CO_2 module testing interface should be approximately 200mV, otherwise, the instrument may not function properly.

System Standby State:

When the instrument displays the main menu status on the screen, it will enter standby

mode if the user does not perform any operation for an extended period. After entering standby mode, the system will automatically flush at the set flushing interval to extend the electrode service life. In case of an emergency, press any key to wake up the instrument and analyze the sample immediately. The standby time can be configured by the manufacturer's engineers in the "Manufacturer Settings" menu.

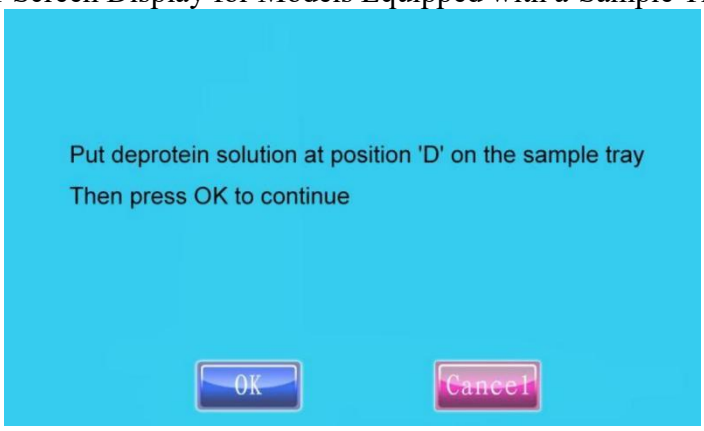
Section 5 Maintenance

Subsection 5.1 Maintenance Menu

There are four functions in the instrument maintenance interface: Protein Removal, Electrode Activation, Liquid Circuit Cleaning, and Reagent Replacement. When a certain number of samples have been tested,, some proteins may deposit in the electrode tube, affecting electrode performance. At this point, please select Protein Removal function to aspirate the deproteinized solution for automatic deproteinization (the instrument will prompt the user to perform this process based on the set deproteinization count). After deproteinization, electrode stability may temporarily decrease. Select the Electrode Activation function to aspirate the activation solution, and the instrument will automatically start a 60-minute countdown for electrode activation (the activation time can be set in the "User Settings" menu). After completing a batch of specimens, please select the Liquid Circuit Cleaning function to thoroughly clean the pipeline. You can either aspirate distilled water or allow the instrument to automatically aspirate Solution A for the cleaning process.

1. Deproteinization

1.1 Protein Removal Screen Display for Models Equipped with a Sample Tray:



At this point, place the deproteinization solution in a cup and press "Confirm" to aspirate the solution for deproteinization.. The instrument's automatically deproteinization cycle is 60

minutes (Configured by the user), or you can press “Stop” to end the process at any time. The timing is at the user’s discretion.

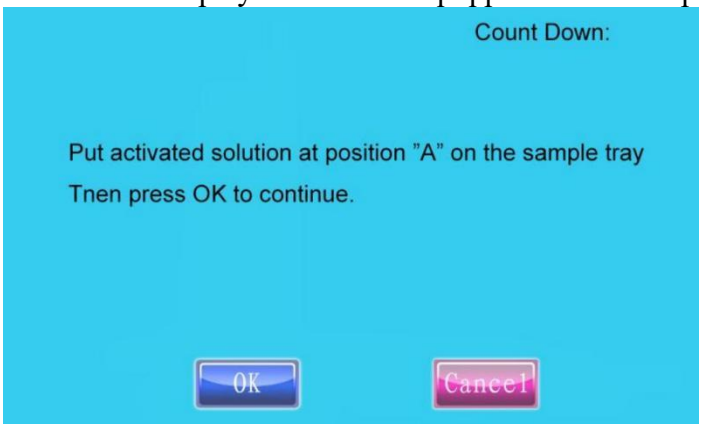
1.2 Deproteinization for Models without a Sample Tray:

The operator should lift the sampling needle, take a small test tube and fill it with an appropriate amount of deproteinization solution. Insert the sampling needle into the tube. The instrument will automatically aspirate the solution (note: During aspiration, the sampling process, the tip of the sampling needle must not be exposed above the liquid surface to avoid drawing in air). When the buzzer sounds to prompt the removal of the test solution, please remove the test tube, and the instrument will automatically aspirate the deproteinization solution into the electrodes (At this point, the operator must ensure that all electrodes completely submerged in the deproteinization solution; ideally, the solution level on both sides of the electrode holder should be controlled at approximately 2 centimeters);

Users can determine the deproteinization time based on actual conditions. The instrument’s preset deproteinization time is 60 minutes, and the operator can also press the "Stop" button to proceed to the next step: "Electrode Calibration".

2. Electrode Activation

2.1 Electrode Activation Screen Display for Models Equipped with a Sample Tray:



At this point, place the activation solution in the cup and press the OK to aspirate the solution and activate the electrode (If OK is not pressed within 30 seconds, the instrument will automatically aspirate Standard Solution A for activation.). The standard automatic activation cycle lasts 60 minutes (this duration is user-configurable), The process can also be terminated at any time by pressing stop. The user has full control over the timing of this operation.

The purpose of activation is twofold:

1. To enable the electrode to stabilize as soon as possible.
2. To extend the service life of the electrode.

Based on the above objectives, we recommend that operators pay attention to the following points when using the activation program: the activation time of the instrument should be controlled at 60 minutes, which its also its default setting (an can be adjusted by the user). After 60 minutes, the instrument will automatically enter the next system calibration. In case of an emergency, operators can directly press the "Stop" button at the bottom of the screen. As shown in the figure above.

Attention: When the instrument has not been used for a long time (e.g., about a week) or the electrode test results are unstable, the activation time should be set to 60-120 minutes or longer.

2.2 Activation of models without a sample tray

The operator should lift the sampling needle, take a small test tube and fill it with an appropriate amount of activation solution. Then insert the sampling needle--the instrument will automatically suck in (Note that during the sampling process, the head of the sampling needle should not be exposed above the liquid surface to avoid inhaling air). After the buzzer sounds to prompt the removal the test solution, please remove the test tube, and the instrument will automatically suck the activation solution into the electrode (At this time, the operator should ensure that all electrodes are completely immersed in the activation solution, and it is perferable to control the solution level on both sides of the electrode holder at around 2 centimeters);

The operator may adjust the activation time based on actual situations. The instrument has a predetermined activation time of 60 minutes, and the operator may also press the "Stop" button to advance to the next "system calibration".

Subsection 5.2 Reagent Kit Card Swiping

When the system prompts that the remaining times of the IC card are insufficient during sample testing, replace the reagent kit. The following introduces the method for replacing the reagent kit, e.g., the card swiping operation.

Firstly, two concepts are defined as follows:

◆"Card Writing" refers to writing special information into the IC card, which is usually done

by the manufacturer.

◆"Card Swiping" refers to reading the information stored in the IC card and can determine whether the read information is correct. This operation is usually performed by the user.

When the instrument leaves the factory, the remaining times information of the internal reagent kit is cleared to zero. However, although calibration or system settings can be performed, the instrument cannot test actual patient samples. At this time, the reagent kit must be installed and the first card swiping operation performed to activate the reagent kit with 350 remaining uses.. You can performed the card swiping operation in the "Maintenance" → "Replace Reagent" menu. In addition, the system will display a corresponding prompt to replace reagent kit when it prompts that the remaining times of the reagent kit are less than 5 during sample testing, or when the remaining times of the reagent kit are found to be zero at start up.

For example, when swiping the card in the "Maintenance" → "Reagent Replacement" menu, first insert the reagent pack into the instrument, ensuring that the reagent kit is fully inserted, then click the "Confirm" button as prompted by the menu. If it is a valid IC card, the screen will display “350 remaining uses”.At this time, clicking the "Confirm" button will enter the cleaning interface and aspirate the reagent from the reagent kit to the distribution valve to complete the card swiping operation. You can check the reagent kit’s remaining uses (350 times) in the "Manufacturer Settings" → "Advanced Settings" menu.

After a period of use, If the remaining times of the reagent kit uses are displayed as less than 50, you can still swipe the same IC card again to reset the remaining uses to 50. However, the card will be invalidated after this swipe. Therefore, theoretically, one IC card can support up to 400 samples tests.

If any problems occur during actual card swiping, please refer to the following:

If “IC Card Search Failed” is displayed, it means that the IC card is not detected at all. There are three possibilities:

◆There is no IC card in the reagent kit.

◆The IC card inside the reagent kit may malfunctioned due to soaking from water leakage of the waste liquid package.

◆The RF IC card inside the instrument is damaged or not working.

If the IC card is detected successfully, but the "Verify Password" or "Read Information" fails, it means:

◆This is an IC card that was not written with correct encrypted information at the factory.

◆This is not a card supplied by our company, and may be a counterfeit card.

If all the above are normal and but “Region Code Error” is displayed, it means:

◆This is an IC card that was not written with the correct region code at the factory.

◆The region code of the instrument is not set correctly and does not match the one in the IC card. In this case, adjust the instrument’s region code accordingly.

Subsection 5.3 Instrument Maintenance

It is necessary to maintain the instrument to ensure it remains in good working condition at

all times.

The following points should be noted during maintenance:

1. Assign a dedicated person to maintain the instrument..

2. The designated maintenance personnel of the instrument should emphasize the importance of maintenance to all users of in daily operations.

3. The responsibilities of the designated maintenance personnel are as follows:

3.1 Storage of commonly used spare parts and consumables.

3.2 Recording the condition of the instrument, this record facilitates the company's future after-sales service for the customer.

3.3 Be responsible for telephone contact with the manufacturer.

Subsection 5.4 Daily Maintenance

1. It is recommended to remove the pump tubes after shutting down the instrument every day to prevent them from sticking together; if the instrument is turned on for 24 hours, there is no need to remove the pump tubes.

2. Regularly check the levels of Drift Calibration Solution A, Slope Calibration Solution B, and carbon dioxide cleaning solution.

3. Check the pipeline and liquid flow system to ensure they are unobstructed. If a blockage is found, refer to the second item of User Troubleshooting.

4. Disinfect the sampling needle and waste liquid tube daily. As there is a risk of skin contact with finger during sampling and waste disposal. Please wear protective gloves.

5. Empty the waste container every day, dispose of the liquid waste according to the "Medical Waste Management Measures", and clean and disinfect the waste container.

5.1 Disinfect the sampling needle and waste tube daily (e.g., with alcohol). During sampling and liquid waste disposal, there is a risk of contact with skin on the figures. Please wear protective gloves.

5.2 Empty the waste container every day, dispose of the liquid waste according to the "Medical Waste Management Measures", and clean and disinfect the liquid waste container.

Subsection 5.5 Weekly Maintenance

1. Check the measurement cell once a week and remove dried solutions and sample residues to keep the measurement chamber clean.

2. Check the level of the internal filling solution in the reference electrode. Ensure the Ag/AgCl internal reference electrode is always immersed in the filling solution. If a decrease in the filling solution is found, add more via the small hole at the upper right of the reference electrode using a syringe, while ensuring the small hole is unobstructed.

3. If the grounding wire is connected to a water pipe, check it weekly to ensure it is securely connected (no loosening or detachment).

4. Run the electrode deproteinization program in the service program weekly, and perform deproteinization once using enzymatic deproteinization solution (electrode cleaning solution (protease)+electrode cleaning solution (protease solution)).

Subsection 5.6 Maintenance of Main Components

1. All tubing on the instrument should be removed, soaked in distilled water, and then thoroughly at least every two months.

2. When the internal filling solution of the reference electrode becomes turbid, the internal filling solution should be replaced; replace the reference electrode if necessary.

3. Regularly check the internal filling solution of electrodes (including potassium, sodium, chloride, calcium pH, lithium, magnesium, etc.) If the liquid level of the internal filling solution is lower than the silver rod of the electrode or the solution is turbid, add internal electrode filling solution (for ordinary electrodes) in a timely manner or replace the corresponding electrode.

4. Requirements for factory repair and transportation: The main unit should be cushioned with shock-absorbing foam and packaged (no reagents include inside). The transportation environment should be 0-40 ℃ with relative humidity below 80%. Handle the unit gently; It must not be inverted.

5. If the instrument is out of used for a long time or needs to be transported, please thoroughly disinfect and clean its external casing before storing or transporting the instrument.

Subsection 5.7 Precautions

1. During operation

1.1 During sample aspiration, be careful not to aspirate blood clots to avoid blocking the tubing.

1.2 When aspirating samples, do not aspirate air bubbles, as this will lead to unreliable measurement results.

1.3 Do not use solutions with mold, turbidity, or precipitation. If found, discard them immediately..

1.4 If 10-15 samples have been tested, or if no measurement have been taken for a long time after calibration, recalibrated the instrument.

1.5 After dispensing any reagent, tighten the bottle caps immediately to avoid leaving the cap off for a long time.

2. During Quality Control Calibration

Before performing quality control calibration, it is essential to ensure the instrument is stably calibrated. It is strictly prohibited to use flame photometer standard solutions as samples for measurement, as they contain concentrated acids and other additives which cannot be measured by the ion-selective electrode (ISE) method--this will cause electrode poisoning. Not all commercially available quality control sera are suitable for ISE measurements: Some manufacturers' quality control sera contain excessive additives that can interfere with ion-selective electrodes (especially the determination of chloride (Cl^-)). If the ambient temperature changes by more than 10℃, recalibration is required.

3. Environmental Requirements

Ensure proper grounding. Ensure stable voltage--it is recommended to connect to a UPS or a regulated power supply. The instrument should be kept away from high-power equipment to avoid electromagnetic interference (EMI) being introduced. Protect the instrument from direct sunlight.

4. During Maintenance

If the tubing or electrode become blocked, remove the pump tubes and use a syringe (with the needle removed and replaced it with a hose) to aspirate distilled water for reverse flushing, allowing water to flow out from the sampling needle. It is strictly prohibited to use hypodermic needles to pierce the electrode membrane, as this will damage the electrodes. If the electrodes are not used for an extended period, rinse the residual solution inside the electrode membrane with distilled water and store it in a sealed container. Daily activation of the electrodes is recommended.

5. Sample Collection and Handling

Sample collection and handling must be completed by qualified personnel to avoid hemolysis, which can affect measurement results. Additionally, the following precautions apply:

Whole Blood Sample:

Whole blood samples must be anticoagulated with sodium heparin or lithium heparin,, as other anticoagulants may cause measurement errors.

Test tubes and syringes pretreated with heparin anticoagulant must be evenly coated with no dead spaces, to avoid residual sodium leading to a significant increase in sodium level in the results.

Whole blood samples must be analyzed promptly and completed within one hour of collection to prevent errors caused by sample degradation. After measurement, the tubing should be cleaned immediately.

Serum and Plasma Samples:

Refrigerated serum and plasma can be used for analysis but must be brought to room temperature prior to testing.

When preparing serum samples, do not add substances that could affect measurement accuracy (such as surfactants and anticoagulants), as these substances can interfere with testing or even damage the sensors. Refer to Appendix 3 for details.

Urine Sample:

Urine sample must be diluted 10-fold (1:9) with urine diluent prior to measurement.

Boric acid is recommended as a preservative for urine samples to prevent interference from other preservatives in measurements.

Chapter 3 Troubleshooting

1. How to resolve detector failure?

The main causes of detector failure are:

1.1 Detector Faults

A The detector plug is loose in the mainboard socket.

B The detector itself is faulty.

1.2 Value Faults:

C The set screw securing the valve core to the motor shaft is not tightened to specification.

D The valve core itself is too tight to rotate.

Once the causes are identified, the corresponding solution can be implemented, in the following inspection order:

C ⟶ A ⟶ D ⟶ B

If it is a model with an automatic sample tray:

1.3 Tray Malfunction Causes

A The securing screw in the middle of the tray is loose, it should be tightened now.

B If the tray rotates too tightly, check for obstructions and prevent debrits from entering the bottom of the tray.

C The detector inside the tray is broken.

1.4 Sampling needle malfunction cause: The position limit switch is not fully depressed. Adjust the limit switch to its proper position.

Once the cause is identified, troubleshoot and resolve it step by step. If necessary, contact our company for assistance.

2. Causes and Troubleshooting for Poor Sample Aspiration

If a sample aspiration fails, perform a stepwise inspection starting from the pump tube and moving forward along the fluid path to identify the exact location of the blockage among the following components:

2.1 Check if the pump tubes are stuck together, have air leakage, or are excessively worn. Stuck pump tubes will produce abnormal noise; If the tubes are excessively worn, remove the pump tubes and manipulate them, or replace the tubes with new ones.

2.2 Check that the tubing at all connections (including between electrode and valves, and between electrode and the pump tubes) is properly connected. If the tubing or electrodes are clogged, remove the pump tubes and use a syringe (with the needle removed and replaced with a hose) to aspirate distilled water for reverse flushing, directing water to flow out from the sampling needle.

Warning It is strictly prohibited to use hypodermic needles to pierce the electrode membrane, as this will damage the electrodes.

2.3 Another important reason for unsmooth sample aspiration is protein deposits in the tubing, especially at connections. Even with new pump tube, the issue may persist; to resolve it, disconnect all connections and clean them thoroughly with water.

2.4 Distribution valve: A clogged distribution valve may result from precipitates in the reagent. This can occur when reagents have been opened and stored at room temperature for an extended period (e.g., 2-3months), typically in workflows with low testing volumes.

Solution: Place the sampling tubing of A and B calibration solutions in an empty bottle. Take a syringe,, remove the needle, and attach a section of rubber tubing to the liquid outlet at the front of center of the distribution valve. Filled the syringe with distilled water, then turn on the instrument. Inject the distilled water while the system is flushing and rotating the distribution valve. The distilled water will flow into the liquid waste container through the A and B calibration tubing respectively. Repeat this operation for repeated cleaning. Finally, replace the reagent. On the electrode holder, there is a stainless steel tube in front of the potassium (K) electrode, and the small hole on it can be directly unclogged with a needle.

2.5 Electrode: Electrode Blockage caused by Hemoglobin Accumulation.

Solution: Remove the electrodes and inspect them one by one to identify the clogged one(s). First, use a syringe (fitted with rubber tubing, no needle) to draw the "protein removal solution (electrode cleaning solution (protease)+electrode cleaning solution (protease solution))" then inject it into the clogged electrodes for soaking. After approximately 3 minutes, rinse the electrode(s) thoroughly with distilled water.

3. Reasons and Solutions for Electrode Drift

3.1 The small hole on the upper right side of the reference electrode is blocked by salt. Use a needle tip to poke open the small hole.

3.2 There are bubbles in the electrode chamber, apply force to shake off the bubbles.

3.3 If there is too little liquid filling in the electrode and the silver rod cannot be touched and sensed, the electrode filling liquid should be added.

3.4 The internal filling solution is overfilled. It must not exceed the 2/3 to 3/4 level of the electrode chamber..

3.5 If the coating on the silver wire inside the reference electrode peels off or turns white, replace the silver wire or the entire reference electrode.

3.6 The most common reason of electrode drift is an improperly connected or faulty ground wire. In this case, have a qualified electrician check the grounding connection.

3.7 Check if the drifting electrode gold plating head is free of dirt or oxide film.

3.8 If the voltage is unstable, it is best to connect to a UPS uninterruptible power supply or a high-quality regulated power supply (poor quality regulated power supplies can cause electrode drift).

3.9 To avoid electromagnetic interference, high-power equipment should be kept as far away as possible from this instrument and have an independent power supply.

3. 10 Check if the calibration solution has been used up.

3.11 If all electrodes drift, check whether the reference electrode has expired or if there are bubbles at the reference film, and apply force to eject them.

3.12 If all calibration values show 204, it is usually due to bubbles in the contact area between the reference electrode and the test solution (some bubbles are very small and difficult to distinguish). At this time, please remove the reference electrode and use your fingers to bounce the bottom of the reference electrode (below the silver rod), repeating this process multiple times.

3. 13 If reagents are expired or contaminated, check calibration solutions A and B for flocculates.

3. 14 After the electrodes have undergone deproteinization treatment, or if the instrument has not been calibrated for an extended period, the first self-test may become unstable. At this time, activate the instrument for 1~2 hours before performing calibration..

4.How to Address a Decrease in Electrode Slope?

A low electrode slope will lead to poor test linearity may also affect electrode repeatability. The main causes are:

4.1 Excessive protein adsorption on the electrode membrane;

4.2 Low temperature or high humidity;

4.3 The electrode is approaching the end of its service life..

In the third scenario, the electrode needs to be replaced. For the first scenario, use the protein

removal solution (electrode cleaning solution (protease)+electrode cleaning solution (protease solution)) for treatment. For the second scenario, if the ambient humidity is too high, use a dehumidifier to reduce humidity; if the temperature is too low, increase the indoor temperature. If neither of these conditions is available,heat and dehumidify the measuring cell with a hair dryer prior to measurement.

Warning Depletion of Calibration Solution A or B, leakage of the reference electrode internal solution, or aging of reference electrode can cause low slope in some or all electrodes. If the low slope is due to these causes, the electrodes themselves are not faulty..

5. Common Clogging Points of the Instrument

5.1 Distribution Valve: Refer to Section (2), Item (4) of the “Troubleshooting” chapter in this manual for details.

5.2 Electrode: Electrode blockage caused by hemoglobin accumulation.

Solution: Remove the electrodes and inspect them one by one to identify the clogged one(s). First, use a syringe (fitted with rubber tubing, no needle) to draw the "protein removal solution (electrode cleaning solution (protease)+electrode cleaning solution (protease solution))" then inject it into the clogged electrodes for soaking. After approximately 3 minutes, rinse the electrode(s) thoroughly with distilled water.

5.3 Tubing or Sampling Needle Blockage: Also caused by protein accumulation or aspiration of clotted blood..

Solution: Rinse thoroughly with distilled water.

6. Abnormal Blood Sample Test Results: Causes and Troubleshooting

When testing blood samples, if abnormal values appear, follow the steps below to check:

6.1 Check if high-power electrical appliances (e.g., centrifuges, refrigerators) are operating or leaking electricity, which may cause voltage fluctuations.

6.2 Clotted blood is aspirated during testing..

6.3 Check if the blood sample container is contaminated or if there are residual disinfectants or other substances.

6.4 Verify that the calibration factor is correct. If abnormalities are detected, clear the calibration factor.

6.5 If the instrument has not been calibrated for an extended period, recalibrate it before retesting.

7. Function and Assembly of Reference Electrode

The reference electrode serves to provide a standard potential for other electrodes in the instrument. If the reference electrode is unstable, all electrodes will become unstable. After a period of use, the saturated potassium chloride inside the reference electrode will gradually permeate outward, causing the reference electrode internal solution to decrease over time. Once a reduction in the reference electrode internal solution is detected, replenish it immediately..

Refilling the Reference Electrode Internal Solution::

7.1 Using a syringe, draw up the reference electrode internal solution and inject it into the small hole on the upper right side of the electrode until the chamber is approximately half full (Do not overfill);

7.2 Perform regular checks to prevent the small hole from becoming clogged with salt crystals.

7.3 If all calibration values display “204”, this is usually caused by bubbles in the reference membrane- the contact area between the reference electrode and the test solution. Some bubbles are very small and hard to detect. In this case, remove the reference electrode and tap the bottom end firmly (below the silver rod) with your fingers, repeating the process several times.

7.4 Inspect the reference electrode regularly. If salt crystals are found on the outer casing, wipe them clean immediately; otherwise, unstable measurement may occur.

8. Explanation of the Relationship between Ionic Calcium (also known as Free Ionic Calcium), Standard Ionic Calcium, Total Calcium, and pH.

The composition of serum is highly complex, containing large amounts of proteins, citrate, and other substances. These components can bind with calcium (Ca) ions to form complex calcium. Complex calcium has no physiological activity, and the standard for regulating calcium balance in the human body is ionic calcium rather than total calcium. However, due to limitations in measurement methods, titration and colorimetric methods are still widely used for total calcium determination. In recent years, with the development of ion-selective electrodes, the determination of ionized calcium has become simple and accurate. Internationally, the ion-selective electrode method is gradually replacing traditional titration and colorimetric methods.

The relationship between total calcium, ionized calcium, and complexed calcium is as follows:

TCa (total calcium)=nCa (ionized calcium)+complexed calcium

The ion calcium value in human serum at pH 7.40 is defined as nCa (standard ion calcium).

Under this condition, TCa ≈ 2nCa

After serum separation, as time elapses and due to centrifugation,, carbon dioxide in the serum escapes, causing the pH value to increases and the ionized calcium to decreases.

The pH displayed on the instrument screen is the measured pH value (usually higher due to carbon dioxide escape). The standard ionic calcium value (nCa) (which can be regarded as the calcium ions in the human body) is then calculated using a formula. Since the measured ionic calcium has no clinical significance, nCa is the primary basis for clinical diagnosis.

When running the serum measurement program, the displayed result is nCa. The printed report includes iCa, nCa, and TCa, where nCa is suitable for clinical diagnostic, and iCa and TCa are for user reference in serum testing.

Due to the irregular escape of carbon dioxide, pH is generally only for reference in serum measurements, and its primary function is to calibrate calcium (Ca) ions. However, when performing aqueous quality control or testing other non-serum samples, there is no issue of carbon dioxide escape. In such cases, refer to the iCa value and the pH displayed on the instrument screen.

9. Precautions for the CO_2 Module

9.1 The calibration values of CO_2 and the correction factors for K, Na, Cl, and Ca retained in the instrument after shutdown, but will not be stored if the battery is depleted. Therefore, perform CO_2 calibration when the battery is depleted or CO_2 test results are abnormal.

9.2 If CO_2 test results are abnormal, follow these steps to check:

a. Recalibrate CO_2. If test results remian incorrect after calibration, proceed with the following

checks:;

b. The four insertion tubes or the waste liquid tube on the CO_2 reaction cell are not properly connected,, causing air leakage;

c. Verify if the CO_2 cleaning solution pump tube is installed backwards.

d. Check if the CO_2 cleaning solution exhausted When replacing theCO_2 cleaning solution, do not wait until it is completely depletely before refilling. If the CO_2 cleaning solution has been fully exhausted, manually rotate the pump head to fill the pump tube with reaction solution. Otherwise, the pump tube will be empty for the first few tests, preventing the reaction solution from being delivered and resulting in incorrect CO_2 values (this does not effect the determination ofK, Na, Cl, Ca, or pH).

e. If there is still a deviation from the standard CO_2 quality control material, calculate the correction factor and enter it in the CO_2 calibration program. If 1.2 entered, all subsequent measurement values will be multiplied by 1.2 automatically.. The correction factor is stored in the instrument once entered and does not need to be re-entered after power-on.

9.3 When sampling, be sure not to aspirate clotted blood. Otherwise, it will cause deviations in CO_2 values and affect subsequent measurements. If CO_2 test results are abnormal with poor repeatability, clean the entire tubing and reaction cell using the protein removal solution (electrode cleaning solution (protease)+electrode cleaning solution (protease solution)) via the “Tubing Cleaning” program..

9.4 The reference value of Drift Calibration Solution A (CO_2 standard 1) is: 30 ± 5mmol/L;
The reference value of Slope Calibration Solution B (CO_2 standard 2) is: 18 ± 5mmol/L.

10. Common Issues with the CO_2 Module

10.1 If the daily sample volume is small and no emergency test are required, it is recommended to remove the upper and lower pump tubes, especially the lower pump tube, after shutting down the instrument each day. The upper and lower pump tubes are tightly tensioned to serve a sealing function. Prolonged inactivity can accelerate pump tube aging and adhesion — particularly for the pump tube used to deliver CO_2 cleaning solution. This will result in insufficient delivery of CO_2 cleaning solution, leading to low CO_2 test results. However, if the instrument operates 24 hours, there is no need to remove the pump tubes. (When reinstalling the pump tubes, do not reverse their direction; otherwise, the instrument will fail to aspirate samples.)

11.2 Recalibrate CO_2 every 1-3 days to ensure the accuracy and reliablity of CO_2 test results.

11.3 Low CO_2 Test Reuslts: Caused by the adhesion of the CO_2 cleaning solution pump tube, resulting in insufficient delivery of the CO_2 cleaning solution.

Solution: First, remove the pump tube and pinch open the adhered section. Reinstall the pump tube, then manually rotate the CO_2 cleaning solution pump head to aspirate the "CO_2 cleaning solution" until it drips into the reaction cell.

11.4 High CO_2 Test Results: May be caused by prolonged failure to recalibrate.

Solution: Recalibrate CO_2.

12. Touch Screen Malfunctions

Solutions：

a. Loosen the display screen mounting screws slightly--do not overtighten them;

b. Access the manufacturer's maintenance menu, then click on the "Screen Calibration" option

to calibrate the touch screen.

Warning The normal service life of this analyzer is 8 years. If the instrument exceeds its service life and is scrapped, it must be disposed of in accordance with relevant laws and regulations--arbitrary disposal is prohibited. Users must read this manual carefully and operate this instrument strictly in accordance with the manufacturer's specified procedures, using only original electrodes and reagents. Otherwise, the user shall bear full responsibility for any adverse consequences arising therefrom!

Chapter 4 Packaging and Storage

1. Requirements for Transportation and Storage Environment

During transportation, the equipment shall be protected from rain, snow, and mechanical impact. It must not be packed or transported together with corrosive substances.

The storage warehouse for the equipment shall be dry, with an ambient temperature of -20℃ to +55℃ and a relative humidity not exceeding 80% (at 20℃). The indoor environment shall be well-ventilated, free from direct strong sunlight and other corrosive gases.

2. Transportation

Transportation environment requirements: Temperature 0℃~+40℃, relative humidity not exceeding 80%, atmospheric pressure 86kPa~106kPa. These requirements also apply to the instrument when being shipped back to the factory.

The markings on the equipment’s packaging box comply with GB/T191-2008 "Pictorial Markings for Packaging, Storage and Transportation". The box is equipped with simple shockproof facilities, suitable for air, railway, road and sea transportation. It shall be protected from rain, snow, inversion, and impact.

3. Storage

If the equipment is stored for more than 6 months, it shall be removed from the packaging box, powered on for 4 hours, and then reloaded into the box in the direction indicated on the packaging. The boxed equipment shall be stored in the warehouse—do not stack multiple units, and do not place them against the ground, walls, or ceiling.

The storage area shall be well-ventilated, protected from direct strong sunlight and corrosion by corrosive gases.

Chapter 5 Appendix

Appendix 1 How to Perform External Quality Control Effectively

What is the function of quality control calibration? How to conduct effective external quality control?

The instrument, electrodes, and reagents are fully calibrated and tested before leaving the factory. However, during user operation, external quality control requires the use of the quality control calibration program if deviations (either high or low),occur due to changes in ambient temperature, humidity, voltage, or quality control standards, or as a result of electrode drift after prolonged use.

Firstly, obtain two levels of assayed quality control material (high and low target values) from the same manufacturer as the external quality control materials. Calibrate the materials before use and allow the electrodes to stabilize. Then enter the calibration program, input the target values of the two different batches into the instrument, and test the two reference materials. The program will exit automatically, and the calibration factors will be applied to subsequent blood sample measurements.

Using the calibration programs, users can achieve favorable results in provincial and municipal quality control assessments. The specific method is as follows: Select known assayed quality control materials (with the same manufacturer and type as the unknown quality control samples issued by the superior authority) for quality control calibration, then test unknown quality control samples to be inspected. (Assayed quality control materials from different manufacturers are incompatible with each other, and cross-testing may sometimes result in significant errors. Therefore, it is necessary to use homogeneous quality control materials for calibration.)

Attention The quality control serum is prepared by freeze-drying processed porcine or human serum, and it often contains added ionized calcium and preservatives. It differs significantly from normal human serum. Therefore, the standard ionized calcium (nCa) measured by the instrument does not comply with the proportion relationship TCa ≈ 2nCa. Additionally, this proportional relationship varies among of different batches of quality control serum. Therefore, total calcium (TCa) cannot be converted from ionized calcium using quality control serum.

Specific Calibration Procedures:

1. Optimize the instrument to its optimal performance

Step 1: Clean and activate the electrodes for one hour after powering on the instrument.

Step 2: Perform calibrate three to four times, record the mv values, and observe their variation. If the mv difference between two consecutive Calibration Solution A tests and two consecutive Calibration Solution B tests is less than 0.5 (excluding pH), the electrodes are stable and you can proceed to the next step. If the mv difference exceeds 0.5 (excluding pH), the electrodes are unstable--repeat the steps for protein removal, activation, and calibration.

Step 3: After stable calibration, run the IMS-972Plus random quality control 1-2 times and check the repeatability. If repeatability is satisfactory, proceed to the next step. If not, recalibrate the instrument and inspect it for issues.

2. Assess the "Two Point Calibration" program: Immediately perform a quality control calibration using assayed quality control materials with known target values (from the same manufacturer as the external quality control materials). It is recommended to start with the assayed quality control material with the target value.

3. Immediately perform Quality Control 2 Calibration using another assayed quality control material with a known target value (high level).

4. Next, in the "Analysis Serum" mode: first run one IMS-972Plus random quality control test, then test the external quality control sample with an unknown target value. Finally, run one test each for the low-level and high-level assayed quality control materials. Analyze all results collectively:. If the final two tests of the low-level and high-level assayed quality control materials are well within the target range, the result of the unknown external quality control

sample is deemed reliable. If the two assayed quality control tests are not within the target range, reactivate the electrodes, recalibrate until stable, perform the two-point calibration again, and repeat the above steps. Only when the certified reference material tests are fully within the target range can the result of the unknown EQC sample be confirmed as reliable.

5. If there are multiple unknown external quality controls samples, recalibrated twice first, then test them one by one following Step 2, 3, and 4.Note: Do not test all unknown external quality control samples at once after a single calibration. Instead, perform the two-point calibration, test only one type of unknown external quality control sample, then recalibrate and (and re-perform the two-point calibration) before testing the second type. Repeat this process until all samples are completed — this ensures the reliability of each result.

Attention Precautions

1. Assayed quality control materials with known target values (for calibration) and external quality control materials must be from the same manufacturer to ensure accurate results (Landau quality control materials are recommended for calibration).

2. If the assayed quality control material is for total calcium (TCa), the target value entered must be the TCa value divided by 2. After testing the TCa value, it is recommended to verify it using an alternative method. This is because the value measured by the instrument is ionized calcium (nCa). If the there is a significant pH difference between the two quality control materials (the assayed quality control material and the external quality control material) or if the proportion of added calcium ions differs, the calculated TCa value may be inaccurate.

3. Once the instrument has stabilized, immediately test the assayed quality control material and the external quality control material measurements must be performed immediately without any interruption in between.

4. When analyzing only patient serum samples routinely, a single-point calibration can be adopted, which requires only one type of assayed quality control material.

5. If the measured value for a quality control material shows instability (typically with chloride, Cl^-), this is often caused by the presence of antimicrobial agents (e.g., gentamicin, etc.) in the material. Which can significantly interfere with the chloride-selective electrode. In such cases, the measurement should be verified using an alternative method (e.g., biochemical assay).

Precautions for Use

1. Avoid direct sunlight and do not install on ventilation outlet. As sunlight may affect the accuracy of optocoupler's detection.

2. Place the instrument on a stable, vibration-free platform, and keep it as far away as possible from potential sources of electromagnetic interference.

3. Strictly follow the prescribed shutdown procedure to ensure that no reagents or samples in the tubing or electrode chamber after shutdown.

4. After blood collection, allow the sample to stand at room temperature for 15 minutes and centrifuge at 3000r/min (with a centrifugal radius of 20cm) for 10 minutes. The serum volume obtained must not be less than 150μL.

5. When a reagent kit is depleted, it should be promptly removed and replaced with a new

one. Ensure the barcode card is scanned prior to replacement.

6. Urine samples must be dilute tenfold with urine diluent (1:9 ratio) prior to testing. It is recommended to use boric acid as a preservative for the urine samples to avoid measurement interference from other types of preservatives.

7. Keep the filling hole at the upper right corner of the reference electrode clear to prevent blockage by salt crystallization. Promptly replenish the reference electrode internal solution when its level is low, maintaining it between 2/3~3/4 of the chamber volume. During operation, replace the reference electrode internal solution at regular intervals to prevent cloudiness.

8. Adhere strictly to reagent expiration dates. The use of expired reagents is strictly prohibited.

Appendix 2 Electromagnetic Compatibility

⚠Attention：

The IMS-972Plus series products comply with the emission and immunity requirements specified in this section of GB/T18268.26, as shown in the table below.

- This equipment is designed and tested in accordance with the Class A specifications of GB4824. In a residential environment, this device may cause radio interference and protective measures need to be taken.
- It is recommended to evaluate the electromagnetic environment before operating the equipment.

⚠Warning：

Do not operate this device near strong radiation sources (such as unshielded RF sources), as it may interfere with normal operation.

Table 1

Electromagnetic launch		
Launch Test	**Basic Standards**	**Compliance**
Radiated Emission (RE)	GB4824	Group 1
Radiated Emission (RE)	GB4824	Class A
Harmonic Emission (Harmonic)	GB17625. 1	Not Applicable
Voltage Fluctuation/Flicker Emission（Flicker）	GB17625.2	Not Applicable

Table 2

Electromagnetic immunity			
Immunity Test Item	**Basic Standards**	**Test Value**	**Meets the Performance Criteria**
Electrostatic Discharge (ESD)	GB/T17626.2	Contact discharge：±2kV，±4kV Air discharge：±2kV，±4kV，±8kV	B
Radiofrequency Electromagnetic Fields	GB/T17626.3	3V/m，80MHz~2.0GHz，80%AM	A

(RS)			
Electric Fast Transient Pulse Train (EFT)	GB/T17626.4	Power Cord：±1kV (5/50ns，5kHz) Signal Line：±0.5kV(5/50ns，5kHz)	B
SURGE	GB/T17626.5	Line to Ground：±2kV Line to Line：±1kV	B
RF Conduction (CS)	GB/T17626.6	Power Cord：3V/m， 0.15MHz~80MHz，80%AM Signal Line：3V/m，0.15MHz~80MHz，80%AM	A
Voltage Dips, Short Interruptions (DIPS)	GB/T17626.11	1 cycle at 0% 5/6 cycles at 40% 25/30 cycles at 70% 250/300 cycles at 5%	B C C C

Performance Criteria：

A. During testing, performance remains normal within the specified limits.

B. During testing, functionality or performance degrades or is lost temporarily but recovers automatically.

C. During testing, functionality or performance degrades or is lost, and requires operator intervention or a system reset to recover.