Labotronics

Electrolyte Analyzer

LB-10ELA

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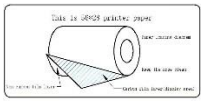
Index

1. Safety Measures

Various safety signs are utilized in this user manual and on the instrument to highlight important safety considerations during operation, as detailed in the table below:

Signs	Remark	Indication
	Biological risk	Used for sample injection probe and waste liquid drain. Indicates that there are potentialbiological risks associated with the medical device.
	Paper Installation Instructions	Install the paper according to the instructions; otherwise, the printer fails to print.
	Direction of rotation	Marked on the peristaltic pump, indicate its rotation direction. Install the pipeline in the direction described in the sign or the instrument may fail to work.
A	Drift correction solution A	Marked on the liquid distribution valve, indicating that the connecting line here isconnected to the A correction solution.
B	Slope correction solution B	Marked on the liquid distribution valve, indicating that the connecting line here isconnected to the B correction solution.
	Prevent dangers of moving parts	Marked on moving parts locations, indicate a potential danger to cause injury to personnel who are not trained or operate not according tothe instruction.
	Caution	When seeing this sign, the user must consult the manual to be aware of the potential danger and prepare. If not following the instructions, the protection function of the instrument wouldfail.
	Earthing protection	For the inner and outer earthing parts, kindly ensure that the instrument is well grounded.
	Upward	The package should be placed upwards.

Signs	Remark	Indication
	Fragile articles	Contents of the distribution packages are fragile therefore they should be handled with care.
	Non-waterproof	The package should avoid rain during transportation.
	Do not roll	The package shall not be rolled or turned over.
	Do not pile	No piling on the package.

Operation Precautions

1) During the sampling process, be careful not to suck up the blood clot to avoid clogging the tubing.
2) Do not draw air bubbles during the sampling process, otherwise the measurement results would be unreliable.
3) Do not use mildewed or cloudy solutions with precipitation.
4) Every time the number of samples reaches 15, or if there is no measurement for a long time after calibration, it needs to be re-calibrated.
5) After taking the solution, the bottle should be sealed immediately to avoid exposure tothe air for a long time.
6) This instrument must be operated by professional or trained personnel.
7) This instrument has no user-repairable components, so kindly do not disassemble it.
8) Ensure that the power supply environment and grounding environment of the instruments are good and stable.
9) Before performing QC, the instrument must be calibrated.
10) If the electrode membrane tube is blocked, use a needleless syringe to absorb distilled water and clean it from the opposite direction.
11) When the electrode is not used for a long time, it must be cleaned and sealed according to the requirements in Appendix D.
12) Do not use this instrument in places with high temperature, high humidity, imbalance, direct sunlight, or heavy dust.
13) To reduce the effects of the external environment on the data results, kindly keep the electrode cover and the front door closed during the data test.

2. Introduction

Electrolyte analyzer LB-10ELA is a benchtop unit with dual sampling mode (automatic and manual). The electrode shielding system aids in preventing external interference. Good stability and accurate results are achieved because of real-time detection of each electrode's working status. Accidental power-off protection and automatic fault diagnosis functions minimize errors.

3. Features

1. Linux operating system, 800 X 480 color LCD touchscreen
2. High-performance electrodes: high precision and wide linear range, with long shelf life (up to 12 months for Na, K and Cl electrodes)
3. Excellent electrode shielding system (good stability)
4. Real-time detection electrode (working status, eliminating electrode drift)
5. Bar-code scanner connectivity
6. Accidental power-off protection and automatic fault diagnosis function
7. High/low value calibrators
8. 3 levels of QC, automatic calibration of slope and intercept values, display of whole QC graphs
9. Environment-friendly: paper-based material reagent pack
10. Operational software can be upgraded through a USB port
11. Automatic liquid level detection
12. Real-time diagnostic (system status, reagent pack status information)
13. Test results storage - More than 100,000
14. Sample results review and printout sample ID Sample

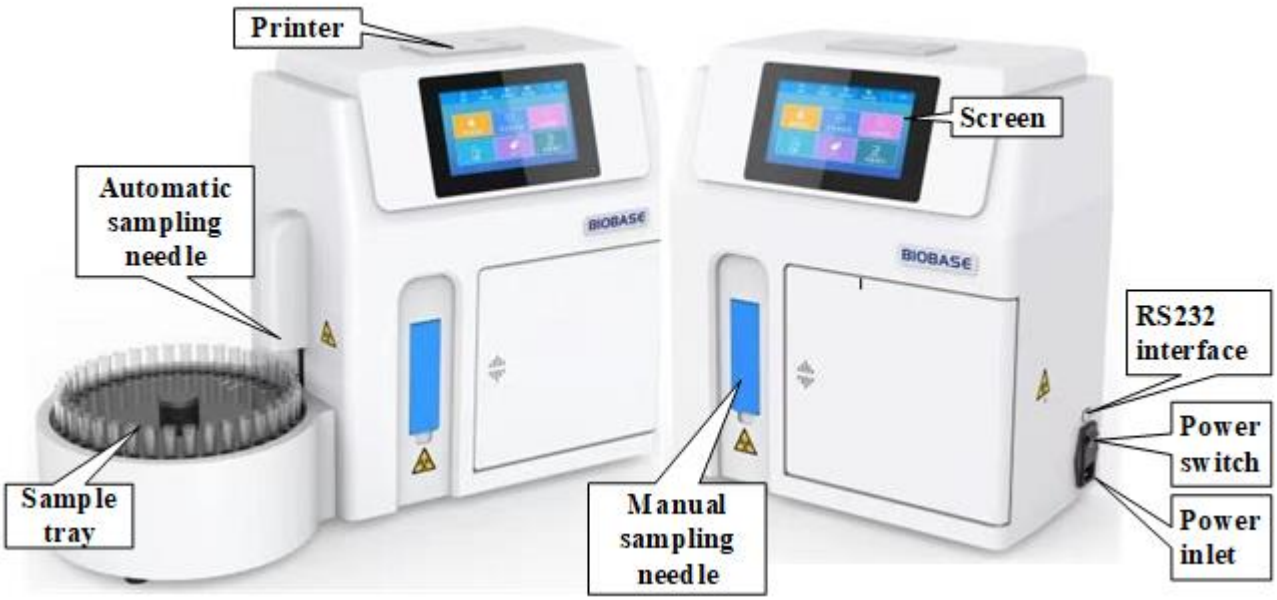
4. Specifications

Model No.	LB-10ELA
Sample	Whole blood, serum, plasma, diluted urine.
Sample volume	100 µL ~ 150 µL
Throughput	up to 60 samples/h
Measuring range	K+ - 0.50 mmol/L ~ 15.00 mmol/L
	Na+ - 30.0 mmol/L ~ 200.0 mmol/L
	Cl- - 30.0 mmol/L ~ 200.0 mmol/L
	Ca2+ - 0.10 mmol/L ~ 5.00 mmol/L
	pH - 4.0 ~ 9.50 (Unit)
	CO2 - 6.0 mmol/L ~ 50.0 mmol/L
Precision (CV%)	K+ ≤ 1.0 %
	Na+ ≤ 1.0 %
	Cl- ≤ 1.0 %
	Ca2+ ≤ 3.0 %
	pH ≤ 2.0 %
	CO2 ≤ 3.0%
Data storage	up to 200 patient result
Calibration	Automatic or On-demand
Input	Touch-screen
Display	Large LCD with backlight
Output	Internal thermal recorder
	RS-232 serial port
Working Environment Temperature:	15 °C ~ 32 °C
Relative humidity	0.85
Input voltage	AC 220V/ 110 V ±10%
	50 Hz / 60 Hz
Power consumption	60 W
Dimensions (H × W × D)	440× 380 ×350 mm
Main unit weight	10 kg
Auto sampler weight (optional)	1.5 kg

5. Applications

Electrolyte analyzers are used in hospital and reference laboratories to measure levels of K+ / Na+ / Cl- / Ca2+ / pH / CO2 in the human body.

6. Instrument Introduction



External Structure Diagram

6.1 Reagents

The Electrolyte analyzers require specific supporting reagents (ISE) for both their operation and maintenance. These reagents are essential for accurately analyzing the electrolyte content in blood and body fluids. The necessary reagents are detailed in the table below:

Name		Size	Function	Storage conditions & expiration date
Reagent for Electrolyte Analyzer (ISE)	Drift correction solution A	350mL	To assist the quantitative detection of Na^+,K^+, Cl^-, Ca^{2+} concentration and pH value inhuman serum and plasma samples.	• Reagents should be stored at 0℃~40℃in a non-corrosive gas environment from light. • Unopened reagents arevalid for 24 months and drift correction solution. • A Slope correction solution B, and correction solutions are valid for 30 days. Do not freeze reagents.
	Slope correction solution B	350mL		
	Reference solution	10mL		
	Filling solution in the electrode	3mL		
	Internal correction solution	100mL		
Electrode ActivationFluid		100mL	To maintain the electrode wake it up quickly and let the electrode reach the working state.	Stored at 0-40℃the validity period is 24 months, and it should not be mixed with

Cleaning Fluid E	100mL	For electrolyte analyzer line cleaning.	toxic, harmful, or corrosive substances and it is forbidden to freeze.
Electrode cleaning Fluid (protease)	25mg×5	Decomposition of proteins for cleaning and flushing of electrodes and pipelines.	Stored at room temperature, the validity period is 12 months, and it should not be mixed with toxic, harmful, or corrosive substances, and it is forbidden to freeze.
Drift correction solution (CO2 marked with 1)	100mL	It is used to quantitatively detect the concentration of CO2 in human serum and plasma samples.	This product is stored at 0-40℃valid for 24 months, shall not be mixed with toxic, harmful, and corrosive substances, and shall not be frozen.
Slope correction solution (CO2 marked with 2)	100mL		
Carbon dioxide acid cleaning solution	100mL		This product is stored at 0-40℃valid for 12 months, shall not be mixed with toxic, harmful, and corrosive substances, and shall not be frozen.

Notes:

- Electrolyte analyzer reagents are for in vitro diagnostic use only.
- Reagents can be refrigerated, but freezing is strictly prohibited.
- If it is taken outof the refrigerator, it should be placed for more than 30 minutes to turn it to theindoor temperature before it can be measured on the machine.
- All reagents should be used within the validity period.
- Some agents may hurt the skin. Kindly use it with care to prevent direct contact with the reagent with your hands or clothes.
- In case of accidental contact, kindly rinse immediately with soap and water.
- In case of accidental contact with eyes,rinse immediately with plenty of water and see a doctor.

7. Installation

7.1 Installation Requirements

1) The instrument should be kept away from equipment that may cause electromagnetic interference, otherwise, the electrode would drift during the calibration.
2) The platform on which the instrument is installed should be stable and even. Avoid direct sunlight and do not install it on the vent.
3) The ambient temperature is +10℃~+40℃,the relative humidity is 30%~80%, and the atmospheric pressure is 86kPa~106kPa.
4) The lab was better equipped with air conditioners and dehumidifiers.
5) The power supply is AC100-240V, 50/60Hz.
6) The lab was better equipped with aregulated power supply or UPS.
7) Do not place the instrument in a location where it is difficult to disconnect the device.

7.2 Power Requirements

- **Power supply**: AC100-240V, 50/60Hz.
- **Instrument power**: 70VA.
- The power socket needs to be well grounded (at least three available 5A sockets).
- Heavy-duty electrical equipment such as air conditioners, refrigerators, and ovens should be connected in the same socket.

7.3 Electromagnetic compatibility requirements

- The radiated and conducted emission of the electrolyte analyzer shall meet the requirementsof CISPR11 group I class A. Its immunity shall meet the requirements.
- The user should ensure the electromagnetic compatibility environment of the instrument so that can work properly. It is recommended to evaluate the electromagnetic environment before use.
- By the design and test according to Group Ⅰ Class A equipment in GB4824. In a domestic environment, this equipment may cause radio interference, requiring precautions.
- Do not use this instrument near strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the equipment's working.

Immunity Requirements

Port	Test item	EMC standards	Testing valve	Class
Enclosure port	Electrostatic discharge （ESD）	IEC 61000-4-2	**Air discharge:** ±2/4/8kV **Contact discharge:** ±2/4kV **Indirect discharge**: ±2/4kV	A
	Radiated electromagnetic fields	IEC 61000-4-3	**Frequency**:80MHz~2.0GHz **Level**: 3V/m **Modulation:** 80%AM@1kHz	A

Port	Test item	EMC standards	Testing valve	Class
	Rated power frequency magnetic field	IEC 61000-4-8	**Level**: 3A/m ,50Hz	A
AC power	Voltage sag	IEC 61000-4-11	0%,1 cycle 40%,5 cycle 70%,25 cycle	A A A
	Voltage interruption	IEC61000-4-11	5%,5s	C
	Burst	IEC 61000-4-4	**1kV**：(5/50ns ,5KHz)	A
	Surge	IEC 61000-4-5	**wire to ground:** ±2kV **wire to wire:** ±1kV	A
	RF conduction	IEC 61000-4-6	**Frequency:** 15kHz~80MHz **Level:** 3V **Modulation:**80%AM@1kHz	A

7.4 Work Environment Requirements:

1) Indoor use only.
2) Power supply voltage: AC100-240V, 50/60Hz.
3) The altitude does not exceed 2000m.
4) Ambient temperature: +10℃~+40℃
5) Relative humidity: 30％~80％.
6) The fluctuation of the power supply voltage is not more than ±10% of the nominal voltage.
7) Typical transient over voltages that appear on grid power.
8) Applicable rated pollution degree.
9) No abnormal noise equipment nearby.
10) The instrument complies with the emission and immunity requirements specified in GB/T18268.
11) It is forbidden to use this equipment near strong radiation sources (such as unshielded radio frequency sources), otherwise, it may interfere with the normal operation of the equipment.
12) Work in a well-grounded environment.

Warning:

- The instrument cannot guarantee normal operation and accurate results in environments other than those described above. If the temperature or humidity cannot meet the above requirements, kindly use the air conditioner and humidifier.
- The heat generated by the instrument would dissipate through the rear of the instrument. The working environment should be well-ventilated and ventilation equipment can be used if necessary. However, the airflow should be avoided from blowing directly to the instrument, otherwise, it may affect the accuracy of the instrument test.

7.5 Software operating environment requirements

- The software components of the electrolyte analyzer do not need to be connected to the internet, and the embedded software is programmed on the control board chip. The operating environment requirements are as follows:
- **Compile and control program software:** Keil uVision.
- **Version number:** V4.02
- **Software**: Keil
- **Control board main control chip**: STM32F207ZET6
- **Memory**: 25Q64FVF

Discharge of waste

Keep the instrument drain hole and pipeline installation unobstructed, and the instrument drain should be higher than the waste bottle mouth (or the waste liquid special discharge port), and the length of the waste pipe should not exceed 0.5m.

Biological Infection Hazard:

Dispose of the waste liquid by local discharge standards. When installing the drain pipeline, be sure to wear gloves, work clothes, and goggles, if necessary, to prevent infection.

Instrument Installation

Warning:

To ensure normal operation after installation, the first installation and initial setting should be performed by authorized personnel of the company.

Unpacking

After the instrument arrives, kindly check the packaging carefully to see if there is any damage. After confirming that the package is perfect, unpack it as follows:

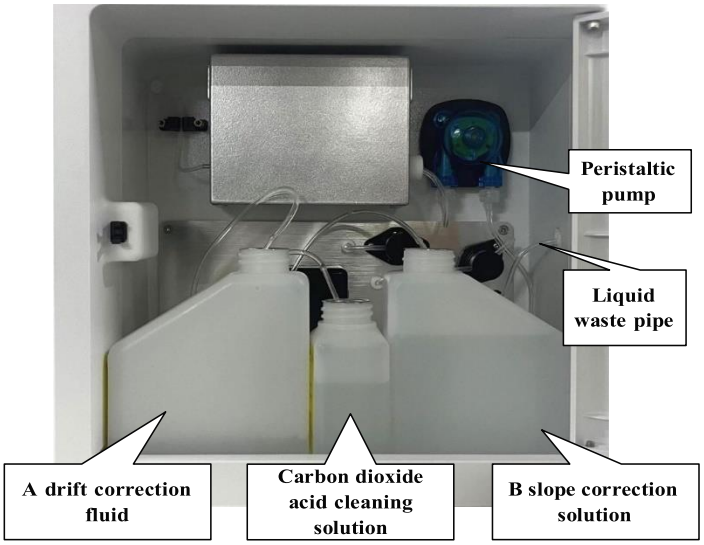
- Make sure the arrow on the box is upright.
- Check whether the accessories are complete against the packing list.
- Check the appearance of the instrument carefully to see if there is any damage to theparts caused by improper transportation.

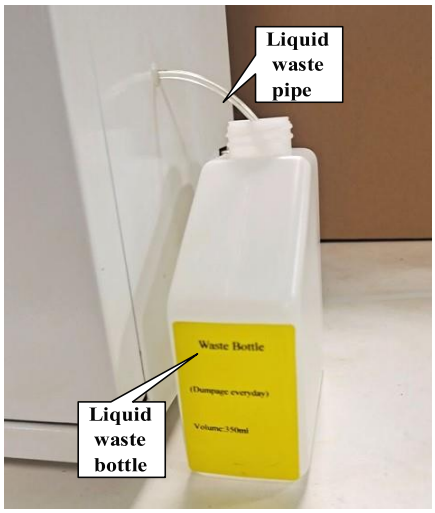
Move method

- Confirm that the appearance of the instrument is intact, and all parts are in goodcondition before carrying.
- During all moving and transportation, the instrument must be kept upright, notinclined or sideways.
- When carrying, try to avoid vibration. After carrying, you should check and debug it first, and then use the instrument after it is normal.

7.6 Installation Steps

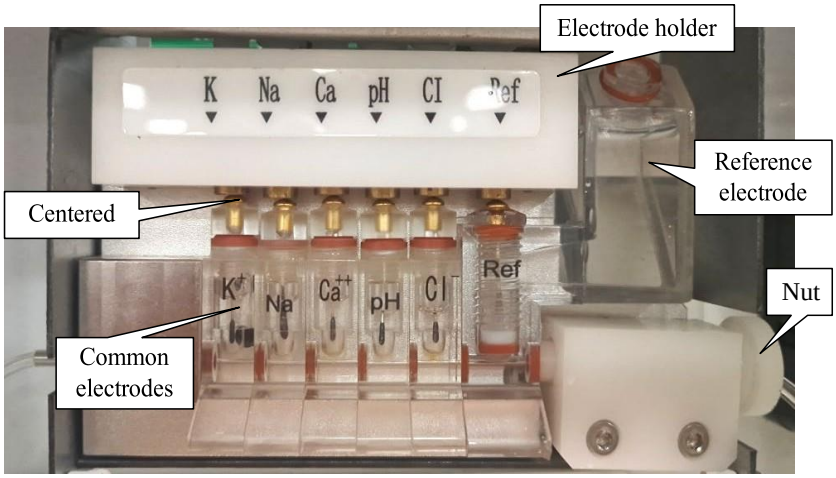
1) After unpacking and checking, place the instrument on a stable and even workbench.
2) Installation of solution and pipeline.
3) Take out the drift correction solution A and slope correction solution B.
4) Push the front doorof the instrument to open and insert the pipes marked A and B on the distribution valve intoeach bottle.
5) The sample pump tube of the carbon dioxide model should be put into a carbondioxide acid cleaning solution.
6) Place solution A and B bottles in the position shown in the picture.
7) The waste bottle is placed on the right side outside the instrument and the waste tube shown in the figure into the waste bottle.





8) Installation of the electrodes:

- Take out the electrodes and install them to the electrode holder in the order shown in the figure.
- After installing the electrodes, tighten the nuts shown in the figure to ensure that the electrodes are installed in the center properly and the electrode pipes are well sealed.

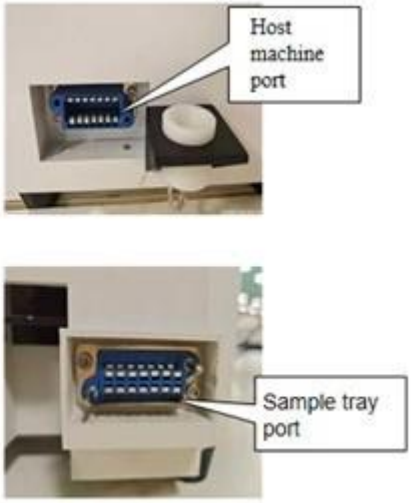


9) Power Connection

- Check whether the power supply is AC100-240V, 50/60Hz, and stable, if unstable, it should be connected to UPS or a good quality regulated power supply.
- Turn the instrument power switch off.
- Use the power cord to connect the instrument and the power socket and do not loosen it.
- The power socket must be well grounded.

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

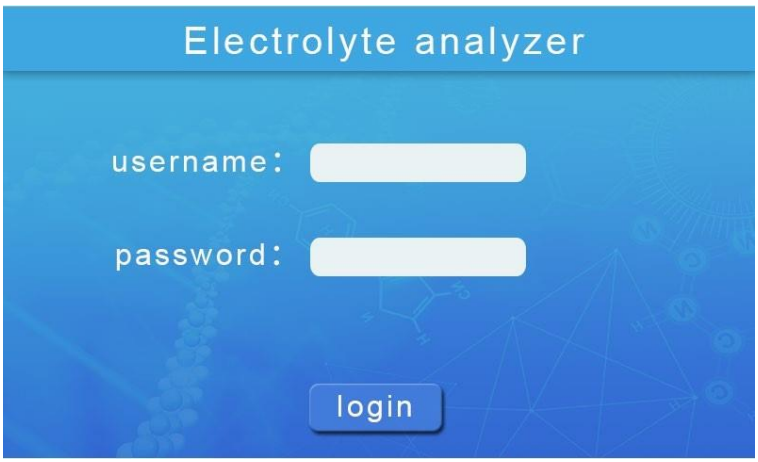
Confirm that the instrument and the sample tray are placed on the same level, align the two blue interfaces shown in the figure, and then insert them smoothly.


Host
machine
port
Sample tray
port

8. Operations

Software Operation

8.1 Power on



Input the username and password to log in (Default username: 111111, password: 1), the system automatically checks the communication connection of the power supply, memory, and printer, makes the internal circuit reach a thermally stable state and then the peristalticpump rotates to flush the system.

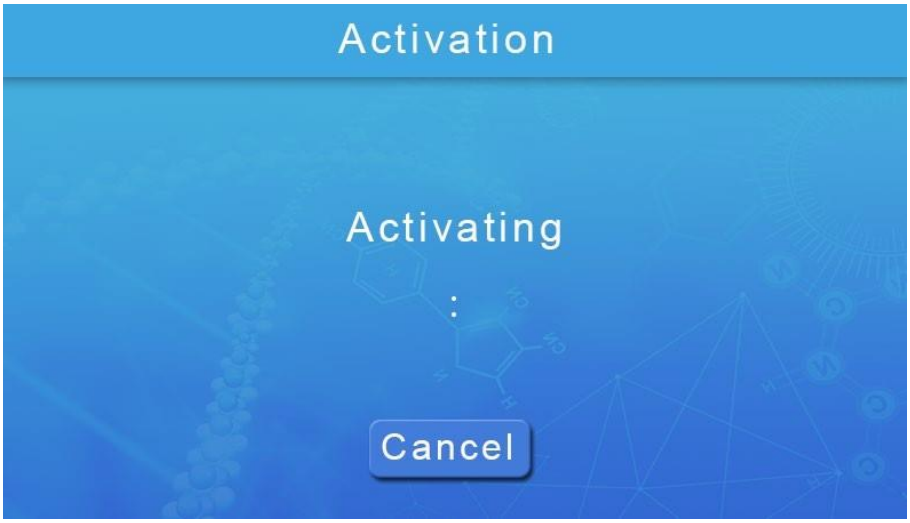
8.2 System Flushing

- The figure indicates that the instrument is under system flushing.
- It inhales slope correctionsolution B, drift correction solution A and air to clean their respective flow paths.
- During system flushing, the user can check whether the A and B correction solutions flow smoothlyand the pipes are blocked or leaked.

- The operator should pay attention: when the system is flushed, kindly observe whether the solution flow in the pipe and electrode is normal.
- If the solution cannot be sucked up, or thereare many air bubbles, kindly refer to the first item of troubleshooting.
- After the system flushing, the instrument switches to the activation procedure.

8.3 Activation

- After the system flushes, the instrument would automatically suck the drift correctionsolution A to activate the electrode.
- The screen shows the default activation time of 30 minutes and after 30 minutes, it automatically conducts the system calibration.
- The purposes of activation are as follows:
  1) Stabilize the electrode as soon as possible.
  2) Prolong the electrode life.
- Based on the above purposes, the operator should notice that the activation time should be controlled within 15 minutes.
- During the activation, the interface is displayed as follows. If you need to exit to analyze the sample, kindly press "Cancel" on the screen.



8.4 Self-check

8.4.1 System Correcting

- After the activation, the instrument sucks drift correction solution A and slope correction solution B in turn for system calibration.
- After the calibration, the instrument of the carbon dioxide model would remind to calibrate carbon dioxide.
- If necessary, kindly press "Yes" to start; if not, press "No" to exit.
- The operator should use "CO_2 correction" to calibrate the CO_2 sensor before analyzing the blood sample. CO_2 calibration should be done once every 2-3 days in normal use.

8.4.2 Self-check

- After calibration, the instrument would automatically suck the drift correction solution A forself-checking.
- The concentration of drift correction solution A is displayed as QC value.
- When the sample test accumulates 15 times, the system automatically performs system calibrationand self-check to ensure the accuracy of the test results.

8.5 Main Menu

After the self-check, the screen will automatically display the main menu, as shown below:

8.5.1 Sample Analysis

- After clicking “Sample Analysis”, the user can set the sample parameters.
- As shown in the figure below, the start position refers to the position of the No. 1 sample to be tested on the sample tray.
- If “Retest” is turned on, the sample quantity is the test times of the samples at the start position.
- If “Retest” is off, the sample quantity is the number of samples would testfrom the starting position.

8.5.1.1 Auto mode

- After setting the sample analysis parameters, place the sample in the sample tray and click [OK] (Note: the sample temperature should range from 10℃to 30℃, the instrument will automatically clean and draw the sample.
- If you need to test an emergent sample, click [Emergency].
- After measuring the current sample, enter the emergency measurement interface automatically.

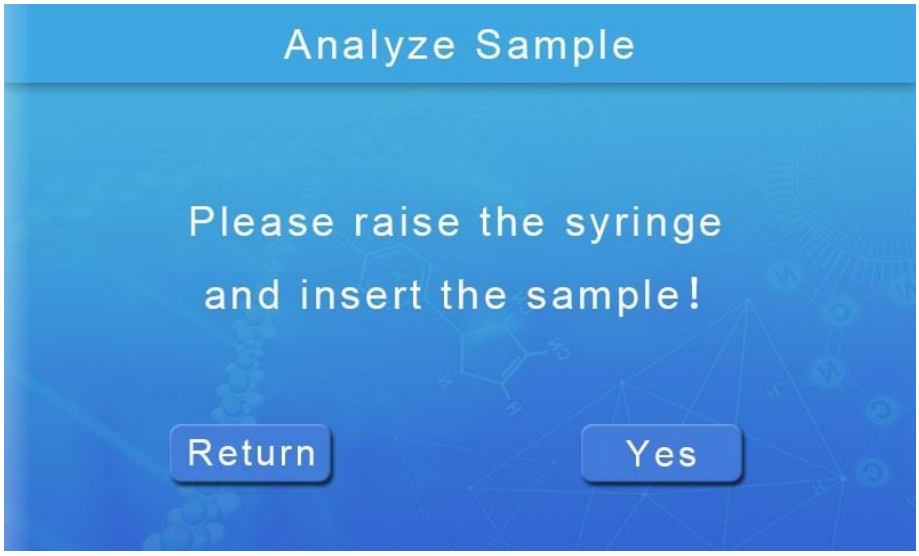
- After measuring the emergency sample, continue to test the ordinary sample and output the test result of the previous ordinary sample.
- After the test, the instrument displays and prints the test result.

Notice:

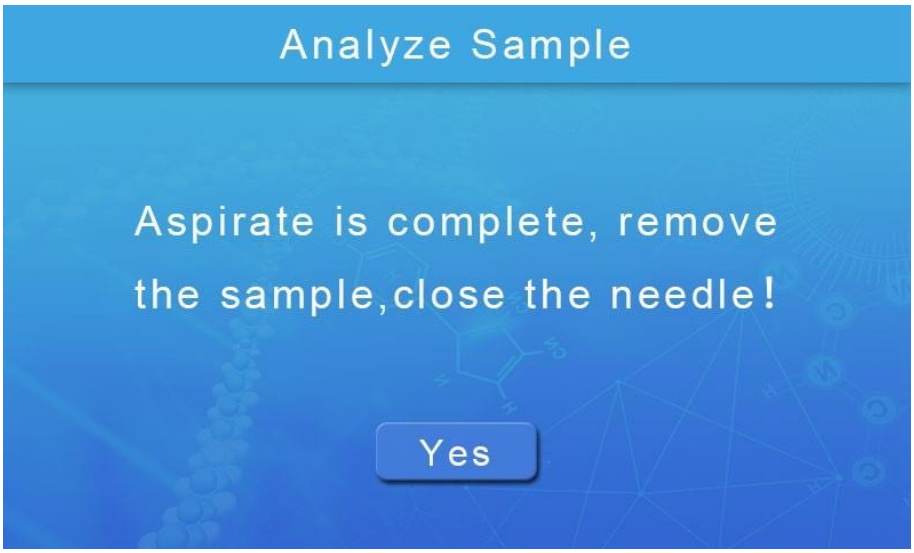
1. Ordinary samples cannot be placed in the four functional cup positions of Deproteinize, Activated Liquid, QC1, QC2" or the 5 emergency positions in the sample tray, otherwise, the sample cup would not be found correctly.
2. The sample ID is reset to 0 every day. If you need to set the sample start number or encounter an unexpected power failure, you can manually set the sample start number.

8.5.1.2 Manual mode

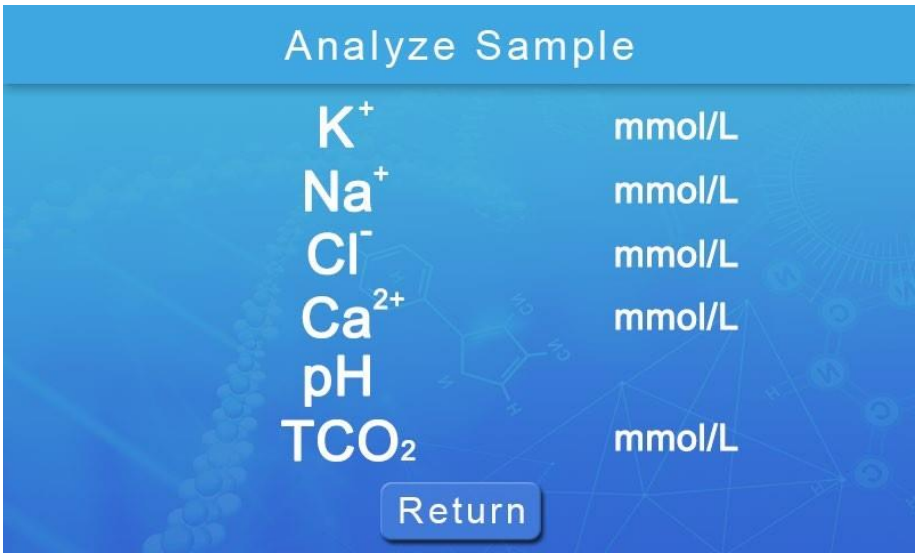
- For instruments that need to manually add samples, click "Sample Analysis" and wait for theprompt as shown in the following figure, then manually lift the blue baffle in front of the instrument, lift the syringe, and insert the needle into the sample.



- If the sample is blood, do not insert the needle into the clot.
- Click "YES", the syringe would suck the sample, after the sampling is completed, the instrument would beep and the screendisplay as follows:



- The instrument transfers the sample to each electrode for measurement automatically.
- After about 30 seconds, the instrument displays the concentration of K^+, Na^+, Cl^-, iCa^{2+}, and pH.



- After the test, the system would conduct system flushing automatically and the printer print out the results automatically.

8.5.2 Analyze QC

This program is set for the user to do QC with a certain target range. The user can perform QC two or three times before observing whether the QC results are within the target range.

8.5.3 System Calibration

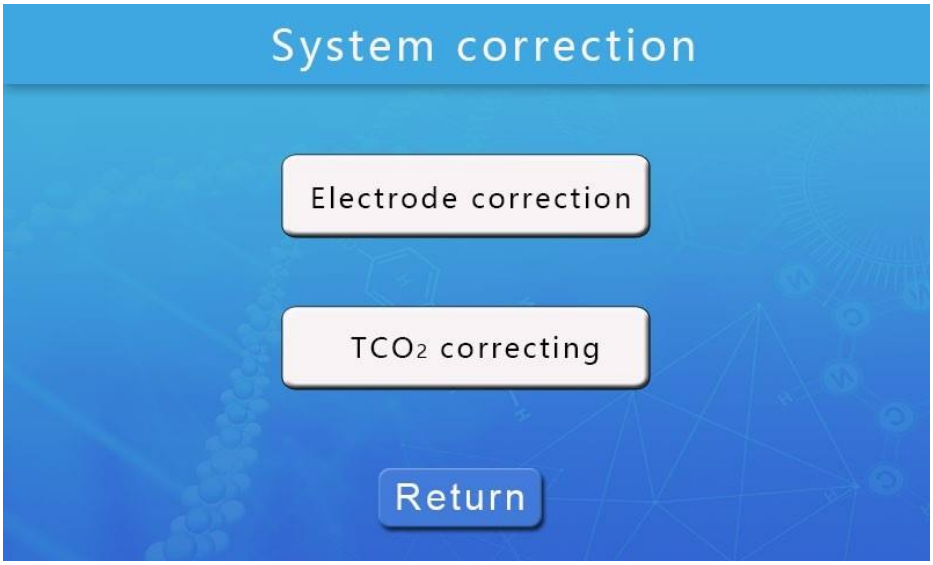
Electrode system correction:

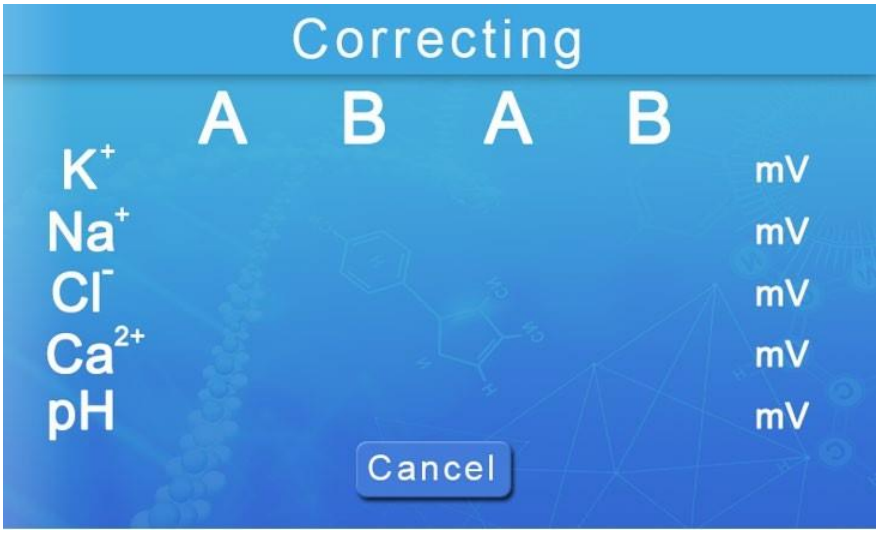
The system calibration of this program is to analyze the A and B correction solutions twice, to reflect the deviation range of the data measurement by calculating the difference between the two groups data, and to calculate the slope through the analysis results of the first set of

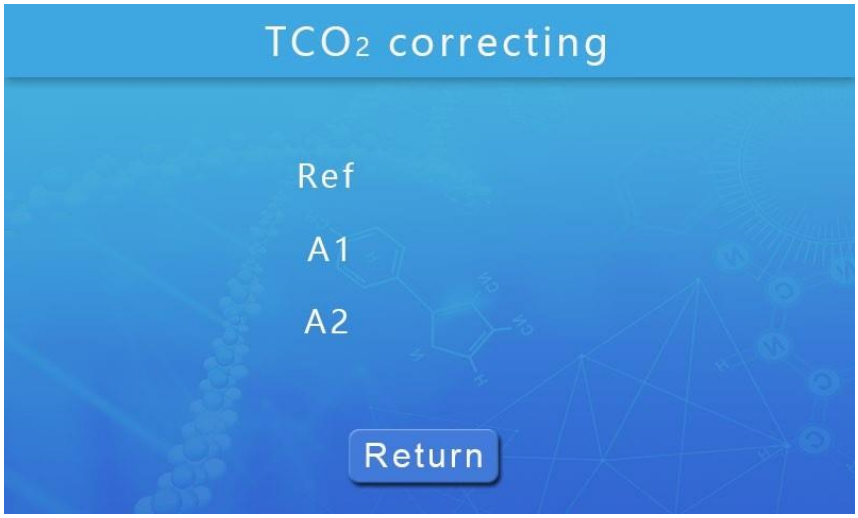
A and B correction solutions. After the calibration, the instrument self-check displays the QC analysis results but not print.

CO_2 system calibration:

This procedure is to measure two groups of CO_2 standard liquid, and put CO_2 standard liquid into the "QC 1". The reference value in the test result refers to the pressure value in the reaction pool before reacting. Value 1 and 2 are the pressure value in the reaction pool after the reaction of CO_2 standard liquid twice. When the difference between the value 1 and 2 is less than or equal to 10, the instrument works normally.







8.6 Service Menu

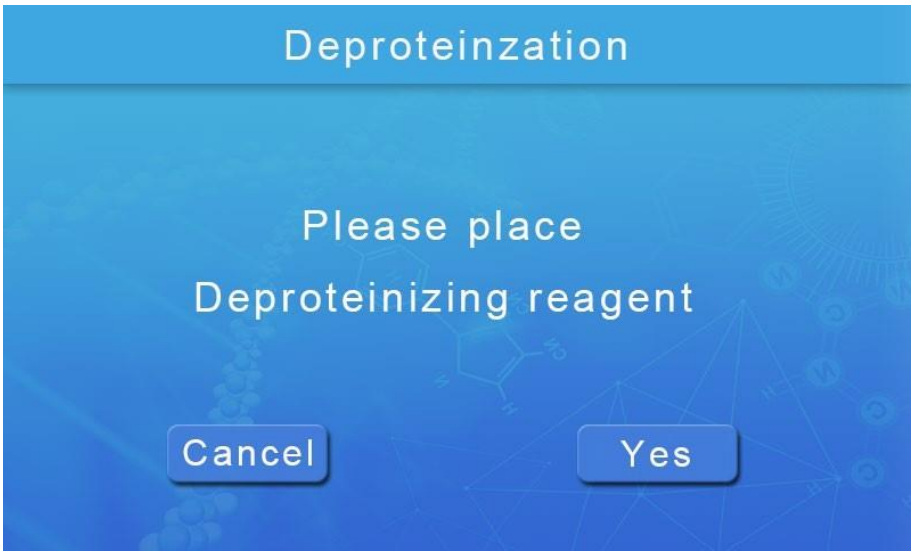
The service menus are designed to facilitate the user to better maintain and use the instrument. After entering the service menu, the upper part of the screen would display: “Maintenance”, “Settings”, “Query”, and “Other”.

8.6.1 Maintenance

There are four main functions in the maintenance program: "Deproteinization", "Washing Tube", "Activate Electrode" and "Electrode Correction", mainly for daily maintenance to prolong the service life and accuracy of the instrument.

8.6.1.1 Deproteinization

During testing some protein would remain in the electrode pipeline, which would affect its normal working. Click “Deproteinization” to see the figure below to suck the protein removal solution to perform automatic protein removal procedure:



Click "YES" to deproteinize. The interface would start to countdown, which lasts for 60 minutes and would automatically continue flushing after deproteinization. The purpose of this program is to wash the pipeline thoroughly to avoid the existence of protein, coagulation and salt in the pipeline and electrodes. Deproteinization should be conducted after the measurement or before the shutdown. (Deproteinization should be done at least once a week, and hospitals with many specimens should conduct the deproteinization once every 2-3 days).

Notice

After cleaning with deproteinizing reagent, if the sample needs to be measured, the electrodes must be activated for 60-120 minutes and then re-calibrated before measuring.

8.6.1.2 Washing Tubes

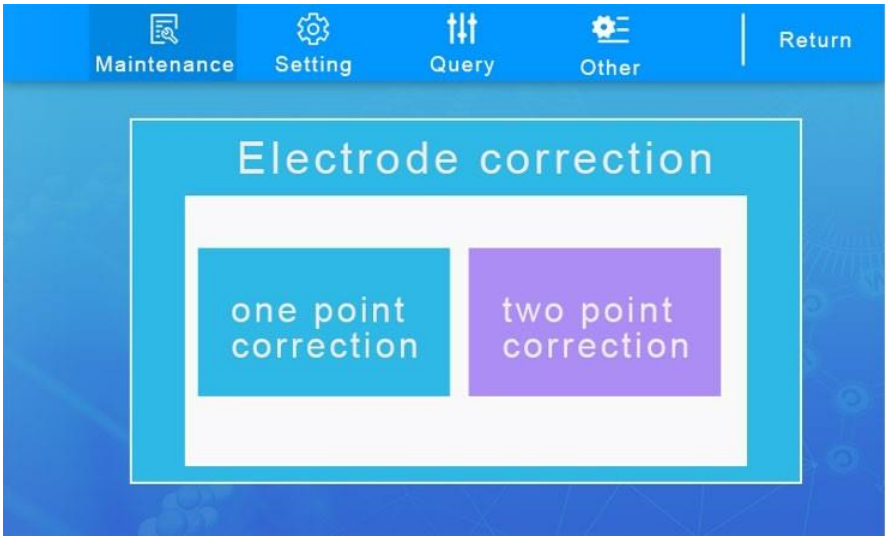
After measuring, select the Washing Tube function to thoroughly clean the channel. Distilled water or slope correction solution B can be sucked to clean.

8.6.1.3 Activate Electrode

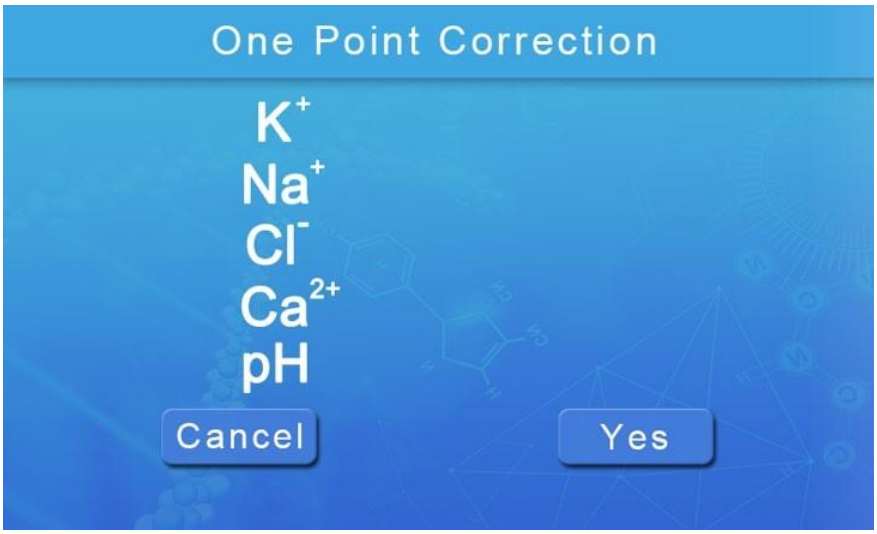
The stability of the electrode would decrease after deproteinization. The user can click “Activate Electrode” to suck the activation solution. The instrument would automatically count down for 30 minutes to activate the electrode. Press "Cancel" in the middle to exit.

8.6.1.4 Electrode Correction

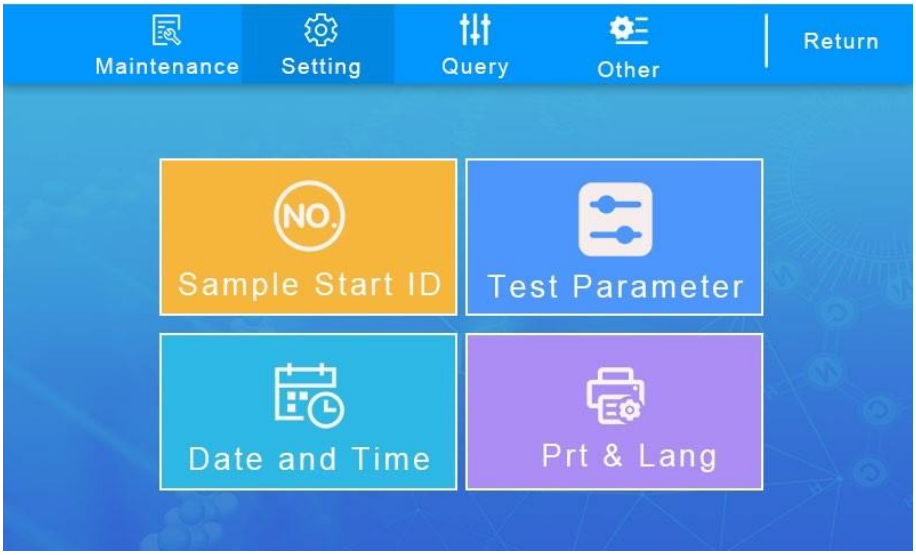
The user can choose one-point or two-point correction. The premise of calibration is that the electrode is stable, so the user should repeat the calibration several times. The calibration is for quality control, and the user can perform two-point (slope and intercept) calibration or single-point calibration (slope calibration) as needed. , (see the appendix A "Inter-laboratory quality control").



Click "one-point correction" and place the QC solution in the QC1 position of the sample tray, click the screen to input the target value and start the calibration. The system would prompt the user when the correction completes.



8.6.2 System Settings



8.6.2.1 Sample Start ID

This function can set the original number of the sample. The current sample number is shown in the interface. Input the starting number and click "OK" to save. The sample number would be used from the set starting number during sample analysis.

Attention: The sample number set by the user must not be less than the current sample number.

8.6.2.2 Test Parameter

This function is the switch setting for the test procedure of the instrument. If you do not need a certain item of the test sample, you can set the corresponding item to OFF under this function, and the test result of this item will not be displayed and printed after the test is completed.

8.6.2.3 Date and Time

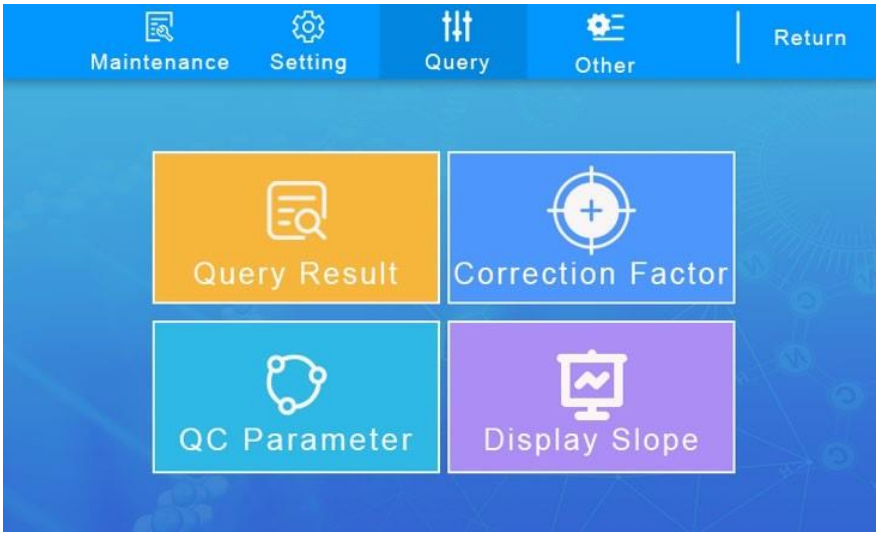
This function can change the time setting of the instrument. The time format is "year-month-day hour-minute-second". Click "Date and Time" to set and "OK" to save.

8.6.2.4 Prt & Lang

The user can choose to print in this interface. The result would not be printed when the printing is cancelled. The user can choose to switch languages between Chinese and English.

8.6.3 Query

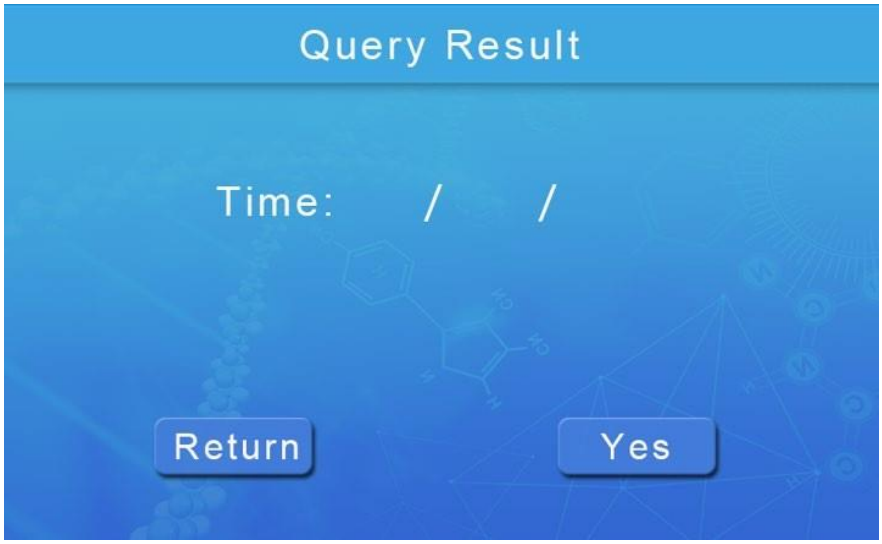
In the Query interface, the user can find the sample test results, QC parameters, instrument correction factors, and electrode slopes displayed.



8.6.3.1 Query Result

The Query Result interface allows the user to check test results according to the date.

The user enters the specific date of the sample inquired, and the sample number to check the test result. The instrument automatically stores at least 10,000 patient samples.



Click "Return" to return to the previous menu.

8.6.3.2 Correction Factor

Correction Factor is a factor automatically calculated by the instrument after QC correction. The user can view, clear, and edit the factor in Correction Factor. If the result is unsatisfactory, the user can turn up the factor in this interface and then conduct a QC test. It is recommended to choose one-point calibration. Select Clear Correction Factor to restore the original factor to the factory default settings.

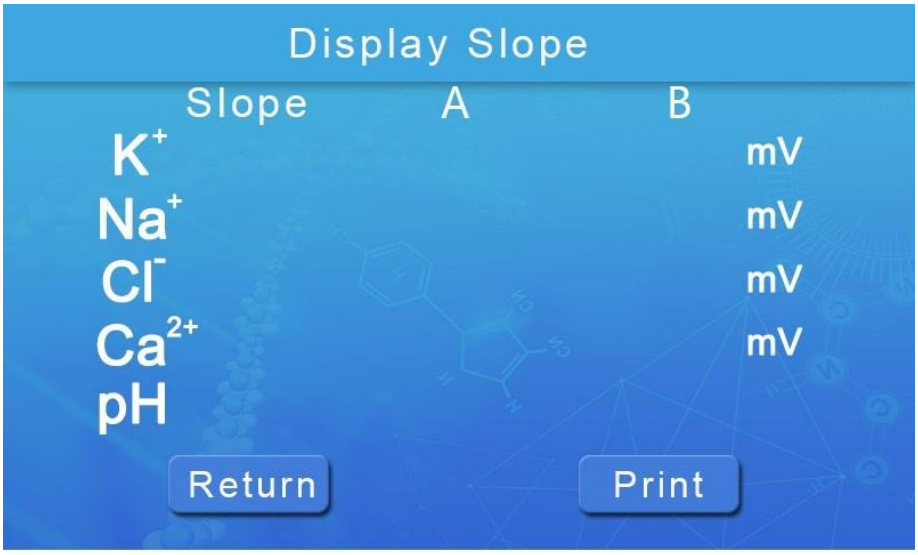
8.6.3.3 QC Parameter

The user can view the average, standard deviation and coefficient of variation of the last five QC tests, namely AVG, SD and CV values, in the "Quality Control Parameters" interface, which can clear and print the QC results. If the user replaces the QC product with a new target value, kindly clear the previous QC data and make a new QC product.

8.6.3.4 Slope

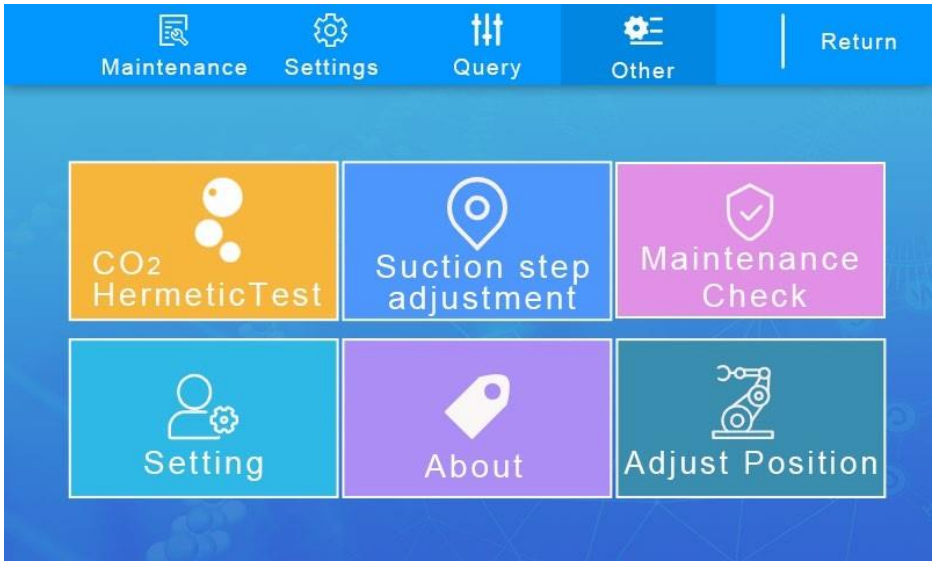
The slope is an important parameter showing the quality of the electrode. Each electrode has a normal range. The purpose of checking the slope is to check the state of the electrode. If the slope is too low, the electrode is in poor condition and needs to be dealt with in time.

The display slope interface is shown in the following figure:



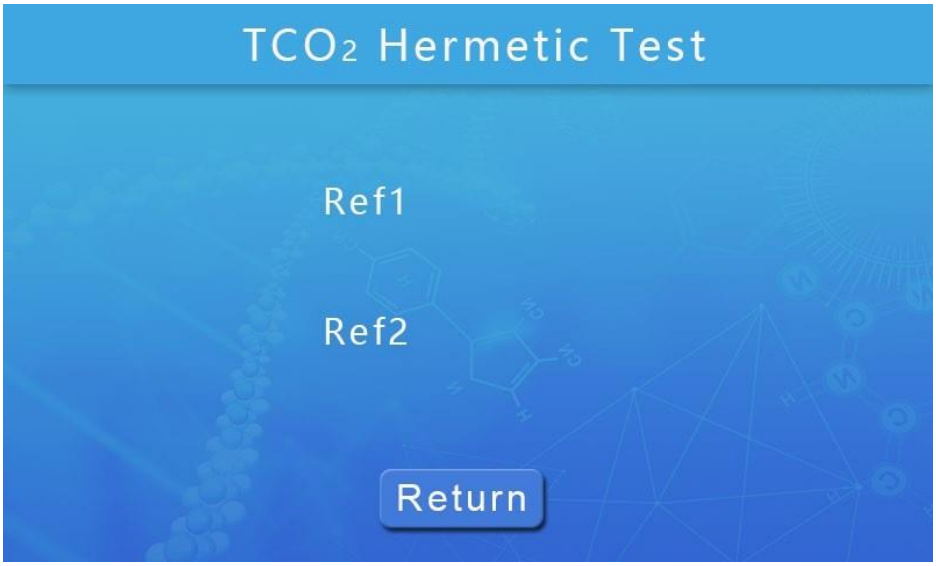
8.6.4 Other

Entering this interface, the screen displays as follows:



8.6.4.1 CO_2 hermetic test

This interface conducts the CO_2 hermetic test of the pipeline. The interface is shown below:

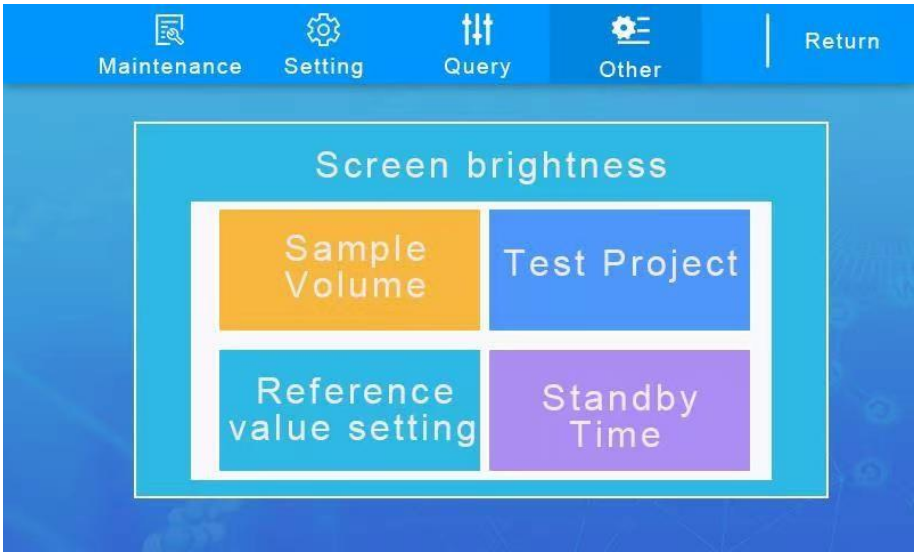


8.6.4.2 Suction step adjustment

This function is used to adjust the number of liquid suction steps. Observe the position of the sample liquid column in the electrode. The left end of the liquid column should be on the left side of K+ ion electrode, and the right end of the liquid column should be on the right side of the Ref electrode. "-" makes the liquid column move to the left, and "+" the right, finally ensuring that the liquid column is inside the ion electrode.

8.6.4.3 Setting

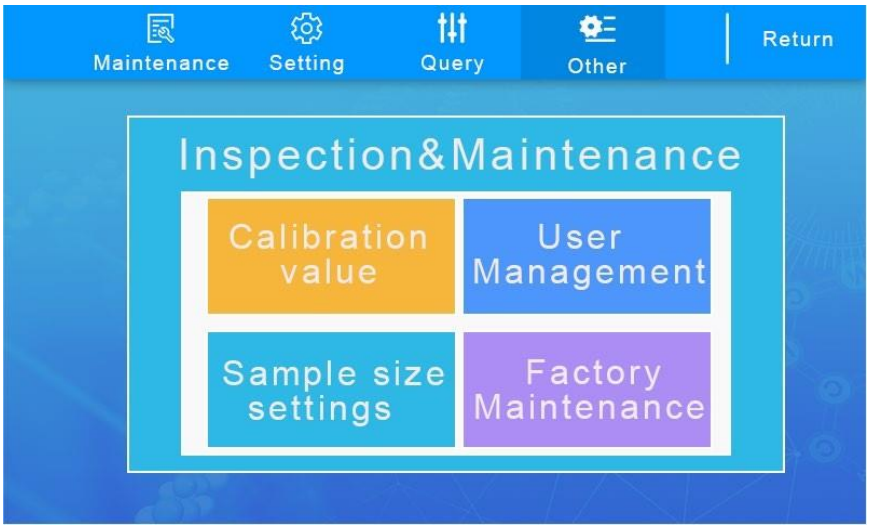
After entering this interface, the screen displays as follows:



1. **Screen brightness**: Adjust the screen brightness.
2. **Sample Volume**: This function can set the drawing volume of the sample.
3. **Sample setting**: This function can select the object of the test sample of this instrument. The default sample type is serum.
4. **Reference value setting:** This function can adjust the reference range of samples and QC. Before sample analysis or QC analysis, users can edit it by themselves.
5. **Standby time:** This function is used to adjust the standby time of the instrument when it is not in operation for a long time. The default standby time is 30 minutes. If the instrument does not perform any operation within 30 minutes, the screen will automatically turn off. After the screen is re-lit, the instrument automatically absorbs the Slope correction solution B to flush the pipeline. After the pipeline is flushed, it will automatically absorb the A correction solution. The self-test is carried out with the correction solutions A and B. The user can adjust it according to actual needs. The standby time can be adjusted from 30 minutes to 270 minutes, and the time adjustment interval is 30 minutes. Standby state: When the instrument does not operate within the standby time, it automatically turns the standby state. The instrument would automatically flush and calibrate every 30 minutes to moisten and stabilize the electrode.

8.6.4.4 Inspection and Maintenance

The interface is shown below:



1. **Calibration value:** This function can used to print the value of the scaling slope, and the factory default setting is "On".
2. **User management**: One administrator and two ordinary users can be set. Users have no right to conduct the following operations, electrode correction, factor correction, mechanical adjustment, user management, factory maintenance and other functions.
3. **Test sample size:** This function can check whether the "Simple size setting" function is normal, after clicking "Start". The instrument sucks air and 150ml of drift correction solution A to correct the amount of sample suction.

4. **Factory Maintenance**: It is used by our company's customer service center engineers to maintain and repair the instrument, seldom used by users. When the instrument is not operated for 30 minutes, it would automatically enter the standby state. The instrument is automatically flushed at intervals to achieve the purpose of moistening and stabilizing the electrode.

8.6.4.5 About

In this interface, you can check the factory number and version number information of the instrument.

The interface is shown below:

8.6.4.6 Position Adjustment

The user can adjust the lowest position of the syringe during cleaning in "Suction fluid position" through clicking "+" and "-".

"The Sample location" can be used to adjust the lowest position of the syringe during aspiration through clicking "+" and "-".

"The distance from No.1" can be used to adjust the position of the No. 1 position of the sample adding disk relative to the sample adding needle through clicking "+" to rotate the disk counterclockwise, and "-" to rotate the disk clockwise.

8.7 QC

1) Before QC, make sure the calibration of the instrument is stable.

2) It is strictly forbidden to use the standard solution of the flame photometer as the sample to measure. Since it contains relatively concentrated acid and other additives, it cannot be measured by the ion electrode method, otherwise it would cause electrode poisoning.

3) Not all QC serums on the market are suitable for the measurement of ion electrode method, some manufacturers' QC serum contains more additives, which would interfere with the ion electrode (especially the determination of Cl^-).

4) If the fluctuation of the ambient temperature is more than 10 °C, it needs to be re-calibrated.

8.8 Environment

1) The socket is well grounded.

2) Stable voltage, preferably connected to UPS or regulated power supply.

3) The instrument must be kept away from high-power equipment to avoid electromagnetic interference.

4) Avoid direct sunlight.

8.9 Sample Collection and Processing

The collection and processing of samples must be completed by professionals to avoid haemolysis affecting the measurement results. Also note the following:

Serum and plasma samples:

1) Serum and plasma stored in the refrigerator can be used for analysis, but they must be returned to room temperature before analysis.

2) When preparing serum samples, do not add substances that will cause errors in the measurement, such as surfactants, anticoagulants, etc. These substances can interfere with the measurement and even cause damage to the sensor. See Appendix III for details.

Urine sample:

1) Before measurement, it must be diluted ten times with urine diluter (1:9).
Boric acid is recommended as a preservative for urine samples to avoid interference with other preservatives.

Others

Standby state: If the instrument does not work for a long time in the measurement state, it will automatically switch to the standby state.

Notes on Instrument Calibration

The instrument can perform one-point correction and two-point correction and can be calibrated individually or with multiple electrodes at the same time.

One point correction: When calibrating one or several electrodes, kindly keep the default value of 000.00 for the electrodes that do not need to be calibrated, prepare the QC solution and put it on the sample plate, enter the QC target value, and then click “OK”.

Two-point correction: In the two-point calibration, it is recommended to measure the low target value QC at the first point and the high target value QC at the second point. Same as one-point calibration, kindly keep the default 000.00 for electrodes that do not need calibration. Do not use a QC solution with a target value for two-point calibration, otherwise, the calibration result will be invalid, and the calibration factor needs to be confirmed and then calibrated again.

Notice:
No matter what kind of electrode calibration method. kindly do not change the initial value of 000.00 for electrodes that do not need calibration. Press “YES” to let it pass. After calibration, be sure to check the calibration factor to check whether the calibration factor is correct. When the data is cluttered, clear the correction factor and calibrate again.

9. Maintenance

1) To ensure that the instrument is always in good working condition, it is necessary to maintainthe instrument regularly.
2) We should pay attention to the following issues in the maintenance process:1） Maintainers are required to maintain the machine.
3) Maintainers should emphasize the importance of maintenance to the user of the instrument.
4) The specific responsibilities of the maintainer are:
   - Storage of commonly used consumables and accessories.
   - The analyzer shell or frequently touched parts are easy to get dirty.
   - In addition, the parts thatmeet samples and reagents, such as the sample tray, syringes, and pipette holders, also needto be cleaned and disinfected regularly to improve the accuracy of detection and reduce biological risks.
   - Use a clean, soft cloth soaked in water and wring it out, gently wipe the surface and if necessary, soak a small amount of soap or 75% medical alcohol. After cleaning,dry the surface with a dry cloth.

Precautions

Warning:
Never spill liquids on the analyzer, as liquid immersion would damage the instrument.

Biological risk:

- Wear gloves and work clothes during maintenance to prevent infection and goggles if necessary.
- Do not throw away the cotton cloth used for wiping, kindly dispose of it properly according to the relevant regulations.

9.1 Daily Maintenance

1) Daily check whether the printing paper of the printer is enough.
2) Daily check the volume of Drift correction solutions A and B correction solution.
3) Check the pipeline daily to ensure that it is unobstructed. If there is any blockage, kindly refer to the second item of user troubleshooting.

4） Disinfect the syringe and waste host every day. When sampling and pouring waste, the infectious solution may meet the skin of the fingers. Kindly wear effective protective gloves for protection.

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

6） Activate it according to the normal startup process before everyday use (the machine conducts it automatically).

7） The pipe should be cleaned before shutdown every day.

First clean: Rinse the pipe once with cleaning solution E, lift the sampling needle in manual mode and place it in cleaning solution E/Replace liquid B reagent with cleaning solution E in automatic mode, and then click "Washing tube" to rinse the pipe once.

Second clean: In manual mode, keep the sampling needle lifted and wipe the surface of the sampling needle; in automatic mode, remove the liquid B pipet from the cleaning liquid E and wipe the surface of the liquid B pipet, and then click "Washing tube" to empty the pipe.

Third clean: Push the manual sampling needle back/liquid B pipette back into liquid B reagent, click "Washing tube" and rinse the pipe with liquid B.

8） Users with a large sample (about 70 samples) should use an electrode cleaning solution (protease) to remove protein once a day after the test. After treatment with "Electrode cleaning solution (protease)", the sample must be reactivated with serum for 30 minutes - 2 hours and re-calibrated before the test.

9.2 Weekly Maintenance

1） Check the pipette holder and sample pan once a week and clean the dried solution and sample to keep the measurement area clean.

2） Clean the screen and shell of the analyzer, then open the front door to clean the solution storage area.

3） Check the volume of the reference solution of the reference electrode, it must be ensured that the internal electrode is always immersed in the reference solution. If the reference solution is not sufficient, use a syringe to add it from the small hole on the upper right of the reference electrode, and ensure that the small hole is unblocked.

4） Use the electrode deproteinization procedure every week and use the electrode washing solution(enzyme) to do deproteinization once a week.

9.3 Maintenance of Main Accessories

1) The pipes on the instrument should be removed at least every two months, soaked in distilled water, and rinsed.

2) When the surface of the reference solution is cloudy and lower than the reference electrode, it should be replaced.

3) Check the reference solution of the common electrode regularly. If the liquid level of the internal is lower than the internal electrode or is cloudy, the internal solution should be added in time, or the corresponding electrode should be replaced.

Note:

1. When the instrument is not in use, it should be powered on once every 3 days to conduct a self-test.
2. If the instrument is not used for a long time, use pure water to flush the pipe 2 to 3 times.
3. If the instrument is not used for more than one month, empty the ion electrode and reference electrode of the internal liquid and reference liquid, and store it away from light.

9.4 Maintenance

1) If the pipe or electrode is blocked, remove the pump tube and use a needleless syringe to suck distilled water for cleaning in an opposite direction, so that the water flows out of the syringe. It is strictly forbidden to use an injection needle to avoid puncturing the electrode membrane and damaging the electrode.

2) If the electrode is not used for a long time, the residual liquid in the electrode membrane should be rinsed with distilled water and the electrode should be sealed and stored.

3) Electrodes should preferably be activated daily.

Note: Kindly use the materials recommended by our company for cleaning and disinfection.

9.5 Precautions for Fuse Replacement

A burnt fuse would lead to a start failure of the machine.

Purpose

Replace the fuse.

Maintenance timing

The maintenance should be performed when the power plug is well connected, but the machine cannot be activated.

Maintenance tools

Flat-blade screwdriver

Instrument status

Make sure the instrument is turned off when maintenance.

Precautions

Do not replace it with other specifications of the fuse.

Steps:

1. Make sure the instrument is turned off and unplug the power cord.
2. Prepare a new fuse (F1AL250V).
3. Use a flat-blade screwdriver to lift out the fuse holder at the power socket on the right side of the instrument and take out the fuse.
4. Observe whether the fuse is blown, burnt black, and other problems.
5. If blown or burnt, replace with a new fuse in the current position.
6. Install and tighten in the reverse order of removal.

This analyzer is valid for 8 years. Kindly read this manual carefully and operate according to the operation method specified by the manufacturer and use the original electrodes and reagents, otherwise, the adverse consequences will be borne by the user!

9.6 Common Problems in the CO_2 model:

1) If the sample size is small and there is no emergent, it is best to remove the upper and lower two pump tubes, at least the lower one, after shutting down every day. The upper and lower pump pipes are severely tightened since they are used for sealing. If the pump pipes are not used for a long time, it would accelerate the aging of the pump pipes and the adhesion of the pump pipes (especially the pump pipes with reaction liquid). The result is that the CO_2 reaction liquid is not enough and leads to a low CO_2 result. But if it works all day, the user does not need to take off the pump tube. (Install the pump tube correctly, otherwise the sample cannot be sucked.)

2) CO_2 should be re-calibrated every 1-3 days, to maintain the true and accurate CO_2 results.

Low CO_2 value: The reaction liquid was not added to the pump tube due to adhesion.

Treatment method: First take off the pump tube, then pinch to disconnect the adhered part of the pump tube, and then install the pump tube. Manually rotate the reaction liquid pump head to suck the "reaction liquid" until it flows to the reaction pool. High CO_2 value: Without re-calibration for a long time.

Treatment method: re-calibrate CO_2.

10. Troubleshooting

10.1 Treatment Methods for Self-check Failed

The main reasons for the failure of self-test:

1) The detector: A, the plug of the detector is loose B, the detector is faulty
2) The valve: C, the fixing screw on the spool and the rotating shaft of the motor are loose D, the spool itself is too tight and cannot be rotated

   Solution:

   The inspection order is:

   C ⟶ A ⟶ D ⟶ B

3) The tray (models including the injection tray)

   A The fixing screw in the middle of the tray is loose, just tighten it.

   B The tray was fixed too tightly. Check if something is stuck and prevent dirt from getting into the bottom of the tray.

   C The detector inside the tray fails to work.

   D The setting screw on the tray is loose from the motor rotation shaft, re-tighten it.

4) The needle:

   If the travel switch is not pressed, adjust it.

10.2 Treatment Methods for Unobstructed Sampling

If it is found that the syringe does not suck the sample, kindly check the sections from the pump forward and check which of the following parts is blocked:

1) Check whether the tube of the peristaltic pump is stuck, whether it is leaking or overworking. The adhesion of the pump tube would cause noises. The pump tube should be removed and kneaded with hands, or a new one if it overworks
2) Check whether the tubes at each interface (including between the electrode and the valve, between the electrode and the pump tube) are inserted properly.

   Notes: If the pipe, syringe or electrode is blocked, remove the pump pipe and use a syringe whose needle is replaced by a rubber tube to suck distilled water from the opposite direction to clean, and let the water flow out from the injection needle (it is strictly forbidden for the injection needle to penetrate the electrode membrane or pipeline).
3) Even if the pump tube is replaced with a new one, the obstructed sample suction still exists. Maybe there is protein precipitation in each pipeline, especially at each joint. In this case, the user needs to remove each joint and clean it with water.
4) Distribution valve: When the number of samples is small and the solution is used for a long time after opening (stored 2-3 months out of the refrigerator), floccules may be generated

in the solution and cause the distribution valve to be blocked.

Treatment method: Put the sample suction tubes of A and B correction solutions in an empty bottle. Remove the needle of a syringe, filled with water, with which a rubber tube connects to the middle of the front of the dispensing valve. Then start the machine, inject distilled water while the system is flushing the distribution valve, and the distilled water would flow into the waste liquid bottle from the A and B pipes respectively. Repeat the above operation for cleaning, and finally replace the solution. On the electrode base, there is a stainless-steel tube in front of the K electrode, and the hole on it can be directly stabbed with a needle.

Check whether the distributing valve will operate when the liquid is not aspirated. Observe whether the circular black plate (with a notch) in the distributing valve will rotate when the liquid is aspirated from the front. If rotate normally means the liquid circuit system is blocked, if not, it means the fixing screw on the valve core and the motor rotation shaft is loose, re-tighten the screw.

5) Blockage of electrodes: Mainly due to accumulation of hemoglobin.

   Treatment method: Remove the electrodes and check them one by one. After finding the blocked electrodes, first use a needleless syringe to suck the Electrode cleaning Fluid (protease)(enzyme) and inject it into the blocked electrodes for soaking, and then rinse with distilled water for about 3 minutes.

10.3 Treatment Methods for Electrode Drift

1) The small hole on the upper right side of the reference electrode is blocked by salt, and the small hole should be opened with the needle.
2) There are air bubbles in the electrode cavity, which can be shaken off with force.
3) If the internal solution of the electrode is not sufficient, the internal electrode cannot be sensed, and the internal solution of the electrode should be added.
4) The Filling solution, which cannot exceed 2/3-3/4 of the cavity, in the electrode is too much.
5) If the inner electrode coating of the reference electrode falls off or turns white, the inner electrode or reference electrode needs to be replaced.
6) Check the drifting electrode surface for dirt or oxide film.
7) Check the drifting gold-plated electrode head or electrode terminal for dirt or oxide film, and lightly polish the contact area.
8) If the voltage is unstable, connect UPS uninterruptible power supply or a good, regulated power supply (poor quality regulated power supply would cause electrode drift).
9) To avoid electromagnetic interference, equipment with high power should be kept away from the instrument, and the power supply should be set independently.
10) Check if the correction solution has been used up.
11) If all electrodes drift, check whether the reference electrode has expired, or if there are air bubbles at the reference membrane, which should be cleared.
12) If all the calibration values are 240, generally there are bubbles in the contact part between

the reference electrode and the test solution (some bubbles are so small that it is difficult to see). Currently, kindly take out the reference electrode and repeatedly flick the bottom end of the reference electrode with your finger (Below the silver rod). The bubbles can be shaken several times.

13) If the solution is expired or contaminated, kindly check whether the A and B correction solutions have flocculent precipitates.

14) After the electrode is deproteinized or the instrument has not been calibrated for a long time, the first self-test is easy to get out of control. The machine should be activated for 1-2 hours and then calibrated.

10.4 Treatment Methods for Electrode Slope Reduction

A low electrode slope would result in poor linearity of test results and sometimes affect the repeatability of the electrode. The main reasons are:

1) Too much protein adheres to the electrode membrane tube, kindly use electrode cleaning solution (enzyme) to remove it.
2) The temperature is too low, or the humidity is too high. When the air humidity is too high, use the dehumidifier to lower the humidity. When the temperature is too low, use the air conditioner to heat the room.
3) The electrode is near expiration. (replace electrodes)

A, B correction solutions have been used up, reference internal solution leakage, reference electrode aging, and other reasons also would cause all or part of the electrode slope to decline, if it is caused by such a fault, it has nothing to do with the electrode.

10.5 Common Blockage Problems

1) **Dispense valve**: Kindly refer to chapter 10.2-4) of this manual for the causes and treatmentmethods of blockage.
2) **Electrodes:** kindly refer to chapters 10.2-5) of this manual for the causes and treatmentmethods of blockage.
3) **Blockage of pipe or syringe:** Kindly refer to chapter 10.2-2) of this manual for the causes andtreatment methods of blockage.

10.6 Treatment Methods for Abnormal Results

When testing blood samples, if there are abnormal values in the test records, kindly follow thesteps below to check:

1) Whether high-power electrical appliances are running or electric leakage (such as centrifuges, and refrigerators), leading to unstable voltage.

2) Check to see if blood clots were sucked during the test.
3) Check whether the sample cup is contaminated and whether there are residual substancessuch as disinfectant.
4) Check whether the correction factor is correct and clear the correction factor if there is anyabnormality.
5) If it has not been calibrated for a long time, do calibration before the test.

10.7 Function and assembly of the reference electrode

The reference electrode plays a role in providing standard potential for other electrodes in the instrument. If the reference electrode is unstable, all electrodes will be unstable. After a periodof use, the saturated potassium chloride in the reference electrode will gradually permeate out,and the reference liquid will gradually decrease.

Filling of reference solution:

1) Absorb a certain amount of reference liquid with a syringe and add it from the small hole in the upper right corner of the reference electrode (Not full, just fill the left cavity).
2) Check regularly to prevent small holes from being blocked by salt crystals.
3) If all the calibration values appear to be 240, it is generally the contact part between the reference electrode and the test liquid - there are bubbles at the reference film. Some bubblesare very small and difficult to see.
4) At this time, kindly take out the reference electrode and flick the bottom end of the reference electrode with your finger (below the silver rod), repeating many times.
5) Check the reference electrode regularly, if find that there are salt crystals on the shell kindlywipe it clean, otherwise, it will lead to unstable measurement.

10.8 The Relationship Between nCa, TCa, iCa and pH

The composition of serum is very complex, containing a large amount of protein and citrate, etc.,which can combine with iCa to form a calcium complex. Since the calcium complex does not havephysiological activity, the standard for regulating calcium balance in the human body is iCa rather than TCa. This instrument measures iCa in serum by an ion-selective electrode. The relationship between TCa, iCa, and Calcium complex is as follows:

TCa =iCa+ Calcium complex

The ionized calcium value of human serum pH=7.40 is nCa (standard iCa)The iCa value in human serum pH=7.40 is nCa.

After the serum is separated, with passing time and the effect of centrifugation, CO_2 in the bloodescapes, the pH value increases, and the iCa concentration decreases, so the iCa value measured at this time is inaccurate. Therefore, the measured iCa has no clinical significance, andthe main basis for clinical diagnosis is nCa. The pH displayed on the screen is the measured pH value, and nCa (which can be considered as the concentration of iCa in the human body) can be calculated using the formula. In the sample analysis results, the screen shows that Ca^{2+} is the standard calcium, and there are three items covering iCa, nCa, and TCa in the printed results, ofwhich nCa can be used for clinical diagnosis, and iCa and TCa are only for user reference duringthe sample analysis.

10.9 Precautions of CO2 Model

If the CO2 test is abnormal, kindly check according to the following steps:

- Re-calibrate CO2. If the test results are still wrong after the calibration, the following checksshall be carried out.
- The tubes on the CO2 reaction tank are not inserted properly, and there is gas leakage.
- Whether the reaction liquid pump pipe is installed reversely.
- Whether the reaction liquid has been used up.
- When changing the reaction liquid each time, do not wait for all the absorption before changing.
- All sucked dry, kindly rotate the pump head sucking reaction liquid by hand, so that the pump tube is full of reaction liquid. Ifnot, the pump tube would be empty.
- Thus, the reaction liquid cannot be added in, resulting in a wrong test CO2 value.
- Pay attention to avoid blood clots during sampling, otherwise it would change the CO2 value and affect the measurement.
- If the CO2 test is abnormal and the repeatability is not good, clean the whole tube and reaction pool with the protein removal solution.

12. Appendix

Function Menu