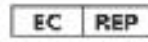


**K-lite 8 series**  
**Electrolytes/TCO<sub>2</sub> analyzer**  
**User Manual**

**MEIZHOU CORNLEY© HI-TECH CO. ,LTD.**



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# Preface

Meizhou Cornley Hi-Tech Co., Ltd. is an enterprise specialized in R & D, manufacture, marketing and service for clinical IVD instrument and life science instrument. The K-Lite8 electrolyte analyzer is designed for accurate and rapid tests on ion concentration of  $\text{Li}^+$ ,  $\text{K}^+$ ,  $\text{Na}^+$ ,  $\text{Cl}^-$ ,  $\text{Ca}^{2+}$  (the standard calcium ion modified pH value), pH value and total carbon dioxide content in serum samples. It uses ion selective electrode technique (ISE) and the pressure sensor to realize every test. Controlled by a microprocessor and equipped with the hierarchical menu software structure, the analyzer is simple and more convenient for users to operate.

The Electrolyte analyzers of Meizhou Cornley Hi-Tech Co., Ltd. inherit all advantages of similar domestic and foreign products and improve in the structure, circuit, software and operating system with colorful touch screen. They are essential assistance for every laboratory as they are able to be a real sense from three to six parameters with high performance.

The operation of every analyzer can be done in a simple hierarchical menu. The specification of the content is about the detailed installation and operation of electrolyte analyzer.

K-Lite 8 electrolyte analyzer combines the advantages of our original analyze to test lithium, sodium, potassium chlorine, calcium / magnesium ion concentration, pH value in one sample with the direct test on total carbon dioxide to improve the efficiency.

At the same time, users can choose an optional automatic sampler according to the actual needs. Automatic sampling can improve the speed of analysis while the manual sampling is still available.

In addition, please install the electrodes of K-Lite8 in order:  $\text{Li}^+$ ,  $\text{K}^+$ ,  $\text{Na}^+$ ,  $\text{Ca}^{2+}$ ,  $\text{Cl}^-$ , pH, Ref according to this manual. If you have any questions, please contact our customer service department.

Meizhou Cornley Hi-Tech Co., Ltd. adopted independent packs of calibration solutions. The user can handle waste more conveniently. The analyzer increases data storage function for 5000 sample test record, 5000 quality control records and 5000 two-point calibration records. Through three levels quality control test and input target value, the analyzer can be automatically calculate the slope and the deviation as well as the use of median verification slope and mean deviation.

The aim of Meizhou Cornley Hi-Tech Co., Ltd. is to provide more advanced and better medical devices for the user.

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# Chapter 1 ABSTRACT

This chapter introduces the scope of application, model characteristics and the composition of the structure about K - Lite8 series electrolyte analyzer,

## 1.1 Applicable Range

1.1.1 This manual applies to K - Lite8 series electrolyte analyzer (hereinafter referred to as the analyzer).

1.1.2 This analyzer for the medical tests on contents of  $K^+$ ,  $Na^+$ ,  $Cl^-$ ,  $Ca^{2+}$ ,  $Li^+$ , pH,  $TCO_2$  in serum samples.

1.1.3 This analyzer should be operated by trained technicians, nurses, doctors in the laboratory, bedside monitoring or designated guardian.

## 1.2 Models

Depending on different configuration, the analyzer has many types. This manual is composed according to the most completed configuration model (K - Lite8D). The manual also applies to other models listed below. The differences between different models are:

- 1) The operation menu and display, such as the menu of calibration, testing and setup to display only some certain parameters.
- 2) The calculated parameters are different.

Model	Parameters	Note
K-Lite8A	$K^+, Na^+, Cl^-, TCO_2$	K-Lite8 series have the same appearance but different parameters.
AFT-800A		
K-Lite8B	$K^+, Na^+, Cl^-, Ca^{2+}, pH, TCO_2$	
AFT-800B		
K-Lite8D	$K^+, Na^+, Cl^-, Ca^{2+}, Li^+, pH, TCO_2$	
AFT-800D		
K-Lite8E	$K^+, Na^+, Cl^-$	
AFT-800E		
K-Lite8F	$K^+, Na^+, Cl^-, Li^+$	

AFT-800F		
K-Lite8G	K <sup>+</sup> ,Na <sup>+</sup> ,Cl <sup>-</sup> ,Ca <sup>2+</sup> ,pH	
AFT-800G		
K-Lite8H	K <sup>+</sup> ,Na <sup>+</sup> ,Cl <sup>-</sup> ,Ca <sup>2+</sup> ,Li <sup>+</sup> ,pH	
AFT-800H		

## 1.3 Features

- ※ Support color TFT touch screen, and brightness adjustable.
- ※ Optional auto sampler
- ※ Support original blood sample tube
- ※ Built-in thermal printer, serial port
- ※ Reagent and waste in one pack※ Storage and search function on quality control, calibration and test results (store 5000 test results; 5000 quality control results or 5000 two-point calibration records)
- ※ Clot alarm and bubble alarm function, automatic and manual clot-removal function
- ※ Support USB printer
- ※ Support network
- ※ Support LIS, HL7
- ※ Automatic and manual calibration, cleaning, quality control and self test functions
- ※ Printing on sample analysis report and sample analysis chart
- ※ Printing on test report, diagnosis report and A5 paper report
- ※ Barcode scanning function to support consumables scan and patient information input
- ※ Automatically identify the expiry date of consumables
- ※ Online software upgrade
- ※ Reagent consumption calculation function
- ※ To review and print test result according to the sample number, test items, test time and patient name
- ※ Support export of calibration, testing and quality control data
- ※ Support multitasking operating and sample edition on patient information

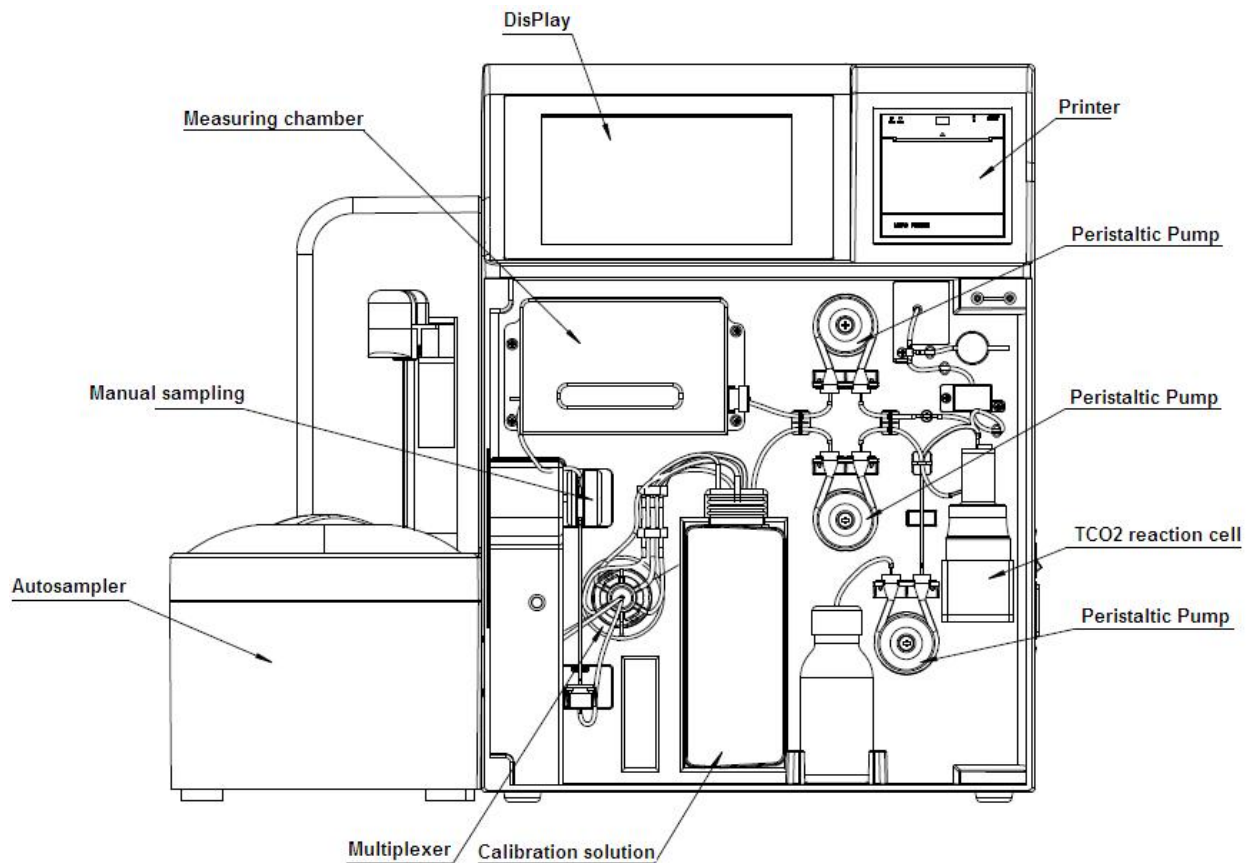
- ※ Automatic cleaning for sampling needle
- ※ Support online graphic guide, automatic error correction and online assistance

## 1.4 Structure

The system includes main analyzer (display, measuring chamber, peristaltic pump, multiplexer, Flow path, printer), autosampler, barcode scanner and reagent pack.

### 1.4.1 Appearance

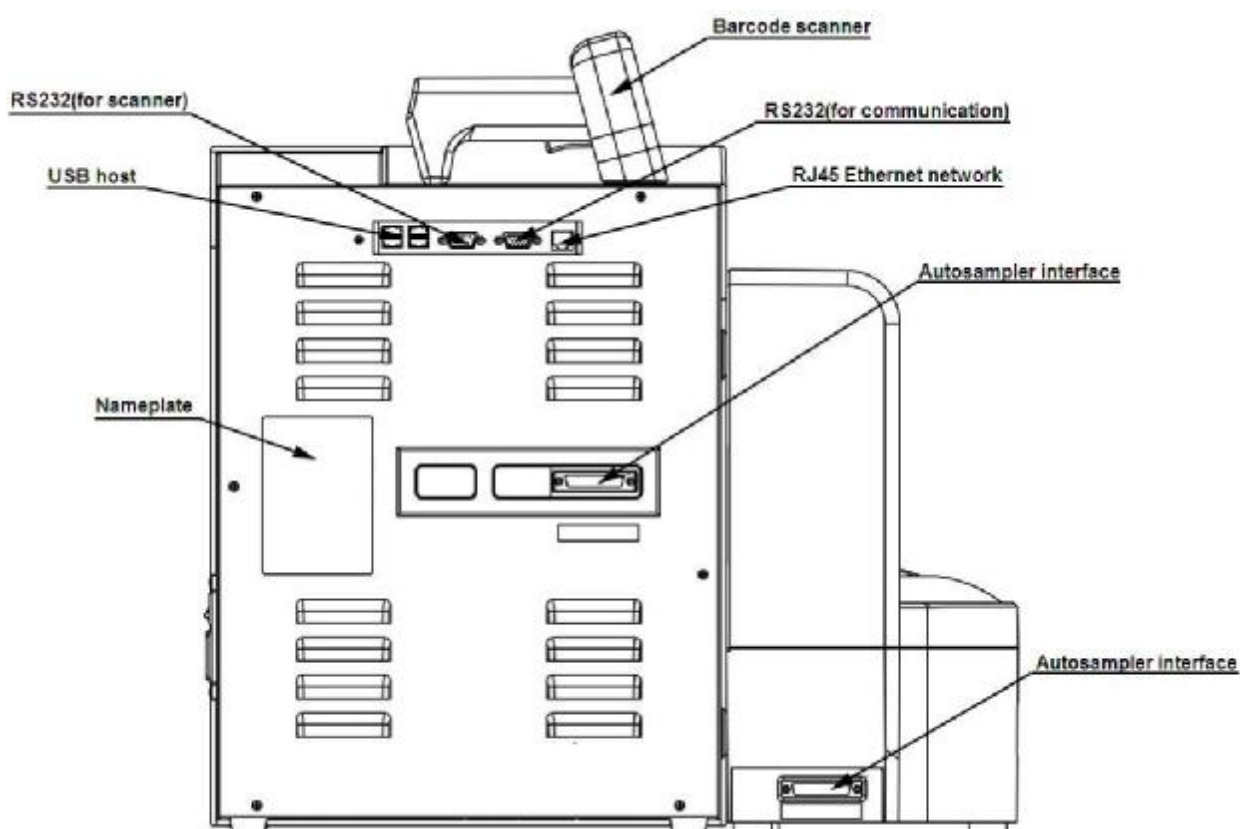
Front



Part	Function
Display	Interface between operator and analyzer
Measuring chamber	The place to do test
Peristaltic Pump	Sample aspiration and waste drain
Calibration solution	The place for both reagent and waste

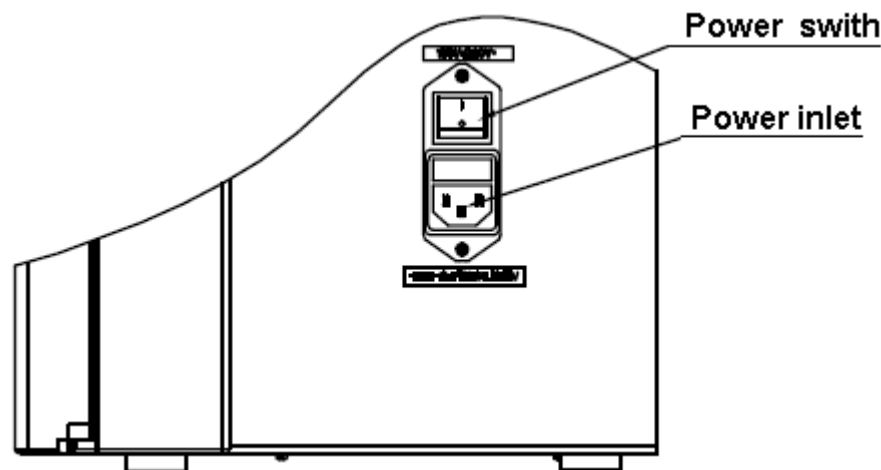
Manual sampling	Aspiration of samples and reagents
Autosampler	For automatic sampling
multiplexer	Control the flow of liquid
TCO <sub>2</sub> reaction cell	The place for sample and reaction solution to generate total dissolved CO <sub>2</sub>
Printer	Print out test results and messages

Back



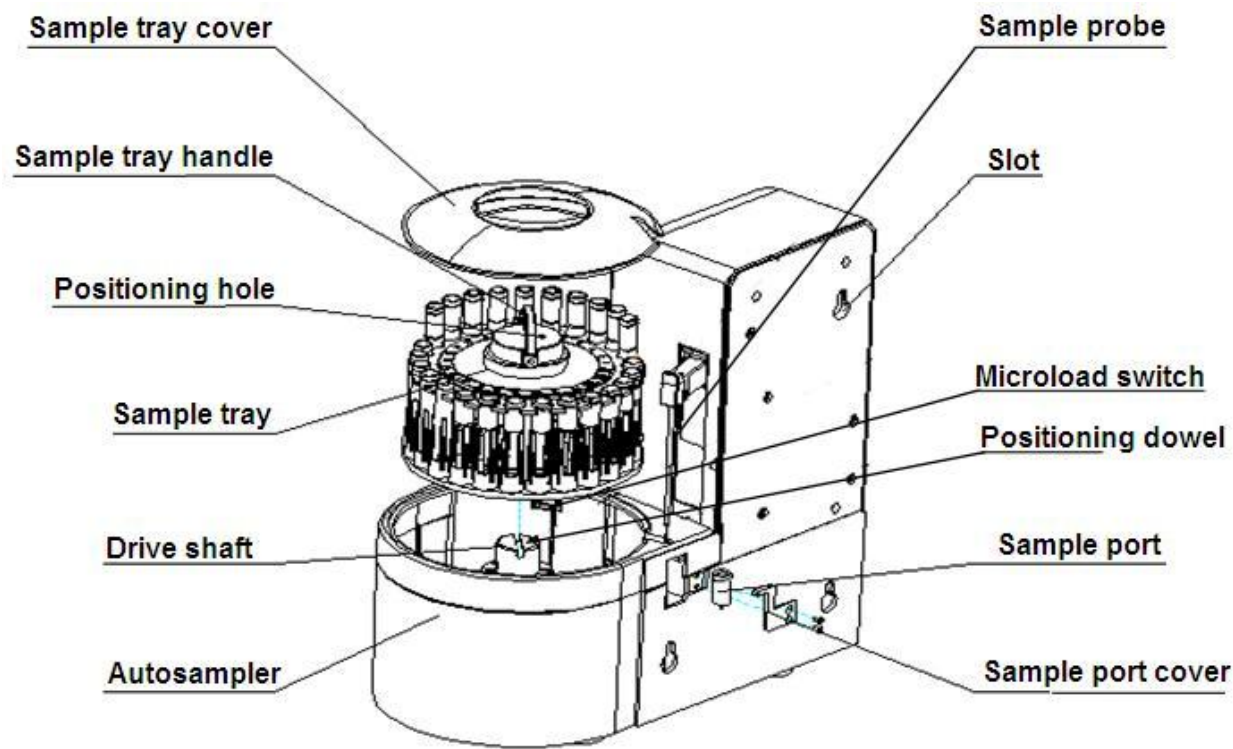
Part	Function
RS232 interface(scanner)	Slot for Barcode scanner
USB Port	For flash disk, mouse or standard keyboard
Nameplate	Describe the basic information and configuration of the analyzer
Barcode scanner	Slot for scanner, read barcode of consumable
RS232 interface(for communication)	May be used for troubleshooting
RJ45interface	Ethernet interface connection
Autosampler interface	Connect analyzer and autosampler

Side



Part	Function
Power inlet	For the analyzer to boot into standby mode  Note: when the analyzer is connected with an external power supply, analyzer is in standby mode. If the analyzer is not connected with any external power supply, the analyzer is in shutdown mode.
Power switch	Turn on or off the power

autosampler(Optional)



## 1.4.2 Sensor System

This sensor system of this analyzer integrates modern technique of microelectrode. It can be used for the measurements of

- Ø Li electrode( $\text{Li}^+$ )
- Ø K electrode ( $\text{K}^+$ )
- Ø Na electrode ( $\text{Na}^+$ )
- Ø Ca electrode ( $\text{Ca}^{2+}$ )
- Ø Cl electrode ( $\text{Cl}^-$ )
- Ø pH electrode (pH)
- Ø Reference electrode(Ref)

## 1.4.3 Barcode Scanner

The barcode systems of reagent pack, electrode and other consumables contain necessary information such as lot number and the validity period. The scanner is for barcode scanning to control the use of consumables.

- I To scan the data of reagents(type, lot number, validity period)
- I To scan the data of electrodes(type, lot number, validity period)
- I To scan the data of pump tubes(type, lot number, validity period)
- I To scan the data of sampling probe interfaces(type, lot number, validity period)



<b>Instruction</b>
--------------------




light source	Visible laser diodes, wavelength 650nm
Scanning speed	48 ± 2 times per second
Interface	RS232,PS2Keyboard,USB
Dimension	Length * width * height: 95mm * 70mm * 160mm
Weight	128g
Voltage	5V
Working current	85mA
Quiescent current	36mA
Safety	Chinese National Safety Standard – level two
Electromagnetic compatibility	CE & FCC DOC compliance
Working temperature	0°C-45°C
Storage temperature	-20°C-60°C
Humidity	Relative humidity 5%-95% (no condensation)

### 1.4.4 Reagents

Calibration of the analyzer system is performed by the solution in the reagent pack. There is standard solution with accurate concentration in the pack. It is placed in the vacuum packaging. At the same time, waste will be collected in the bag automatically after calibration and test. As standard calibration solution and waste are sealed in the pack, it can effectively avoid the pollution of the environment.

The standard calibration solutions are used to calibrate  $\text{Li}^+$ ,  $\text{K}^+$ ,  $\text{Na}^+$ ,  $\text{Ca}^{2+}$ ,  $\text{Cl}^-$  electrodes.

	After reagent is used out, the pack may contain biochemical dirt. The user is asked to avoid the contact with waste import. The pack should be handled in accordance with relevant provisions of biochemical sewage.
---	--

One standard reagents pack includes:

Type	Specification	Function	Storage
Calibration solution	Cal A /Cal B	To calibrate $\text{Li}^+$ , $\text{K}^+$ , $\text{Na}^+$ , $\text{Cl}^-$ , $\text{Ca}^{2+}$ , pH electrodes	Storage Temperature: 5-25°C.  No refrigeration
	Flush solution	To flush the Flow path	
	De-fat solution	To de-fat for the Flow path	
	Waste Bag	To collect waste	
	TCO <sub>2</sub> standard solution ,20ml/ bag	To calibrate TCO <sub>2</sub>	
TCO <sub>2</sub> reaction solution	100ml/bottle	To generate CO <sub>2</sub> with the sample	

## 1.5 Working Environment

Temperature:  $5^{\circ}\text{C} \sim 40^{\circ}\text{C}$ ;

Humidity:  $\leq 80\%$ ;

Air pressure:  $86\text{kPa} \sim 106\text{kPa}$ ;

Power Supply:  $100\text{V}-240\text{V} \sim 50\text{Hz}/60\text{Hz}$ ;

Working power:  $300\text{VA}$ ;

Sampling temperature:  $5^{\circ}\text{C} \sim 40^{\circ}\text{C}$ ;

- I Desk Dimension:  $\text{Length} * \text{Width} \geq (1.5 * 0.6) \text{ m}^2$**
- I away from strong electromagnetic interference source and direct sunlight**
- I The analyzer after packing should be stored in an ambient temperature of  $-20^{\circ}\text{C} \sim +55^{\circ}\text{C}$  and relative humidity of not more than 80%. It must be placed in a ventilated room without any corrosive gas. For long-term storage, the analyzer requires a power on and dehumidification for at least one hour once a month.**

# Chapter 2 Operation

## 2.1 Operation

No reagent of flame photometer or biochemistry analyzer can be used on this analyzer as such reagent may damage ion selective electrodes.

Only the original reagent of Cornley can be used.

Only the trained professional can operate the analyzer.

Never use mildew or precipitated sample. Such sample should be abandoned immediately as it will affect the test result negatively.

Never open the cover of measuring chamber when doing a test.

Please protect the unique serial number on every electrode. There will be no after-sales guarantee for any electrode without such serial number.

Please perform routine maintenance for the analyzer according to this manual.

The analyzer needs stable voltage and good grounding.

The serum must be separated well. The sample should be tested within 1 hour after collection.

The TCO<sub>2</sub> reaction cell for the sample must be cleaned by distilled water and dried.

The adjustment on "slope" and "Deviation" parameter must be done very carefully. Only the extremely fresh serum can be used for those adjustment. Please do not adjust the slope or deviation frequently. Generally, a micro adjustment will be OK enough.

Please remain the analyzer power-on to guarantee the normal working of electrodes and test accuracy.

Please avoid direct sunlight or other strong light on multiplexer

Pressure sensor is a maintenance-free component. The replacement of this sensor can only be done by a professional appointed by Cornley(applicable for the models with TCO<sub>2</sub> parameter)。

If the power of the analyzer is off for more than 24 hours, the left calibrator in the Flow path may be crystalized. This will ruin the future two-point calibrations on the analyzer.

The protection of the analyzer may be damaged if the analyzer is not operated according to this manual.




The handling of waste has to be done according to local standard and the guidance from the local distributor.

This analyzer is a precision instrument. After transportation, it needs to run at least 48 hours to return reliable.

If the analyzer has any damage as the user does not supply stable power according to this manual, Cornley will not be responsible for the loss.

## 2.2 Labels

For safe and effective operation of the analyzer, this manual lists several warning information. This part is very important. Please read carefully before the operation.

Symbol	Definition
 Biological contamination	To remind the user to abide by the instructions. Otherwise there will be the risk of biological contamination.
 Alert	To remind the user to use of equipment safely and effectively.
 Caution	To illustrate the procedure of important information or other information which need to remind to the users.

**All risk warnings of this manual are listed as follows:**

### 2.2.1 Sampling



**Biological contamination:** The collecting samples must follow the basic rules of prevention as all blood samples are potentially infectious. In order to reduce the possible risk, the collector must master the correct treatment of blood collection to wear gloves and take the necessary protective measures.

---

### 2.2.2 Environment Pollution



Biological contamination: Please always remember environment protection when you handle biological waste or its container.

---

### 2.2.3 Reagents

---



Biological contamination: There will be waste after the usage of every reagent pack. Please never touch the waste interface. Handle the splashed liquid with flush solution carefully. For the used packs of calibration solutions, please handle them according to local laws about biological waste.

---

### 2.2.4 Analyzer

---



Biological contamination: Please switch off the analyzer and disconnect the power supply when cleaning the analyzer. Gloves are also advised for this cleaning.



Alert: Never clean the sample probe with wet cloth or anything similar.

---

### 2.2.5 Restrictions in operation

---



Alert: Before being applied to clinical diagnosis, all test results of the analyzer need to be checked by the doctor according to the clinical status of the patient.

---

### 2.2.6 Storage

---



Alert: All reagents have to be removed before shut-down of the analyzer.



Alert: For long term storage of the analyzer, the power supply must be shut down. Necessary shut-down procedures have to be followed also.

---

### 2.2.7 Maintenance

---



Alert: Please observe the sample status in the measuring chamber to guarantee the integrity of the sample.



Alert: Please perform de-protein and conditioning for the electrodes regularly.

---

### 2.2.8 Pump Tube

---



Alert: Please install the tube correctly on the pump wheel to guarantee the normal rolling of the wheel.

---

### 2.2.9 QC

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Alert: Never use any QC with Fluorine carbon compounds

---

### 2.2.10 Troubleshooting

---



Biological contamination: When flushing any part of this analyzer, please be careful for the liquid outlet from the Flow path.



Alert: Before being applied to clinical diagnosis, all test results of the analyzer need to be checked by the doctor according to the clinical status of the patient.



Caution: In order to guarantee a good EMC, please use protected cable at communication port.



Caution: please contact the local distributor whenever necessary.

---

### 2.2.11 Safety

In order to use this analyzer safely, please read the content below carefully. There will be danger for the analyzer or the operator if the operation does not apply such safety instructions.

---



Alert: If the user does not follow this manual, the safety protection system of this analyzer may fail.

---

### 2.2.12 Electric shock prevention

To prevent electric shock, please notice that:

---



Alert: Never open the back board of the analyzer when the power is on. Never put any reagent or sample on the analyzer. If any reagent or sample is splashed into the analyzer, please shut down the power immediately and contact the local distributor or Cornley for professional advice.

---

### 2.2.13 Moving Parts

To prevent the injury by the moving part of the analyzer, please notice that:

---



Alert: Please do not touch or put your hand inside the range of moving part when the analyzer is working.

---

### 2.2.14 Laser Radioactivity

To prevent the injury by Laser light source of the barcode scanner, please notice that:

---



Alert: Please do not look at the laser light source directly. It is harmful for the eyes.

---

### 2.2.15 Blood Pollution

To prevent the blood pollution for the operator, please notice that:



Alert: Please never touch blood sample, interface of reagent pack, QC, calibrator and reaction solution. Please do wear gloves and necessary uniform to prevent possible pollution. Spectacles are also required if necessary.

If any sample is splashed on the skin, please handle with care and consult a doctor.

---

#### 2.2.16 Chemical Danger

To prevent chemical danger, please notice that:

---



Alert: Some reagents and chemical flush solution are harmful for skin. If any of such liquid is splashed into eyes by accident, please wash with plenty of clean waters immediately and see a doctor without delay.

---

#### 2.2.17 Waste

To prevent waste pollution, please notice that:

---



Biological risk: some contents of QC, calibrator, flush and waste are dangerous. Please handle them according to relevant local laws.

Please do wear gloves and necessary uniform to when handling waste. Spectacles are also required if necessary.

---

#### 2.2.18 Used analyzer

To handle used analyzer safely,

---



Alert: some materials of the used analyzer may cause pollution. Please handle them according to relevant local laws about waste electrical products.

---

## 2.3 Sample collection and storage



- 2.3.1 Blood samples must be sent to the laboratory immediately after collection, especially when the environment temperature is over 22°C.
- 2.3.2 The tubes for blood samples must be sealed and placed vertically with mouth upwards. This is to reduce the coagulation completely by possible vibrations and to prevent contamination, evaporation and splashing, etc..
- 2.3.3 Blood samples can be collected according to the conventional method. The collected blood samples shall be handled gently to prevent hemolysis by possible vibrations.
- 2.3.4 The collected blood samples should be processed as early as possible. Generally, the isolation of serum from the samples must be done within two hours since collection.
- 2.3.5 The delivery of collected blood samples must be done with great cautious. The professional requests on packaging, temperature sample and processing methods must be strictly followed to ensure the stability of components. Sample tubes must be sealed and placed upward vertical during transportation.
- 2.3.6 The collected samples must be fully agglutinated. The samples with anticoagulant can be centrifuged immediately after collection. The samples with coagulant must be centrifuged within 5~15 minutes after collection. The samples with anticoagulant cannot be centrifuged if for tests on Lithium, Zinc and Protoporphyrin.
- 2.3.7 Blood samples before centrifugation should be agglutinated naturally. Please never use stick or anything similar to separate blood clots. For normal room temperature (22 ~ 25°C), the samples can be completely agglutinated after 30~60 minutes of collection. Frozen blood samples will be agglutinated slowly. They may need some coagulants to accelerate agglutination (gently reverse and mix 5~10 times to ensure the functions of coagulants).
- 2.3.8 It is better to complete sample centrifugation in one time. If a second centrifugation is needed, it should be done in a very short time after the previous one. But the samples with separated substances cannot be centrifuged again.
- 2.3.9 The storage of serum in 22~25°C cannot be over 8 hours.
- 2.3.10 If the centrifugation cannot be completed within 8 hours after collection, the serum should be kept in the environment of 2°C~8°C.
- 2.3.11 If centrifugation cannot be completed within 48 hours after collection, or the serum samples should be stored for 48 hours, the samples should be stored in -20°C.

2.3.12 For anticoagulants, the ones with heparin lithium shall not be applied when the tests include parameters about lithium. By the same means, the anticoagulants with heparin sodium shall not be applied when the tests include parameters about sodium. Otherwise the results of relevant parameters will be abnormal.

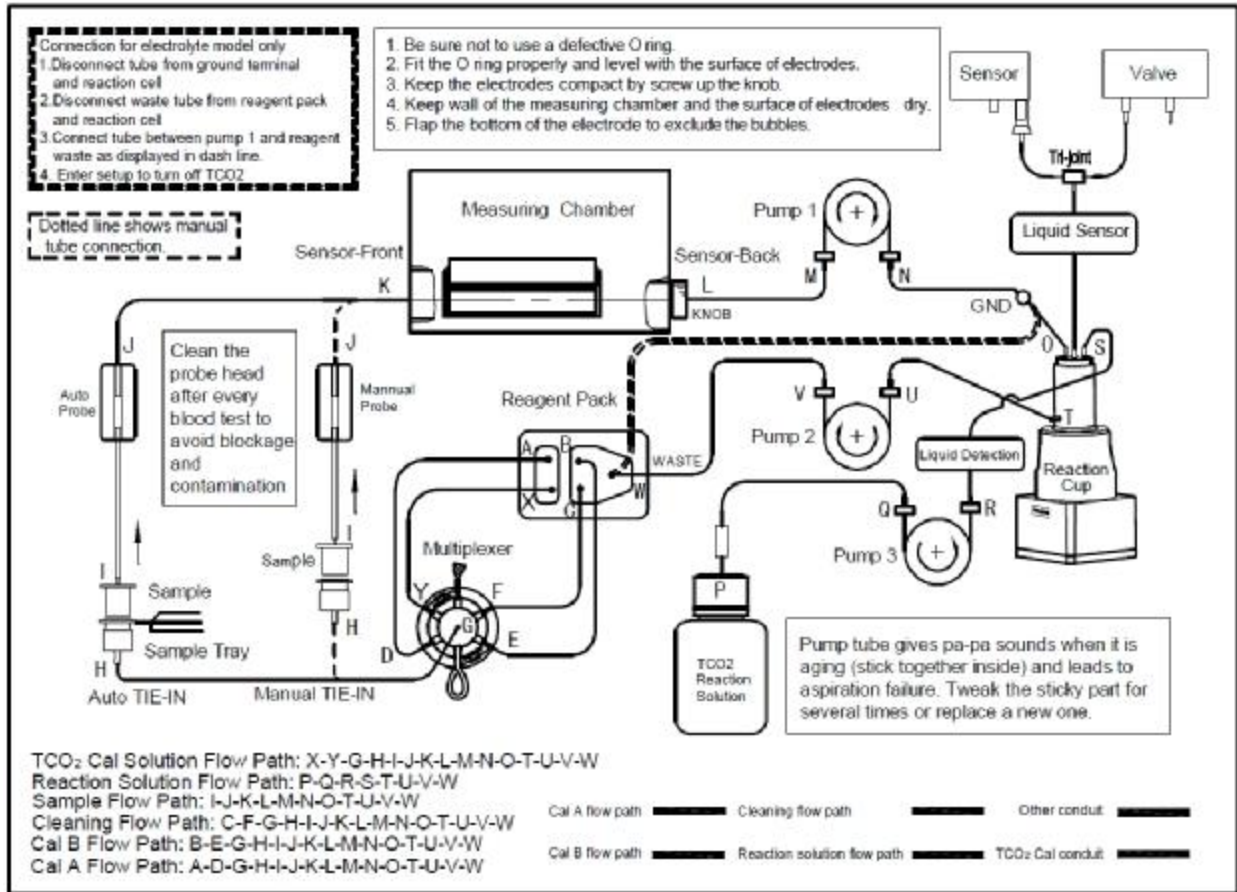
2.3.13 The serum samples cannot be frozen and thawed repeatedly. They can only be frozen and thawed once. Such samples cannot be stored in frost free refrigerator as this kind of refrigerator will bring frequent temperature changes on the samples.

2.3.14 Serum samples shall be stored in sealed tubes.

2.3.15 All calibration solutions for the instrument should be stored in 5°C~25°C and clean environment. Direct sunlight and long-term open in the air must be avoided.

# Chapter 3 Working Principle

## 3.1 Flow Path



1) After a sample is sucked into the Measuring Chamber, there are  $\text{Li}^+$ ,  $\text{K}^+$ ,  $\text{Na}^+$ ,  $\text{Ca}^{2+}$ , pH,  $\text{Cl}^-$ , Ref inside for seven electrodes. (each type electrode vary) in response to samples of the  $\text{Li}^+$ ,  $\text{K}^+$ ,  $\text{Na}^+$ ,  $\text{Ca}^{2+}$ , pH,  $\text{Cl}^-$ , Ref. These signals will display the testing results after amplification analog to digital conversion and after being sent to the microcontroller for statistics and calculation. The printer will print the results accordingly.

2) After a sample and reaction solution are sucked into TCO<sub>2</sub> reaction cell, the  $\text{HCO}_3^-$  ion and the reaction solution are in the full reaction after mixing to generate CO<sub>2</sub>. The pressure inside the TCO<sub>2</sub> reaction cell changes accordingly and will attract the pressure sensor. These signals will display the testing results after amplification analog to digital conversion and after being sent to the microcontroller for statistics and calculation. The printer will print the results accordingly.

## 3.2 Measuring Principle

### 3.2.1 Reference Electrode

[Introduction]

The reference electrode is made up of a small silver bar (coated with AgCl) dipped in KCl saturated solution and along with a cellulose diffusion membrane.

[Principle]

The constant temperature system can control the temperature of KCl saturated solution at 37°C. In the solution of Cl<sup>-</sup> ion solubility unchanged, the reference electrode to maintain a constant potential. In the process of measurement, the sample and KCl solutions have diffusion potentials as the diffusion rate of each ion are different. The potential is sent to the measuring device so that the potential and pH electrodes can be compared. The potential of reference electrode potential will change with the extension of time. But the change in the relative measurement error will not bring significant.

### 3.2.2 pH Electrode

[Introduction]

The pH electrode adopts ion selection technique (ISE). It constitutes an electrochemical cell with external reference electrode. It consists of Ag/AgCl core soaking in a buffer with constant H<sup>+</sup> concentration and a H<sup>+</sup> sensitive membrane.

[Principle]

pH electrode measures the concentration of hydrogen ions in the sample according to the changes of voltage on the sensitive membrane. H<sup>+</sup> ion sensitive membrane will separate buffer solution and sample. When the sample contacts the sensitive membrane of pH electrode contact, half-cell potential is generated due to H<sup>+</sup> ion exchange. The potential is sent to the measuring device and compared with the potential of reference electrode. The potentials of the two electrodes reflect the H<sup>+</sup> ion concentration in the sample solution and pH value of the sample is calculated.

The voltage of a reference electrode is always constant.

The relationship between voltage and pH at a special temperature can be calculated by the Nernst formula.

[Nernst Formula]

Generally, the voltage change of a pH unit in the solution at 37°C is 61.5 mV. So:

$$E = E_0 + 61.5 \times \text{pHs}$$

E = Measured potential (mV)

E<sub>0</sub> = standard potential between electrodes (mV)

61.5 = theoretical sensitivity of electrode (mV/pH)

pHs = H<sup>+</sup> of sample

### 3.2.3 ISE

[Introduction]

The analyzer includes ion selective electrodes to measure Li<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup> and Cl<sup>-</sup> ion concentration in human blood. Each ion selective electrode has the external electrode as reference. Li<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup> and Ca<sup>2+</sup> electrodes have solid sensitive membranes of ion selective. The Cl<sup>-</sup> electrode contains electrolyte materials and is covered with an ion selective membrane.

[Principle]

The ion sensitive membrane has high selectivity through capacity. Proportional relations are applicable between the concentration of ionic signal and the of the electrode output of sample. This conforms to the Nernst formula.

[Nernst Formula]

The sensitive membrane potential in the electrolyte electrode in the differential can be calculated as

$$E = E_0 - \frac{RT}{ZF} \log_e [a_{\text{ion}}]$$

E = Measured voltage (mV)

E<sub>0</sub> = Standard voltage (mV)

R = Gas Constant (8.314 J mol<sup>-1</sup> K<sup>-1</sup>)

T = Temperature

Z = The ion charge

F = Faraday constant (96458 C mol<sup>-1</sup>);

a = Ion activity

# Chapter 4 Technical Feature

This chapter presents major features and parameters of K-Lite8 serials analyzers

## 4.1Parameter

### 4.1.1 Measured Parameter

Parameter	Description
$\text{Li}^+$	Lithium
$\text{K}^+$	Potassium
$\text{Na}^+$	Sodium
$\text{Ca}^{2+}$	Calcium
$\text{Cl}^-$	Chloride
pH	Hydrogen
$\text{TCO}_2$	Total carbon dioxide

### 4.1.2 Calculated Parameter

Parameter	Description
AG	Anion Gap
$\text{Ca}^{2+}(7.4)$	$\text{Ca}^{2+}$ corrected
$\text{TCa}^{2+}$	Total $\text{Ca}^{2+}$

### 4.1.3 The normal ISE concentration range of Serum

Parameter	Unit	Range
$\text{K}^+$	mmol/L mEq/L	(3.50~5.50)mmol/L (3.50~5.50)mEq/L
$\text{Na}^+$	mmol/L mEq/L	(135.00~145.00)mmol/L (135.00~145.00) mEq/L
$\text{Cl}^-$	mmol/L mEq/L	(96.00~106.00) mmol/L (96.00~106.00) mEq/L
$\text{iCa}^{2+}$	mmol/L mEq/dL	Adult: (1.10~1.35)mmol/L (4.40~5.40)mg/dL
$\text{nCa}^{2+}$	mmol/L	Adult: (1.10~1.35)mmol/L

	mEq/dL	(4.40~5.40)mg/dL
TCa <sup>2+</sup>	mmol/L mEq/dL	Adult: (2.20~2.70)mmol/L (8.80~10.80)mg/dL Infant: (2.25~2.67)mmol/L (4.40~5.40)mg/dL
Li <sup>+</sup>	mmol/L mEq/L	(1.00~1.20) mmol/L (1.00~1.20) mEq/L
pH		6.00 ~ 9.00
TCO <sub>2</sub>	mmol/L mEq/L	(20.00~29.00)mmol/L (20.00~29.00) mEq/L
AG	mmol/L mEq/L	(8.00~16.00) mmol/L (8.00~16.00) mEq/L

#### 4.1.4 Testing range and Slope reference range

Parameter	Testing Range	Slope Reference Range (mV)
K <sup>+</sup>	(0.5~15.0)mmol/L	40~70
Na <sup>+</sup>	(20.0~200.0)mmol/L	40~70
Cl <sup>-</sup>	(20.0~200.0)mmol/L	35~70
Li <sup>+</sup>	(0~3.0)mmol/L	20~70
Ca <sup>2+</sup>	(0.1~5.0)mmol/L	22~35
pH	6.0~9.0	40~70
TCO <sub>2</sub>	(6.0~50.0)mmol/L	

#### 4.1.5 Electrode Parameters

Electrode	Normal Range	Limit for New Refilling Solutions	Slope Range
Li <sup>+</sup>	50 mV~140 mV	< 50mV or >140mV	+5.0 mV~+9.0 mV
K <sup>+</sup>	45mV~140mV	<45mV or >140mV	+13.5mV~+21.0mV

Na <sup>+</sup>	45mV~120mV	<45mV or >120mV	-6.0mV~-10.6mV
Ca <sup>2+</sup>	35mV~100mV	<35mV or >100mV	+6.6mV~+10.5mV
Cl <sup>-</sup>	50mV~120mV	<35mV or >100mV	+3.9mV~+7.8mV
pH	70mV~170mV	<70mV or >170mV	+18mV~+28mV

## 4.2 Sample type

Serum samples from human blood

## 4.3 Test Speed

40 samples per hour

## 4.4 Minimum sample volume

80 μ L

## 4.5 Output

Liquid crystal display, built-in thermal printer and RS232 output

## 4.6 Dimension and weight

Main Unit (Length×width×height): 344mm×283mm×455mm

Autosampler (Length×width×height): 335mm×192mm×372mm

Net weight of main unit: 14kg

Net weight of autosampler: 4.8kg

## 4.7 Fuse

2×F3.15AL250V。

## 4.8 Memory

64Mb built-in memory, flash of 256Mb。



## **4.9 Display**

Resolution 800×480; touch screen of 7 inch

## **4.10 Communication Agreement**

HL7 two-way

## **4.11 Printer**

Automatic thermal printer

Paper width: 30 mm(W) × 57 mm(D);

Speed: 15mm/s;

Resolution: 240×128 Pixels

# Chapter 5 Installation

## 5.1 Unpacking

Steps of unpacking:

1. To check whether the outside carton is intact or not.
2. To check the quantity and quality of all items according to the packing list. Please contact the local distributor if anything is absent or broken.
3. Carefully take out the analyzer. Place it on a dry platform. Let the panel be close to the power socket.
4. Check the outside power part :
  - 1) Switch the multimeter to AC 750V position.
  - 2) Connect the power as the picture:



- 3) Insert the red pen(positive pole) of multimeter into the live wire on the other end and insert the black pen(negative pole) into the hole neutral wire. It is normal if the multimeter shows the voltage between the neutral wire and live wire is 220V(or 110V, depends on electric supply).



4) Insert the red pen(positive pole) of multimeter into the ground wire inlet while keep the black pen(negative pole) unchanged. It is normal if the multimeter shows the voltage between the ground wire and the neutral wire is 1V.

5) Then insert the red pen into the live wire inlet while insert the black pen into ground wire hole. It is normal if the multimeter shows voltage between the grounding wire and the live wire is 220V(or 110V, depends on electric supply).



The analyzer shall be installed by the professional engineer of the distributor. The distributor can send some engineers to Cornley for necessary training before installation.

## 5.2 Installation of Accessories

1. Installation of electrodes

Please refer to 5.3

2. Installation of pump tubes

Please refer to 5.4

3. Installation of printing paper

Please refer to 5.5

4. Installation of reagent

Please refer to 5.6

5. Installation of auto-sampler

Please refer to 5.7



7. Please put the scanner beside the analyzer as a stand-by

7. Switch on:

1) Switch off the power and battery first

2) To connect one end of the power cord to the back of the analyzer while plug the other end into the power supply inlet.

3) Switch on the power and battery to start the analyzer. There must be an adjustment on touch screen for the first usage. The analyzer will start a self test after such adjustment (please refer to 6.2 for the details about self test).

	<ul style="list-style-type: none"><li>! The analyzer must use three core power cord. The power grounding must be correct. Incorrect grounding may result in electric shock or analyzer damage.</li><li>! Please confirm the power supply inlet is qualified enough for the analyzer. The fuse must be installed to the analyzer before power-on.</li></ul>
	Please remain power-off for the analyzer before the connection of power cord.

## 5.3 Installation of electrodes

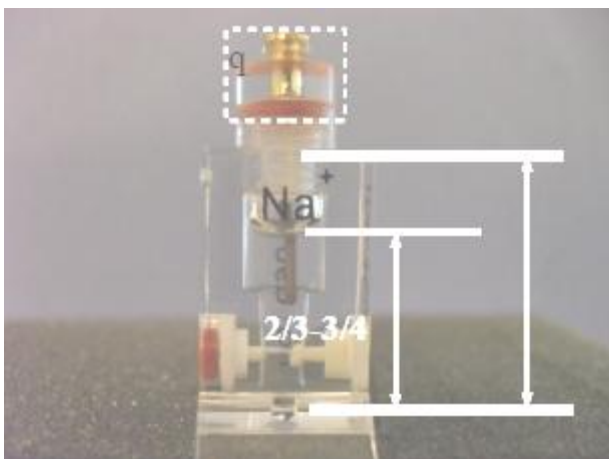
According to different functions, the electrodes can be grouped as below:

**ISE electrodes:**  $K^+/Na^+/Cl^-/Ca^{2+}/pH$ . Refillable. The  $K^+, Cl^-, Ca^{2+}$  electrodes need to refilling solution before installation. When solution less height than 1/2, user need to dry the electrode and refill .The refilling solution has to be replaced for every 3 months.

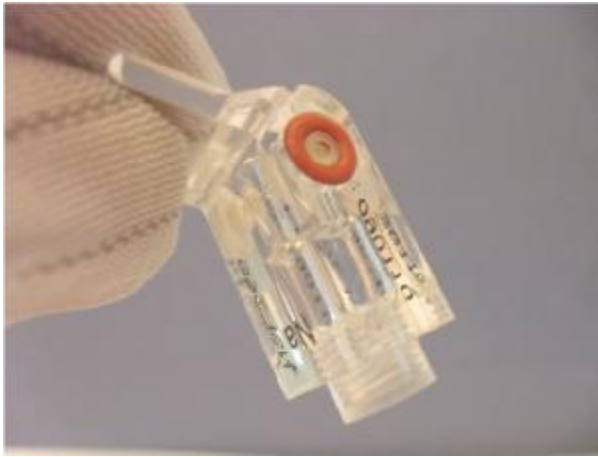
**Reference electrode:** Fixed type with internal solution.

The steps to add refilling solution to ISE electrodes:

1) Open the contact terminal of  $Li^+, K^+, Na^+, Ca^{2+}, pH, Cl^-$  electrode (taking  $Na^+$  electrode as the example in the pictures):



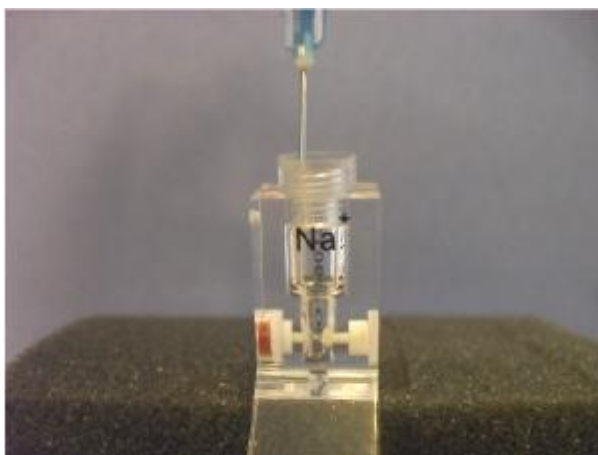
2) Empty the internal electrode solution.



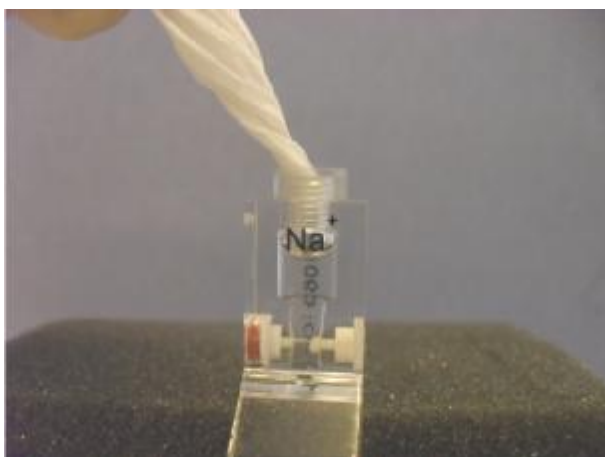
- 3) Cut the bottle of refilling solution with a scissors. Use a syringe to aspirate the liquid.



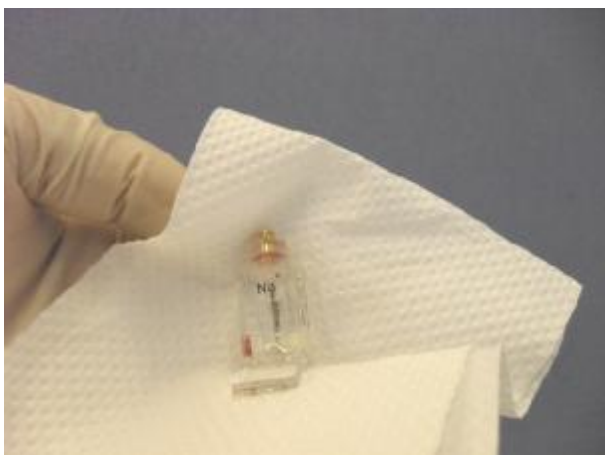
- 4) Use the syringe to inject refilling solution into the electrode (The needle of the syringe can never touch the bottom of the electrode. Otherwise the membrane may be broken)



- 5) To dry the rest refilling solution on the terminal of electrode by tissue paper.



- 6) The electrode terminal must be properly tightened. Then seize the electrode to upright position. Please click the bottom of electrode several times with a finger to remove bubbles at the bottom of the inner cavity of the electrode.
- 7) To dry the rest refilling solution on the electrode by tissue paper again.



The steps to add refilling solution to Ref electrode:

- a) Spin out the cap and terminal of Ref electrode
- b) Open the small bottle of refilling solution for Ref electrode. Use a sucker or a syringe to aspirate the liquid.
- c) After the smaller inner cavity of the Ref electrode is filled with refilling solution to the inner cavity mouth, please tighten the electrode terminal of this side first. Then added some more refilling solution to 4/5 of the inner cavity of the bigger side and tighten the electrode terminal of this side.

- d) Seize the electrode to upright position. Please click the bottom of electrode several times with a finger to remove bubbles at the bottom of the inner cavity of the electrode.
  - e) The refilling solution for Ref electrode is an oversaturated solution. There will be white crystal inside the inner cavity of the electrode during the usage. The refilling solution may volatilize after long time usage. So please add refilling solution for Ref electrode one time. (When replace refilling solutions for ISE electrodes, the original liquid inside the electrodes must be empty first. However, it is OK to add refilling solution for Ref electrode directly no matter the electrode is empty or not. Please notice that the refilling solutions for ISE electrodes and Ref electrodes are different. Please only add correct refilling solution to the correct electrode(s).)
6. After inject enough refilling solution into the electrodes, please install them into the measuring chamber according to the order (from left to right) of  $\text{Li}^+$ ,  $\text{K}^+$ ,  $\text{Na}^+$ ,  $\text{Ca}^{2+}$ ,  $\text{Cl}^-$ , pH and Ref.


**Installation steps:**

1. Open the front cover of the analyzer and the cover of measuring chamber.
2. For the first usage of all electrodes, or the refilling solution in one electrode is less than half of its inner cavity, new refilling solution must be injected into the electrode(s).
3. Before installation, please use a clean paper towel to clean the measuring chamber and the electrode terminal.
4. Pull the spanner to right
5. Check whether the O-rings on the both sides of each electrode are normal or not. Use a tissue paper to clean the channel of each electrode.
6. Place the electrode head tightly against spring. Then press to inner side and trim all electrodes from left to right according to the correct order.
7. Install the Ref electrode at last.
8. Level all electrodes again when all of them are installed into the right places.

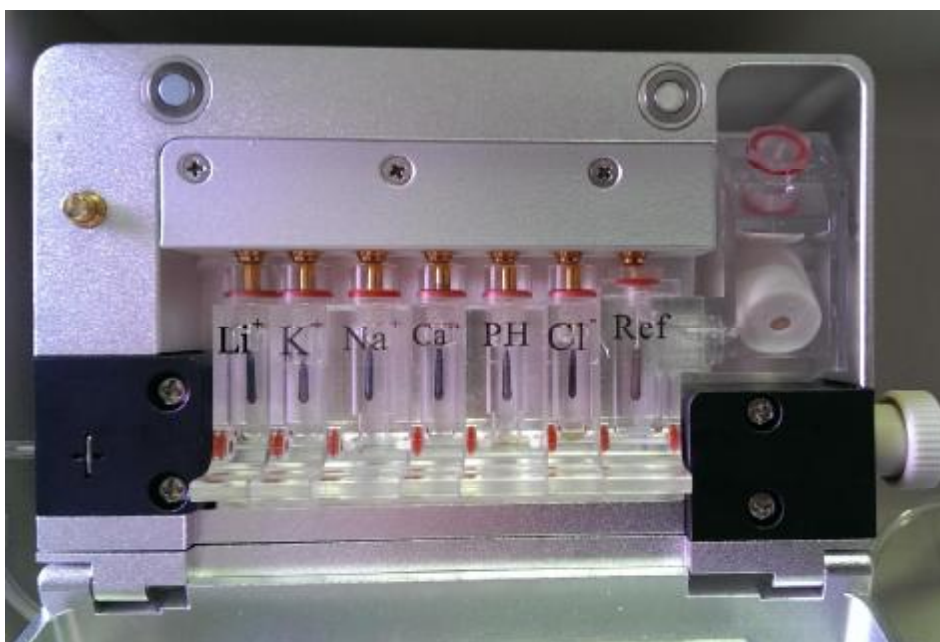
9.Release the hand slowly so that the spanner can press all electrodes tightly.


10.Check whether all electrodes are leveled or not at last.

11.Close the cover of the measuring chamber.

	<ul style="list-style-type: none"><li>Electrodes shall maintain a channel end to end to form of a Flow path (no dislocation)</li><li>After installation, please check whether there is any bubble at the bottom of every electrode. If yes, please tap the bottom of the electrode several times to remove the bubble.</li></ul>
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Correct position of each electrode is shown in the picture below.



	<ul style="list-style-type: none"><li>The replacement of the electrode is similar to the installation. The parameter of each electrode is in 4.1.5 section.</li></ul>
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## 5.4 Installation of pump tube

The steps of pump tube installation are as below.

1. Please wrap the pump tube to the peristaltic pump. (To avoid failure due to long-term taut, the tube must be removed from the peristaltic pump during transportation).
2. Rotate the wheel of peristaltic pump to card the tube into the pump wheel slowly. When the whole tube is carded into the wheel, card the other end into peristaltic pump.



3. Rotate the pump wheel anticlockwise first and clockwise later until the tube is rotated just in the middle of the wheel.
4. Check whether the ends of the pump tube are in the correct position or not.
5. Insert the Tygon tube into the joint pipe of pump tube for at least 5 mm.



Please remain power-off during the installation of pump tubes.

## 5.5 Installation of printing paper

The steps to install printing paper are as below.

1. Push the open key on the printer and open the cover of the printer.



2. Load a new roll of paper inside the compartment. Please notice that thermal surface of the paper must be upward (use a hard objects scratches both sides of the paper. The side with black scratch is thermal surface).



3. Drag the paper out for about 3 cm.
4. Steady the paper and close the printer cover.
5. Tear off the redundant paper



Never pull the paper from inside. It may damage the gear of the printer.

## 5.6 Installation of Reagents

### 5.6.1 Installation of calibration solution




- ! Generally, please always remain power-on for the analyzer. If the analyzer is power off for more than 24 hours, there may be crystal in Flow path.
- ! The barcode for each calibration solution cannot be used again after a

	successful installation.
--	--------------------------

**The steps to install/replace calibration solution:**

1. Open the front cover of the analyzer, release the reagent connector, and take out the previous pack. (Ignore this when install the first pack of calibration solution)
2. Hold a new pack at hand. Tap the “consumable” on the main menu to enter the sub-menu of consumable management. Use the scanner to scan the bar code on the pack.
3. Remove the sticker “please remove before usage” on the new pack and expose the exhaust holes of the pack. Remove the plastic cover over the pack connector.
4. Connect the pack connector with the reagent connector of the analyzer.
5. Place the plastic cover of the new pack over the pack connector of the old pack to seal the waste inside the old pack.



- |   |   |
|---|---|
|  | <ul style="list-style-type: none"><li>! Do wear gloves when replacing the packs.</li><li>! Put the old pack in upright position and cover its connector with the plastic cover once it is taken out.</li><li>! Please destroy the old packs according to relevant local laws.</li></ul> |
|---|---|

### 5.6.2 Installation of TCO<sub>2</sub> Reaction Solution

Place the bottle of TCO<sub>2</sub> reaction solution at the front groove of the analyzer. Get through the tubes then.

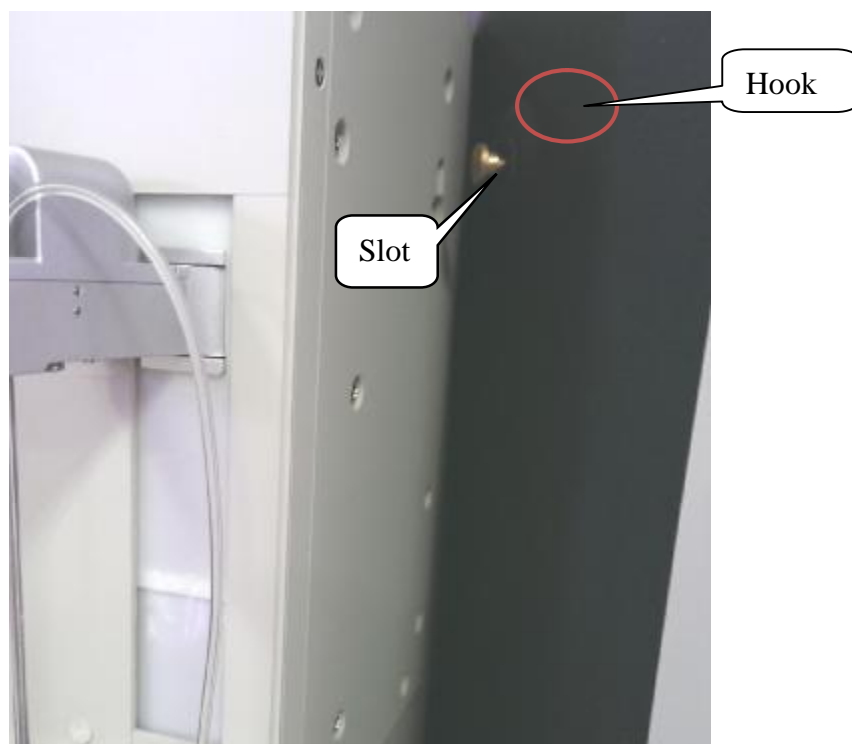


## 5.7 Installation of autosampler

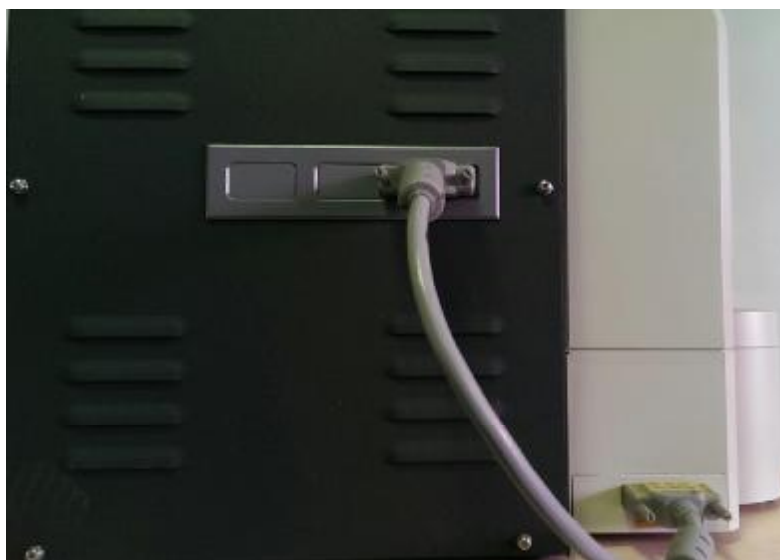
1. Connect tube 1 with the upper interface of the sample probe of the autosampler, connect the tube 2 with the lower interface of the semi-automatic sample probe. Please ensure the joint length of each point is  $\geq 5\text{mm}$  as the picture below



2. Lift up the autosampler and hook on the the analyzer.

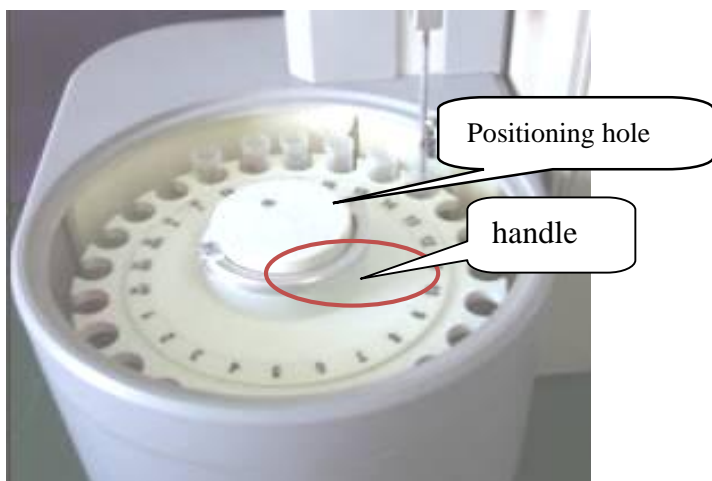


3. Connect two sockets of auto sampling on the analyzer and the autosampler with the data cable.




**Never connect these two sockets when the analyzer is power on.**

4. Lift the autosampler by the handle. Set the positioning hole right on the positioning pin at the bottom. Then flat the handle as the picture below.



5. Match the gap on the cover of autosampler to the gap of the autosampler. Place the cover over the sampler and confirm it is fixed.

	<ul style="list-style-type: none"><li>! Autosampler is only for the automatic models.</li><li>! The sampler disc can only be taken out when the handle is totally upright.</li><li>! Never remove the cover of autosampler during testing. Otherwise the test will be halted automatically. The test will only be continued when the cover is correctly placed again.</li></ul>
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## Chapter 6 Main Menu

### 6.1 Power on

This analyzer uses colorful touch screen. Tap the icons or texts on the touch screen to operate the software.

After the installation of all hardware, please switch on the analyzer. There is a “Touch panel calibration” button on the screen. Please tap the button adjust the touch screen or tap “Cancel” button if the touch screen does not need such adjustment.



If the operator does not tap any icon of this screen for 10 seconds, the analyzer will enter the menu of self test and start a self test automatically.

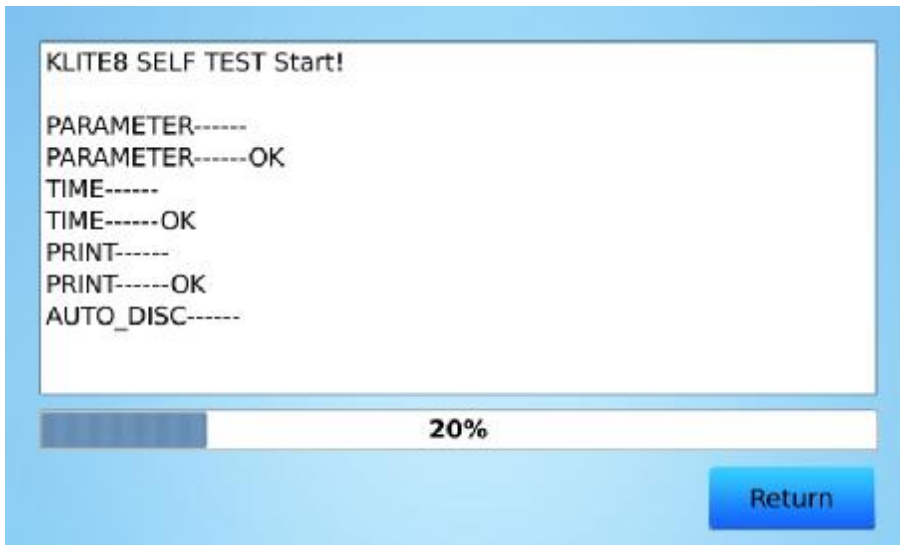
### 6.2 Self Test

The self test of the analyzer includes the checks on sampling module, motor module, sensor module and liquid level detection module.

Flush and calibration solution is aspirated and emptied to set up liquid and air reference with the cooperation of pumps and multiplexer. If any part of this self test fails, the analyzer will alarm the operator to stop the self test.

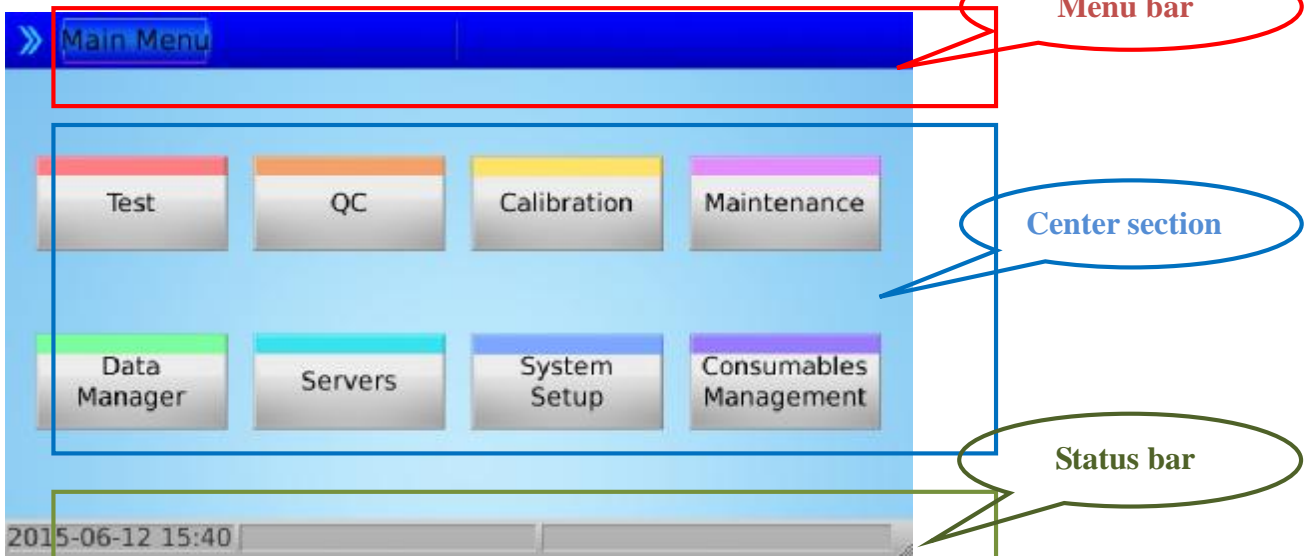
After a successful self test, please tap “OK” to enter the main menu. At this moment, the

self test is still running in the background.



## 6.3 Main Menu

When the analyzer completes the self test, it will enter the main menu:



Menu bar: display the consumables status(CAL pack, pump tube and electrodes) and a failed parameter.

Center section: display QC,Calibration,Test and Sytem Setup menu, etc.

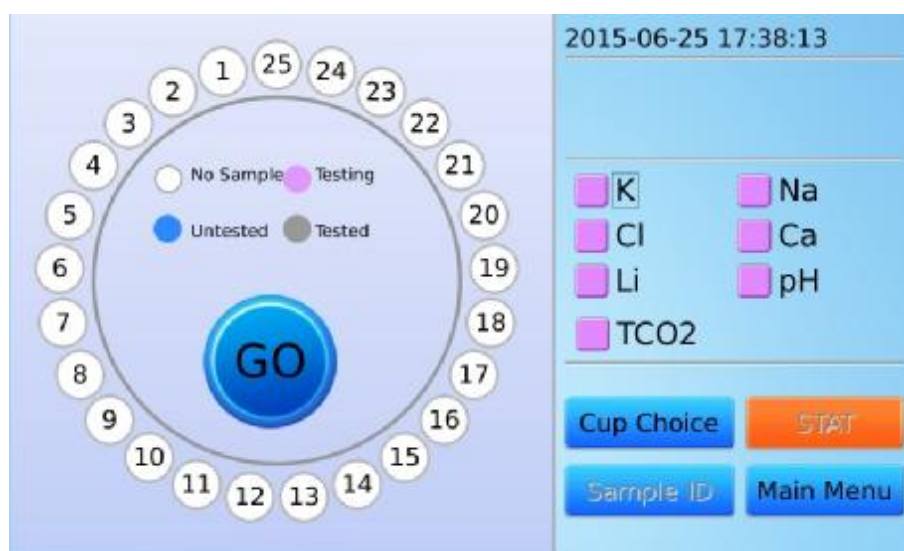
Status bar: display system time and status message.

## 6.4 Test Menu

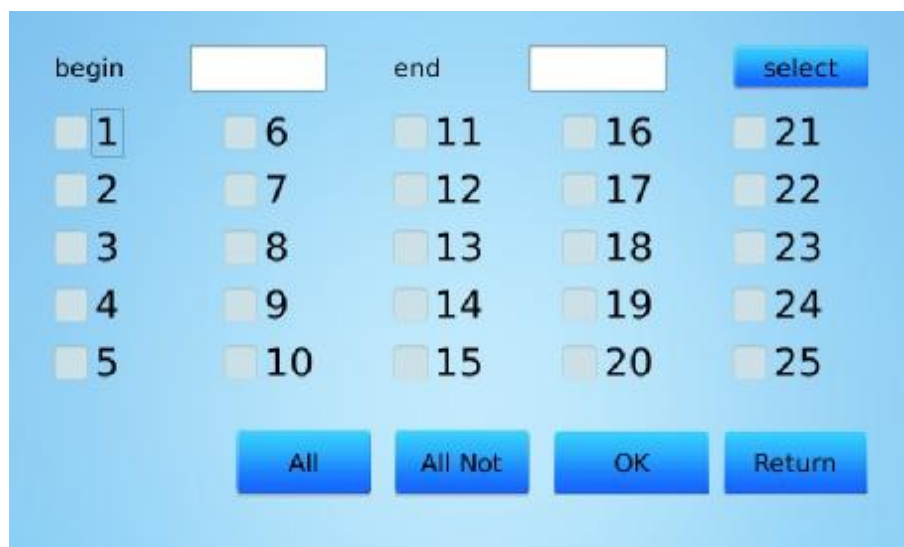


### 6.4.1 Serum test

1) Tap the “Test” button of the main menu. The analyzer will enter the test menu as the picture below, select the testing parameter. Tap the sample number on the screen, then the color turn blue (White indicates that there is no sample; Pink indicates that the sample is testing now; Blue indicates that the sample is not tested yet; Grey indicates that the sample has been tested).



2) Also you can tap the button to select sample number, as below:



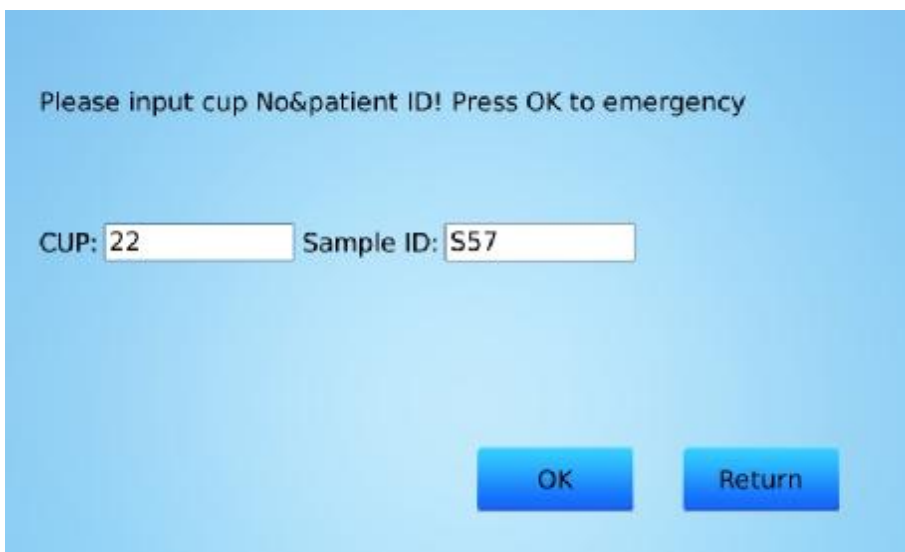
3) Place the sample into the right position and tap “Go” button directly. The sample will be aspirated into the measuring chamber. After the test, the result will be printed automatically. Also, you can check the results by tapping the sample number.

## 6.4.2 Emergency test

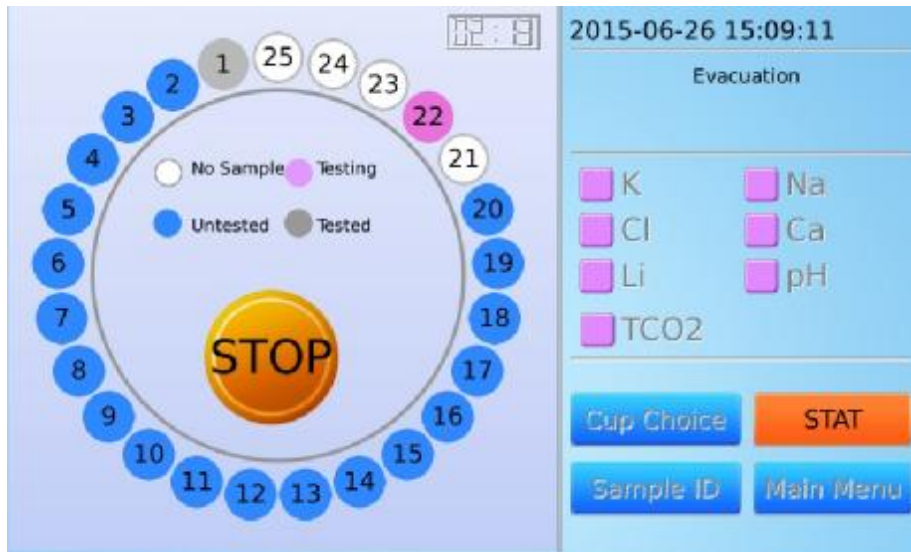
1) For urgent sample, the user can tap “STAT” button as below :



2) Place the urgent sample on the empty position (like number 22), input the number accordingly.

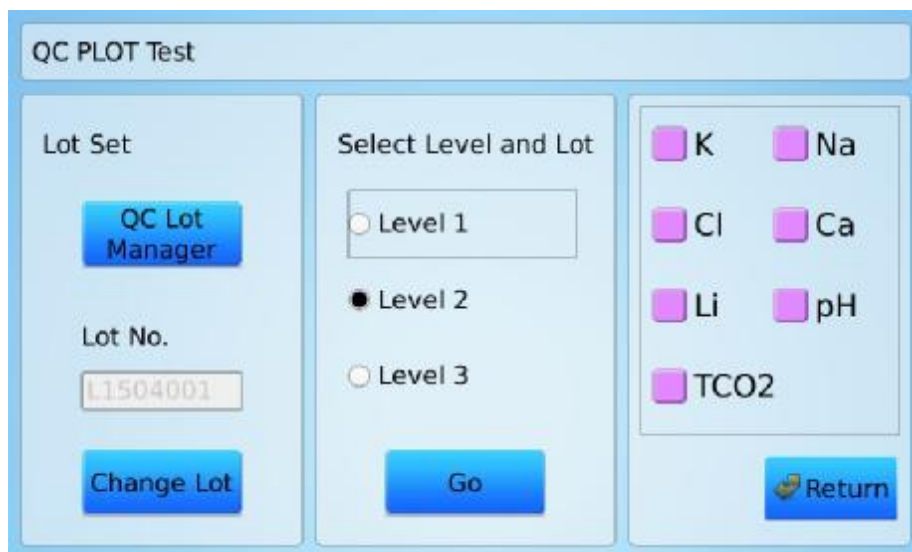


3) The rest steps are the same as 6.4.1.



## 6.5 QC Plot

- 1) Tap the “QC” button of the main menu. The analyzer will enter the QC Plot Test menu as the picture below:



- 2) Place QC solutions on the right position, “Level 1” correspond with (# 25 QC1), “Level 2” correspond with (# 24 QC2), “Level 3” correspond with (# 23 QC3).
- 3) Select “QC Lot No.” , “Level”, then tap “Go” button to test the QC solutions:

ISE Test Result		02-001	00:04
	Voltage	Value	Unit
K	78.79	4.52	mmol/L
Na	88.71	158.59	mmol/L
Cl	91.80	122.96	mmol/L
Ca	49.69	1.83	mmol/L
Li	62.11	1.07	mmol/L
pH	73.40	7.39	
TCO2			mmol/L

Stop

4)After test, the user can check results at “Main Menu→Data Manager→QC Plot Data”.

## 6.6 Maintenance Menu

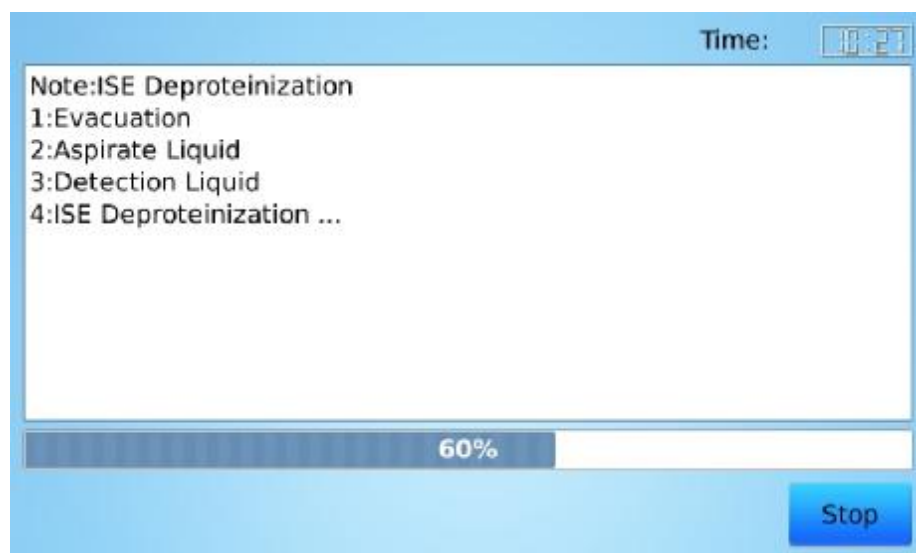
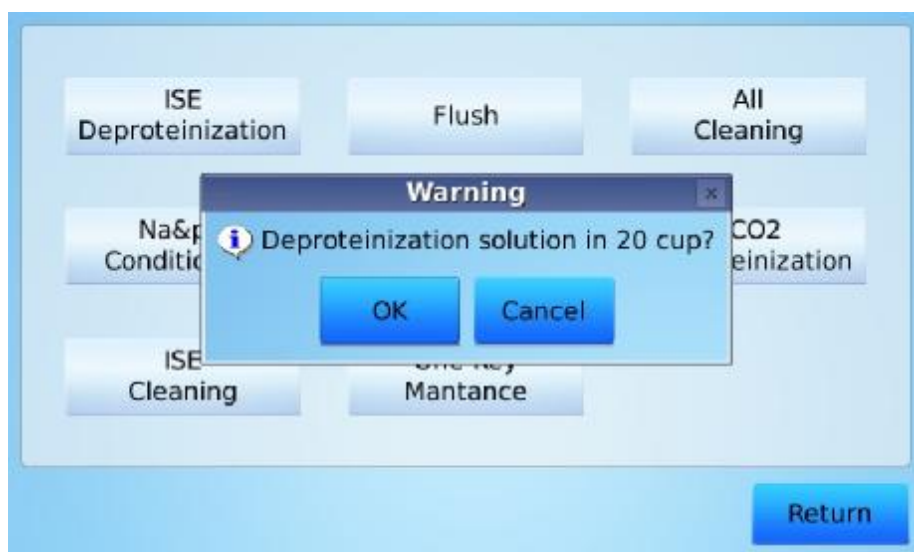
To obtain high reproducibility of measure results and high stability of sensors, it is essential to maintain the unit regularly. Tap the “Maintenance” button of the main menu to enter the submenu of maintenance.



### 6.6.1 ISE Deproteinization

Use this procedure to clean the sample path with deproteinization solution once 10 days or every 100 samples. Deproteinization removes protein buildup from the sample path.

Wait 10 minutes for the **ISE Deproteinization** cycle to finish.

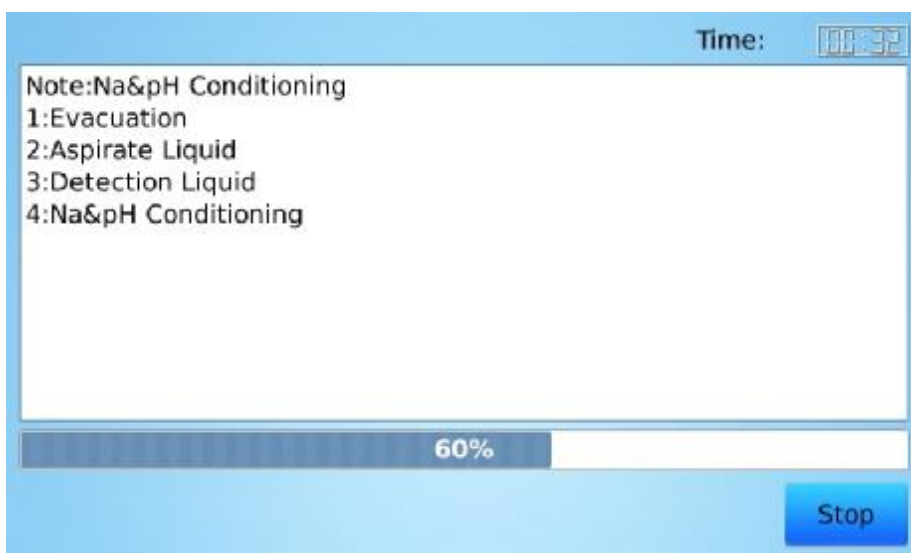
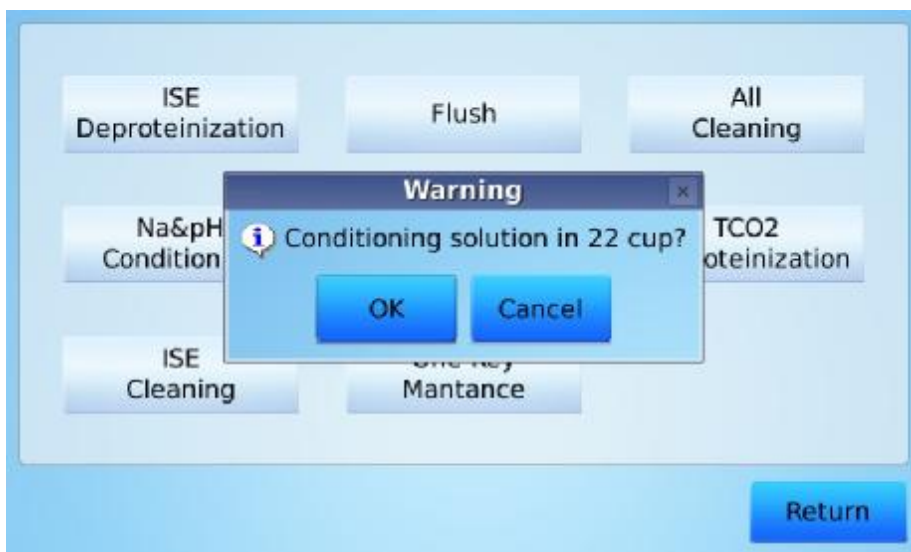



Caution: The deproteinization solution is for single use.

## 6.6.2 Na&pH conditioning

“Na&pH conditioning” works for Na and pH, place the Conditioning solution in #22 cup.

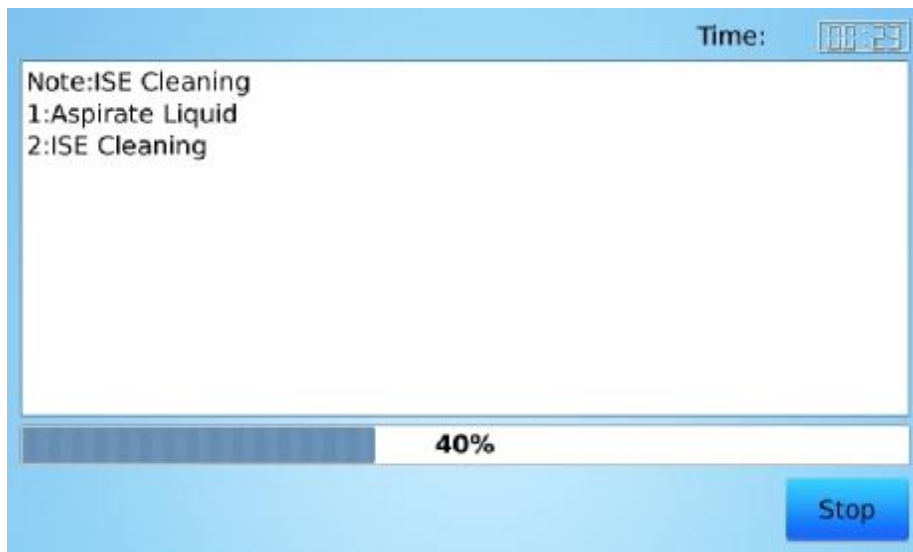
Wait 5 minutes for the **Na&pH conditioning** cycle to finish.



 Caution: The Na&pH conditioning is for single use.

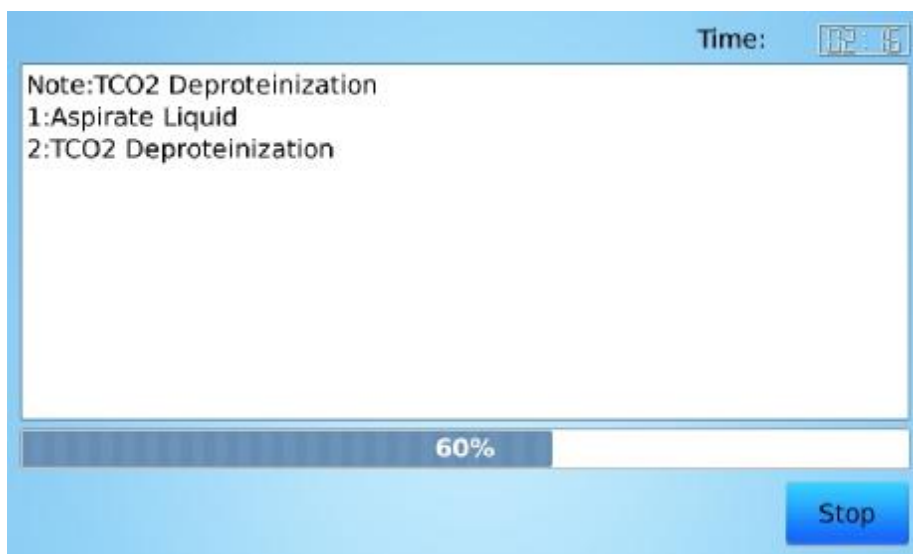
### 6.6.3 ISE Cleaning

Tap the button “ISE Cleaning”, the analyzer will aspirate cleaning solution automatically. Wait 5 minutes for the **Na&pH conditioning** cycle to finish.



### 6.6.4 TCO<sub>2</sub> Deproteinization

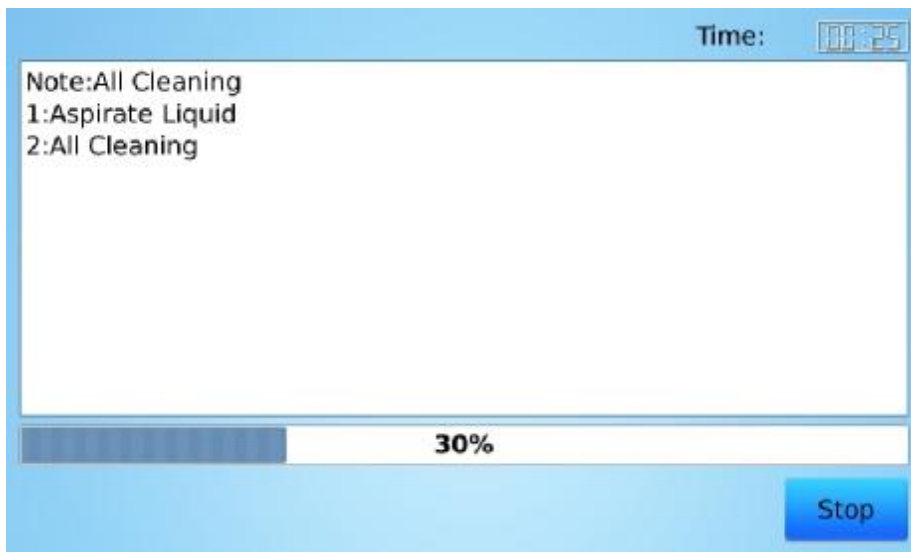
After long-term use, protein buildup in the reaction cup. Please remove protein regularly. Wait 5 minutes for the **TCO<sub>2</sub> Deproteinization** cycle to finish.



### 6.6.5 All Cleaning

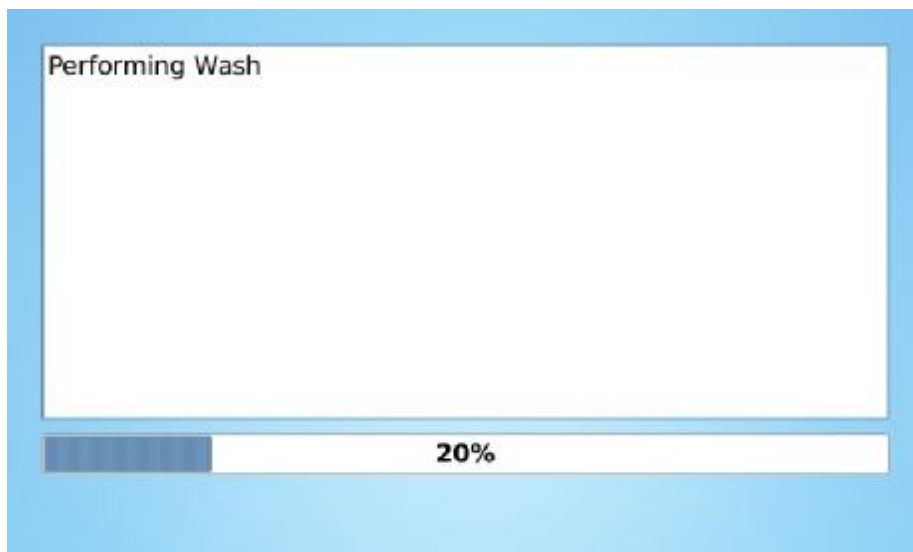
Tap the “All Cleaning” button, the analyzer will perform “**ISE Cleaning**”, “**TCO<sub>2</sub> Cleaning**” and flow path cleaning. Wait 20 minutes for the All Cleaning cycle to finish.





### 6.6.6 Flush

Tap the “Flush” button, the flow path will be flushed automatically.



### 6.6.7 Serum soak

Tap the “Serum soak” button, prompt will instruct the user to place Serum in #21 cup.

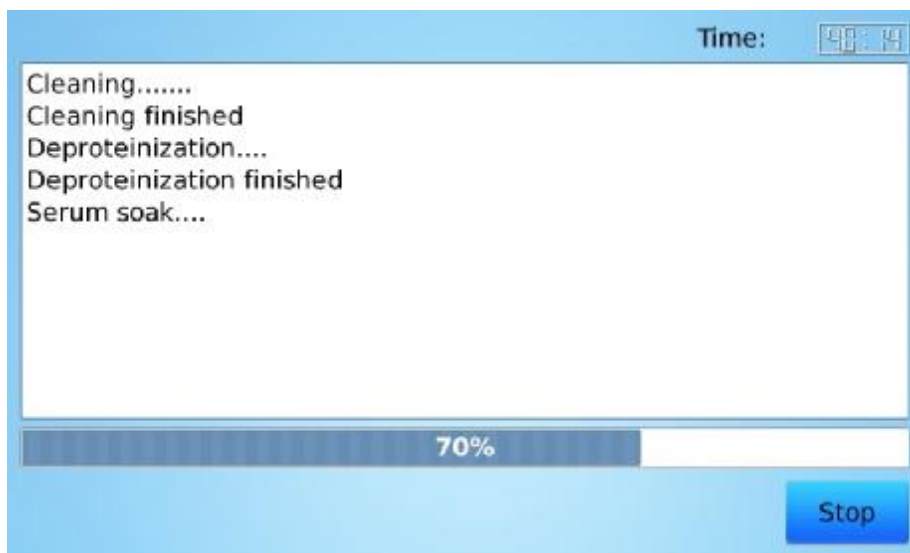
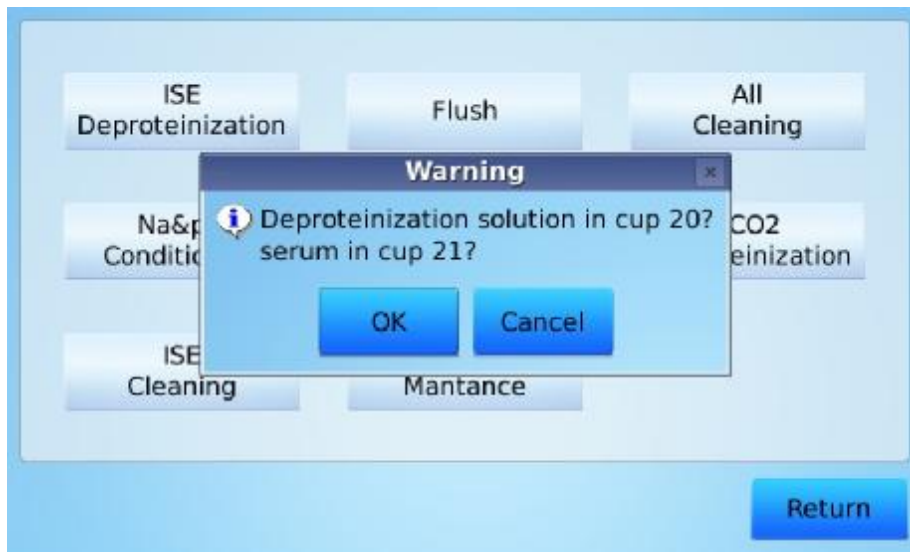
Wait 10 minutes for the **Serum soak** cycle to finish.





### 6.6.8 One key Maintenance

Tap the “**One key Maintenance**” button, the analyzer will perform “**All Cleaning**”, “**ISE Deproteinization**”, “**Na&pH Conditioning**”(if triggered) , “**Serum soak**”. Wait 45 minutes for the **One key Maintenance** cycle to finish.



## 6.7 System Setup

Return to the main menu, tap “System Setup “ button to enter the submenu of system configuration.



The analyzer has 16 parameters for the user to meet various demands of clinical diagnostics.

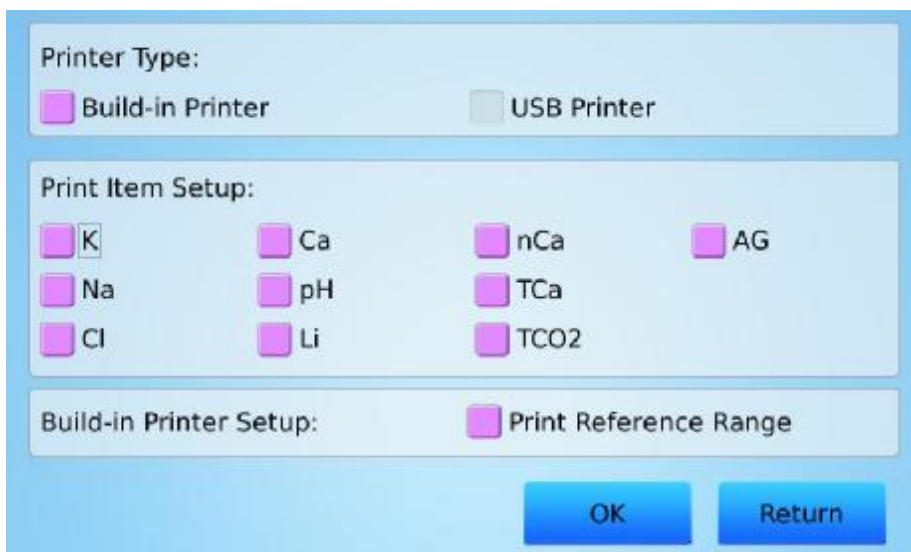
### 6.7.1 Unit Configuration

At the submenu of system configuration, tap “Unit Setup” button to enter the screen of unit configuration, the analyzer provides a variety of units for measured parameters.



### 6.7.2 Printer Setup

At the submenu of system configuration, tap “Printer Setup” button to enter the screen of printing configuration. The user can choose “Printer Type”, “Print Item Setup” and “Print Reference Range”.



Printer Type:

☒ Build-in Printer ☐ USB Printer

Print Item Setup:

☒ K ☒ Ca ☒ nCa ☒ AG

☒ Na ☒ pH ☒ TCa

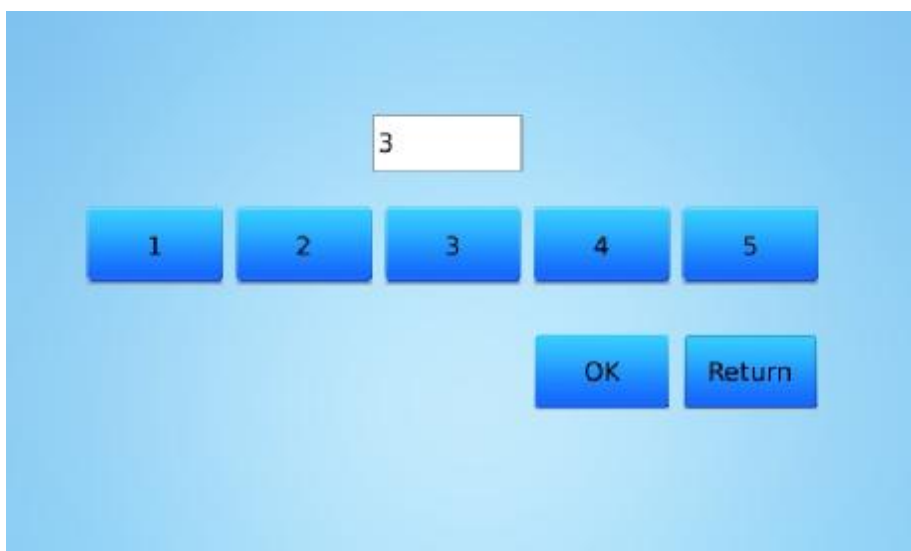
☒ Cl ☒ Li ☒ TCO2

Build-in Printer Setup: ☒ Print Reference Range

OK Return

### 6.7.3 Sample Volume Configuration

At the submenu of system configuration, tap “Sample Volume” button to enter the screen of sample volume configuration. The user can select the volume of sample aspirated, which is increases from 1 to 5.



3

1 2 3 4 5

OK Return

### 6.7.4 Time&Date Configuration

At the submenu of system configuration, tap “Time&Date” button to enter the screen of time configuration. The user can modify date and time in the analyzer.

Date		Time	
Year:	2015	Hour:(24H)	18
Month:	6	Minute:	4
Day:	29		

Return OK

### 6.7.5 Testing Parameter

At the submenu of system configuration, tap “test parameter” button to enter the screen of test parameter configuration. The user can select measured parameters.

<input type="checkbox"/> K	<input type="checkbox"/> Na	<input type="checkbox"/> Cl	<input type="checkbox"/> Ca
<input type="checkbox"/> pH	<input type="checkbox"/> Li	<input type="checkbox"/> TCO2	

OK Return

### 6.7.6 Language Configuration

At the submenu of system configuration, tap “Language” button to enter the screen of language configuration. The user can select language of analyzer.



### 6.7.7 Calibration Intervals Configuration

At the submenu of system configuration, tap “Calibration Intervals” button(pass word: 77) to enter the screen of Calibration Intervals configuration. The user can select frequency of one-point calibration. The system default interval for one-point is 60 minutes, and the default interval for two-point is 120 minutes. The user can define system standby time, during the time there only liquid movement. The system default interval for Li-K value is 7 days, please refer to chapter 7 for details.

Calibration Interval      Sleep Time

☒ 60 Minutes    ☐ 120 Minutes    start    0 : 0  
☐ 180 Minutes    ☐ 240 Minutes    end      0 : 1

Li-K value calibration Interval

After  days to run k value calibration

OK    Return

### 6.7.8 Reference Range Configuration

At the submenu of system configuration, tap “Reference Range” button to enter the screen of reference range configuration. Tap “Reset” button for the default reference range.

K	<input type="text" value="3.50"/>	<input type="text" value="5.50"/>	mmol/L
Na	<input type="text" value="135.00"/>	<input type="text" value="145.00"/>	mmol/L
Cl	<input type="text" value="96.00"/>	<input type="text" value="106.00"/>	mmol/L
iCa	<input type="text" value="1.10"/>	<input type="text" value="1.35"/>	mmol/L
Li	<input type="text" value="0.00"/>	<input type="text" value="0.30"/>	mmol/L
pH	<input type="text" value="7.35"/>	<input type="text" value="7.45"/>	
TCO2	<input type="text" value="20.00"/>	<input type="text" value="29.00"/>	mmol/L
nCa	<input type="text" value="1.10"/>	<input type="text" value="1.35"/>	mmol/L
tCa	<input type="text" value="2.20"/>	<input type="text" value="2.70"/>	mmol/L
AG	<input type="text" value="8.00"/>	<input type="text" value="16.00"/>	mmol/L

### 6.7.9 Correlation Coefficient Configuration

At the submenu of system configuration, tap “Correlation Coefficient” button to enter the screen of Correlation Coefficient configuration. Tap “Reset” button for the default reference range. This setup screen allows the user to mathematically adjust the analytical results of the analyzer based on results from a reference analyzer or reference material. The correlation coefficients can be specified for slope and intercept for each measured parameter. The correlation coefficients of  $K^+$ ,  $Na^+$ ,  $Cl^-$ ,  $Ca^{2+}$  can be calculated automatically. Please refer to chapter 7 for details. Tap “Reset Slope” button for the default correlation coefficients of  $K^+$ ,  $Na^+$ ,  $Cl^-$ ,  $Ca^{2+}$ ,  $Li^+$ , pH 和  $TCO_2$ . Tap “Reset K-value” button for the default K-value.

	Slope	Intercept
K	1.00	0.00
Na	0.93	7.18
Cl	1.00	0.00
Ca	1.00	0.00
Li	1.00	0.00
pH	1.00	0.00
TCO2	1.00	-5
K_value	130	

### 6.7.10 Screen Configuration

At the submenu of system configuration, tap “Screen” button to enter the screen of Screen configuration. “Protect Screen Switch”, “Protect Screen Setup” and “LCD Brightness” can be adjusted by user.

**Protect Screen Switch**

☒ Open Protect Screen
 ☐ Close Protect Screen

**Protect Screen Setup**

Wait  Minute

LCD Bright

**LCD Brightness Setup**

LCD Brightness

### 6.7.11 QC Control Configuration

At the submenu of system configuration, tap “QC Control” button to enter the screen of QC Control configuration.

The QC rules which is not optional in the system:

- 1)  $1_{2s}$  One control measurement exceeding 2 standard deviations of control limits either



above or below the mean. This rule is used a warning rule to trigger careful inspection of the control data.

- 2) **1<sub>3s</sub>** This rule is commonly used with a Levey-Jennings chart when the control limits are set as the mean +3 standard deviations of control limits. A run is rejected when a single control measurement exceeds the mean +3 control limits.

The QC rules which is disable in the system:

**2<sub>2s</sub>** The control run is rejected with 2 consecutive control measurements 2 standard deviations of control limits on the same side of mean with this rule.

**R<sub>4s</sub>** This rule rejects a run if two control measurements in a group exceed the mean with a 4 standard deviation difference between the 2 controls.

**4<sub>1s</sub>** This rule rejects a run with the 4th consecutive control measurement exceeding 1 standard deviation on the same side of the mean.

**10<sub>x</sub>** This rule rejects a control run when there are 10 consecutive controls on the same side of the mean.

QC Control Enable:

☒ Enable ☐ Disenable

QC Rule:

☐ 1-3s

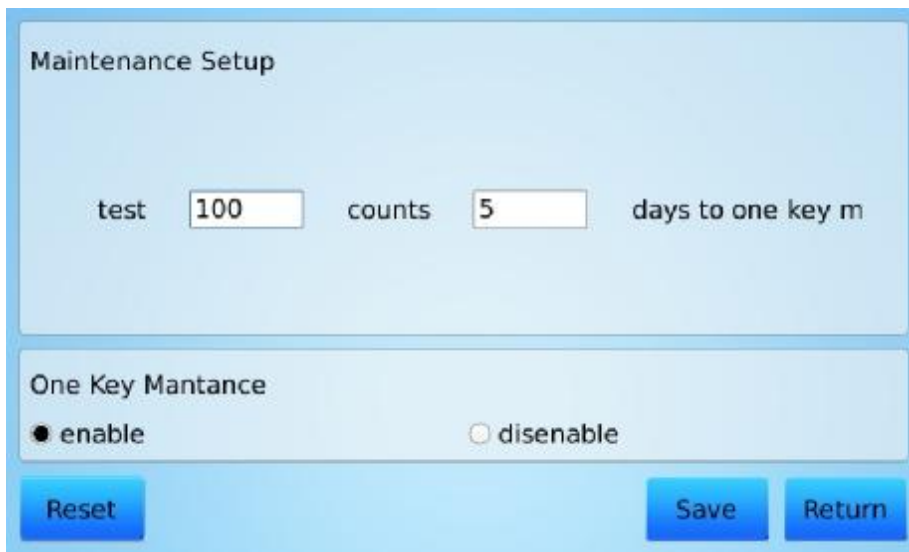
☐ 2-2s ☐ R-4s

☐ 4-1s ☐ 10-X

OK Return

## 6.7.12 Maintenance Setup

At the submenu of systematic configuration, tap “Maintenance Setup” to adjust the days or sample tested counts.



Maintenance Setup

test  counts  days to one key m

One Key Mantance

☒ enable ☐ disenable

Reset Save Return

### 6.7.13 LIS Interface

At the submenu of system configuration, tap “LIS Interface “ button to enter the screen of LIS configuration.



HL7 Server Setting Local Network Setting

Return

1) At the menu of LIS configuration, tap “HL7 Server Setting” to set up the IP and port of the server. Tap “save” to save the configuration.

LIS Server Setting:

Server IP: 192 . 168 . 1 . 35

Server Port: 6178

☐ Enable

☒ Non-Enable

Save

Return

2) At the menu of LIS configuration, tap “Local Network Setting”. All settings can be done manually. After the setting, tap “Save” to save the current configuration.

NetWork Config:

☐ Configure IP and DNS automatically(D)

☒ Configure Local IP manually

IP add: 192 . 168 . 1 . 6

NetMa: 255 . 255 . 255 . 0

Gatew: 192 . 168 . 1 . 2

DNS: 221 . 5 . 88 . 88

MAC : 10:23:45:67:89:ab

Save

Return

## 6.7.14 Resistance Setup

For customer service staff.

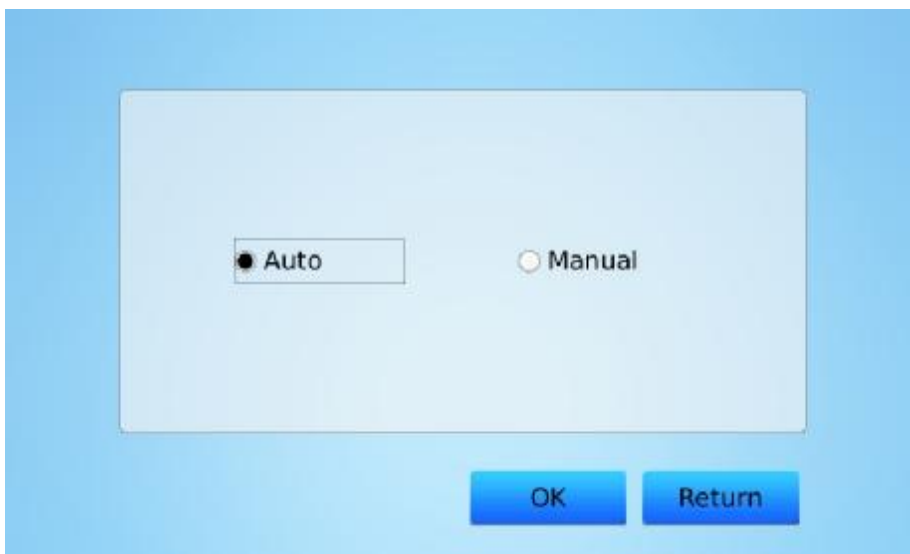
## 6.7.15 Other

At the submenu of systematic configuration, tap “Other “ to select “bubble”, “clog”, “TCO<sub>2</sub>res” and “AutoScan”.



### 6.7.16 Sampling Mode

At the submenu of systematic configuration, tap “Sampling Mode” to select “Auto” or “Manual” mode.



## 6.8 Data Manager

Tap “Data Manager” button of the main menu to enter data management section.



### 6.8.1 Test Results

Tap “Test results” button at data management menu to enter test results search interface:

The screenshot shows a search interface with a light blue background. At the top, there are two search fields: 'Patient ID:' with a text input and a 'Search' button, and 'Date Range:' with two date pickers (showing 2015-04-01 to 2015-07-01) and a 'Search' button. Below these is a table with 8 rows of test results. The table has columns for 'Date', 'Time', 'HL7 Send ID', and 'HL7 Send Status'. The first row is highlighted in blue. Below the table are several buttons: 'More', '<<', '<', '>', '>>', and a blue 'Return' button with a right-pointing arrow.

	Date	Time	HL7 Send ID	HL7 Send Status
1	2015-06-26	15:21:39		
2	2015-06-26	15:19:14		
3	2015-06-26	15:16:48		
4	2015-06-26	15:14:27		
5	2015-06-26	15:12:43		
6	2015-06-26	15:10:10		
7	2015-06-26	15:07:32		
8	2015-06-26	15:03:43		

1. The upper side of the interface is the search field. The user can search by time period and "Sample ID" (Patient ID). The middle part is to display test results. The lower part is for function keys.
2. Input sample ID or test date then tap “search” button to search relevant data.
3. Tap “more” button to check more details like basic information, test results, A5 test report, analysis report, edit, etc.

## 6.8.2 ISE CAL Results

1. Tap “ISE CAL Results” button at data management menu to enter ISE calibration result search interface:

Calibration Data

Date Range: 2015 . 06 . 25 -- 2015 . 06 . 28

	Date	Time	Cal Type	K_vol	Na_vol	Cl_vol	Ca_vol	pH_vol
1	2015-06-28	23:27	A-1	77.70	86.05	96.84	46.41	95.27
2	2015-06-28	22:25	B-1	96.05	79.88	102.66	54.38	113.59
3	2015-06-28	22:24	A-1	77.27	85.70	96.56	45.98	94.38
4	2015-06-28	21:23	A-1	77.46	85.86	96.64	46.09	94.06
5	2015-06-28	20:22	A-1	77.54	85.94	96.76	46.21	93.55
6	2015-06-28	19:20	B-1	95.86	79.18	102.42	54.18	111.88
7	2015-06-28	19:19	A-1	77.11	84.96	96.37	45.78	92.58

Buttons: More, <<, <, >, >>|, Return, Delete, Delete All, Empty DB, Search

2. Input calibration time and search relevant data.
3. A user can select delete or delete the current one to perform relevant operation. Select “empty database” to delete all calibration record.
4. Tap “more” button to check more calibration data or to print these calibration results.

## 6.8.3 TCO<sub>2</sub> CAL Results

Similar to ISE CAL Results, which is used for checking calibration results of TCO<sub>2</sub>.

Calibration Data

Date Range: 2015 . 06 . 26 -- 2015 . 06 . 26

	Date	Time	Cal Type	TCO2_vol
2	2015-06-26	14:59	TCO2-1	36.75
3	2015-06-26	14:35	TCO2-1	36.88
4	2015-06-26	14:14	TCO2-1	37.61
5	2015-06-26	12:08	TCO2-1	37.36
6	2015-06-26	10:04	TCO2-1	37.43
7	2015-06-26	07:05	TCO2-3	37.36
8	2015-06-26	07:03	TCO2-2	37.85
9	2015-06-26	07:02	TCO2-1	39.62

Buttons: More, <<, <, >, >>|, Return, Delete, Delete All, Empty DB, Search

### 6.8.4 Data Export

1. Tap “Data export” button at data management menu to enter data export interface



2. Insert a flash disk into the USB interface at the back of the analyzer, select time and data type.
3. Tap “Export” button to export the data, when the progress bar shows 100%, it means the data export is completed. Please remove the flash disk.

### 6.8.5 QC Plot Data

1. Tap “QC Plot Data” button at data management menu to enter QC Plot data interface:



2. Select the query level, date range, click the "search", it can query to the relevant data.
3. Select a data quality control, click the "Delete", you can delete this item; click "Empty DB", you can empty the quality control data.

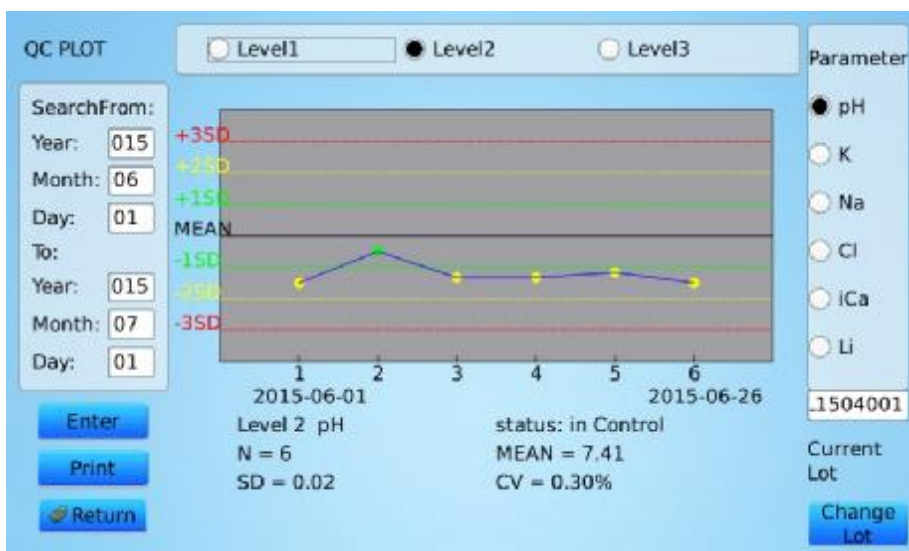


4. Select a data, click "more", check out the more detailed data and information.



## 6.8.6 QC Graph

1. Tap “QC Graph” button at data management menu to enter QC Graph interface:



2. Select the query level, date range, click the "Enter", it can query to the quality control chart is needed.

3. Select a test parameter, quality control chart interface intermediate will appear this parameter.

4. The “Current Lot “ refers to the current quality control chart of batches, click on the "change the batch number" can re select.

## 6.9 Servers

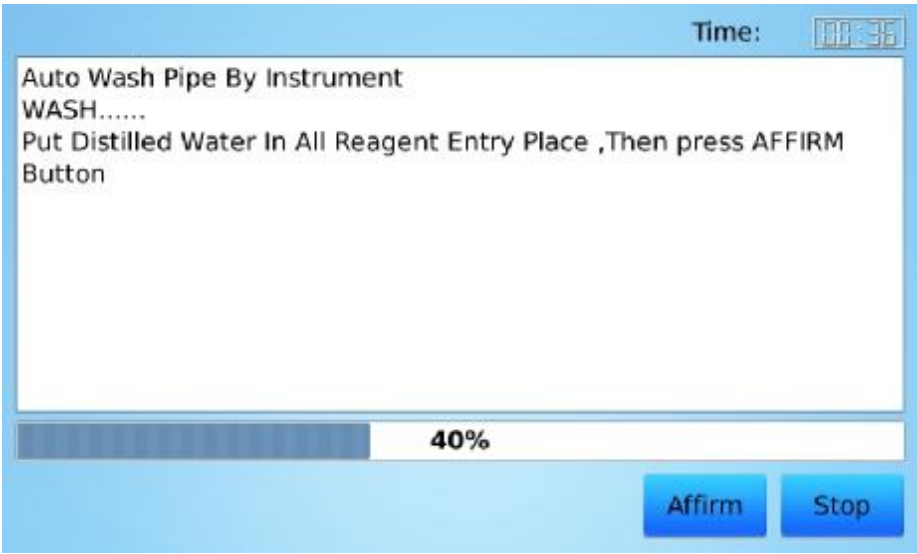


Return to the main menu, tap “Servers” button to enter the submenu of Servers:



6.9.1 ShutDown

Tap “ShutDown” button to shutdown the system:

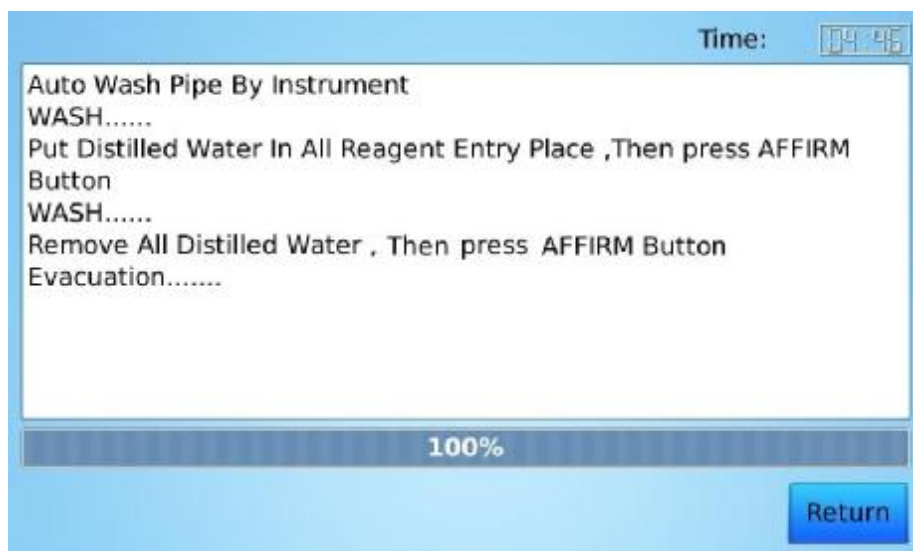


Take off Calpack, link the connector in the accessory box. Put all entry pipes(Cal A, Cal B,TCO2 and Cleaning solution) in distilled water, and put waste pipe in a cup or bottle, then



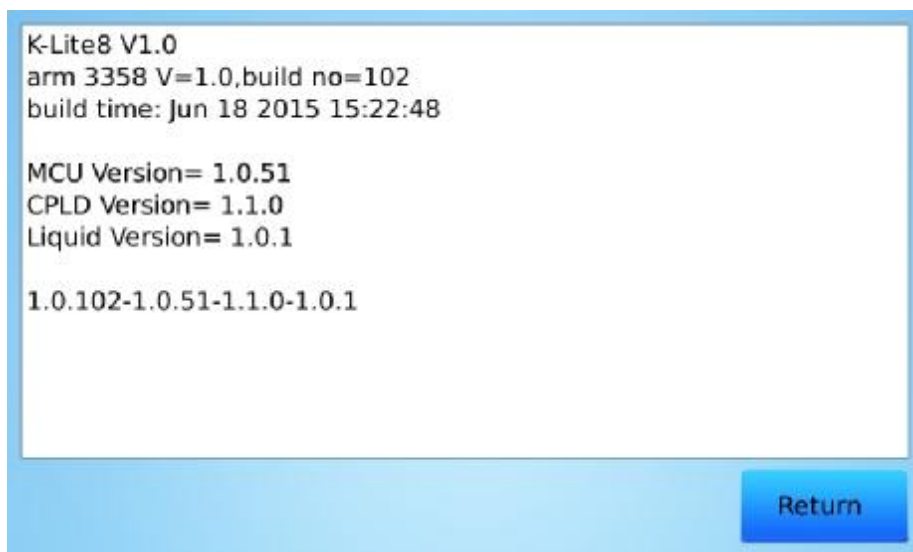
press AFFIRM button.

Then remove distilled water, leave all entry pipes in the air, press AFFIRM button. When the progress bar is 100%, the system can be shutdown now.



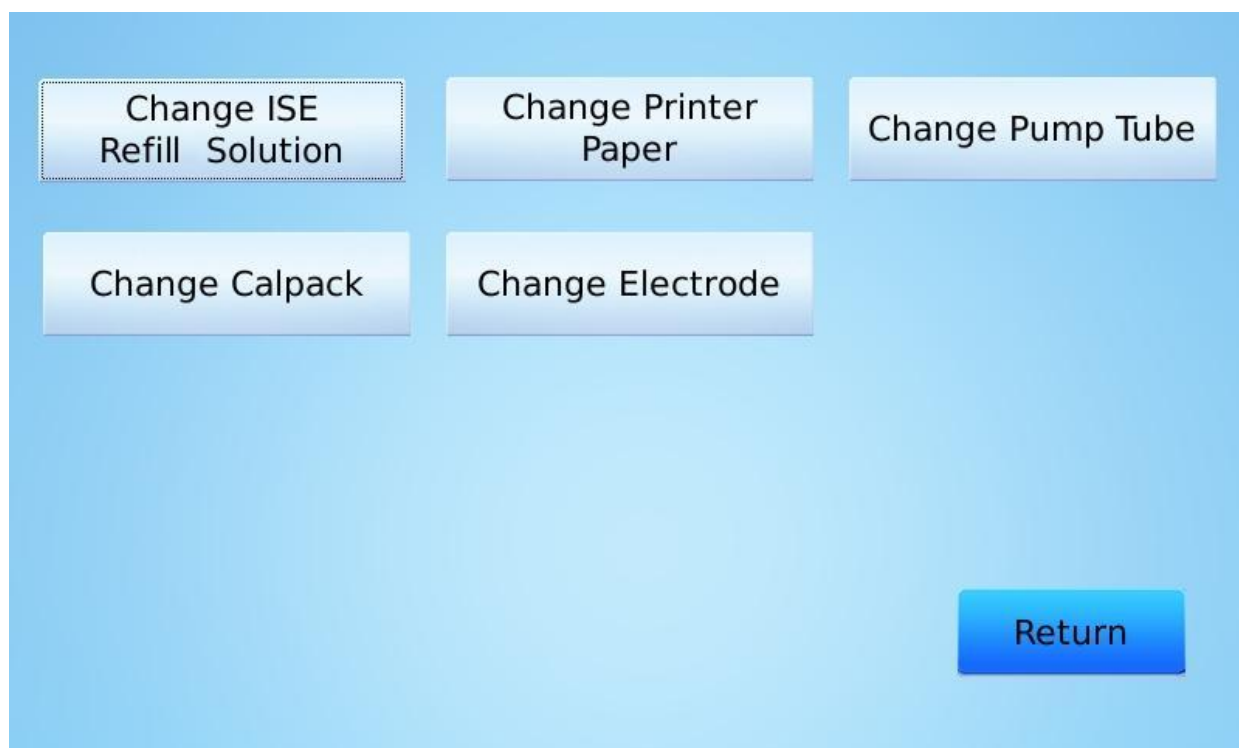
## 6.9.2 Version

Tap "version" button to enter Help interface:

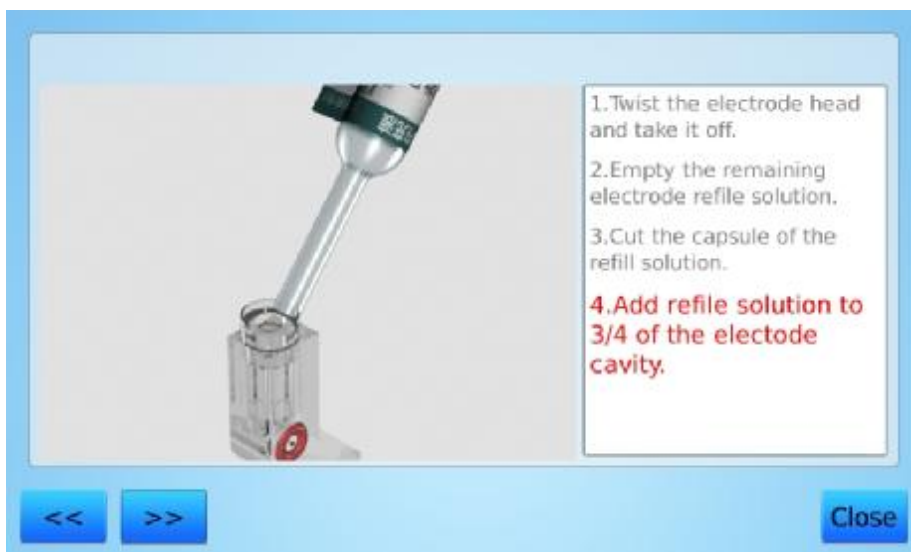


### 6.9.3 Help

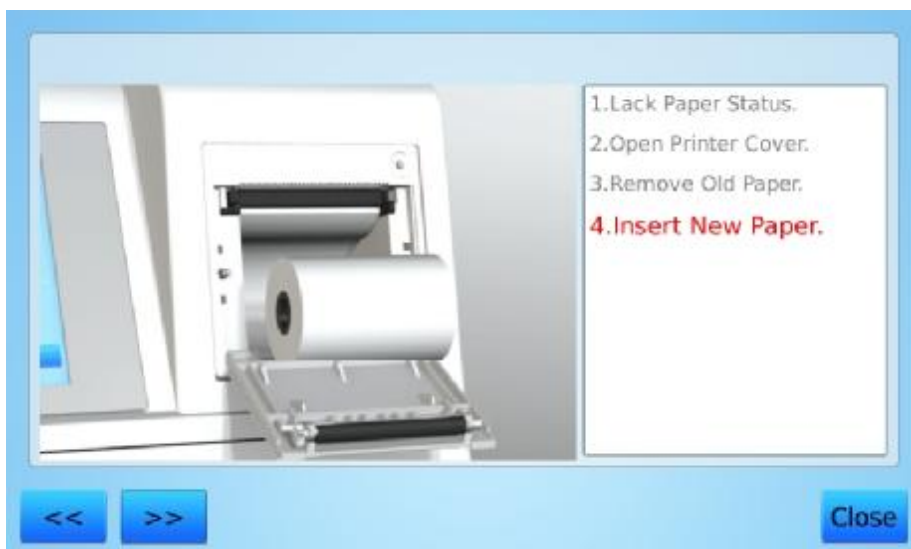
Tap “Help” button to check the consumables replacement tutorials.



Change ISE Refill Solution:



Change Printer Paper:



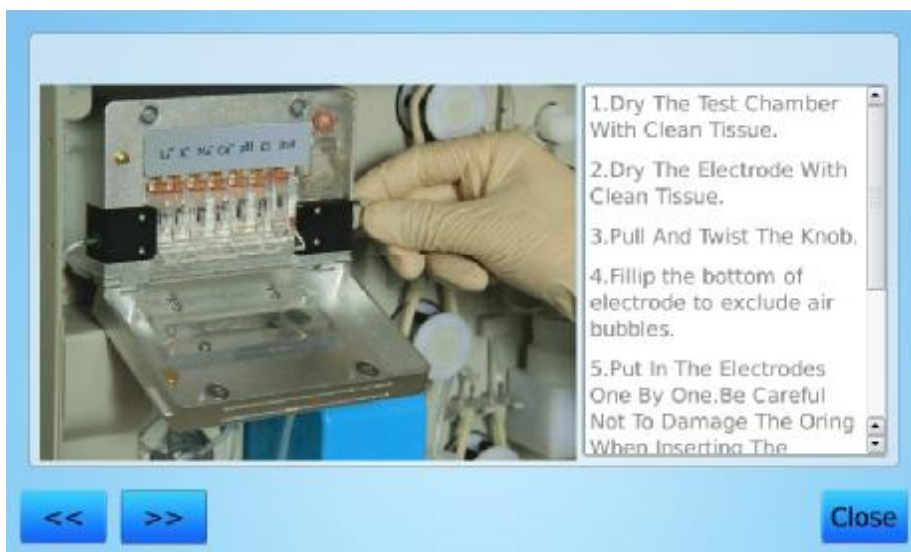
Change Pump Tube:



Change Calpack:



Change Electrode:



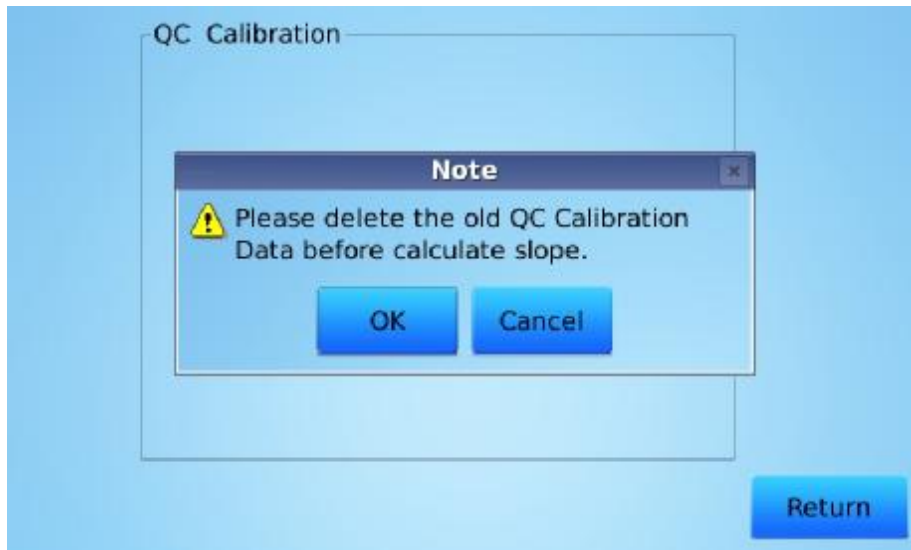
### 6.9.4 Multiplexer Check

Tap “Multiplexer Check” button to check whether the multiplexer can aspirate Cal A, Cal B, TCO<sub>2</sub> Cal and Cleaning solution.



### 6.9.5 QC Calibrate

Tap “QC Calibrate” button then “QC test” button, where shows a note box “Please delete the old QC Calibration Data before calculate slope”. Tap “OK” button the data will be deleted, while “Cancel” means not delete the data:



**QC LOT Manager:** Used to enter “QC Lot No.”, “Expiration”, “Target value”;

**Test Count:** Used to enter test number of every level;

**Select Lot:** Used to select lot of QC solution, if the Lot numbers are different, “Correlation Coefficient” can not be calculated by the system automatically;

**All:** System will test the QC solution from level 1 to level 3 automatically.

**Cup number on the sample tray:** Level 1(# 25), Level 2(# 24), Level 3(# 23);

QC data:



QC Data    ☒ All Levels    ☐ Level 1    ☐ Level 2    ☐ Level 3

	Date	Time	Lot No.	Level
1	2015-07-02	09:46:10	L1504001	3
2	2015-07-02	09:44:47	L1504001	3
3	2015-07-02	09:43:26	L1504001	3
4	2015-07-02	09:40:17	L1504001	2
5	2015-07-02	09:15:50	L1504001	2
6	2015-07-02	09:14:25	L1504001	2
7	2015-07-02	09:13:03	L1504001	1
8	2015-07-02	09:11:38	L1504001	1

Calculation  
Statistics  
Delete  
Delete All

More    |<<    <    >    >>|    Function    Return

Select level of QC Data;

Choose a data ,Tap “More” button to enter the QC Cal Result interface, where the user can check “Date”, “Lot No.”, “Level”, “Item”, “value”, “target” and “2SD”.This interface can be used to evaluate accuracy of QC Cal Results.

Tap “Function” button to show or hide four buttons: “Calculation”, “Statistics”, “Delete”, “Delete All”. If “All Levels” is selected, the “Statistics” button is not available.

Tap “Calculation” button (pass word: 99) , the user can get “Correlation Coefficient” of  $K^+$ ,  $Na^+$ ,  $Cl^-$ ,  $Ca^{2+}$ ;

Level 1    Level 2    Level 3

Lot No.: L1504001    Select Lot

	Slope	Intercept	
K	1.00	0.00	Calculate
Na	0.93	7.18	Reset
Cl	1.00	0.00	
iCa	1.00	0.00	Return

Save

Tap “Select Lot” button to choose lot of the QC solution;

Tap “Calculate” button to get slope and intercept from the QC data;

Tap “Save” button to save current slope and intercept;

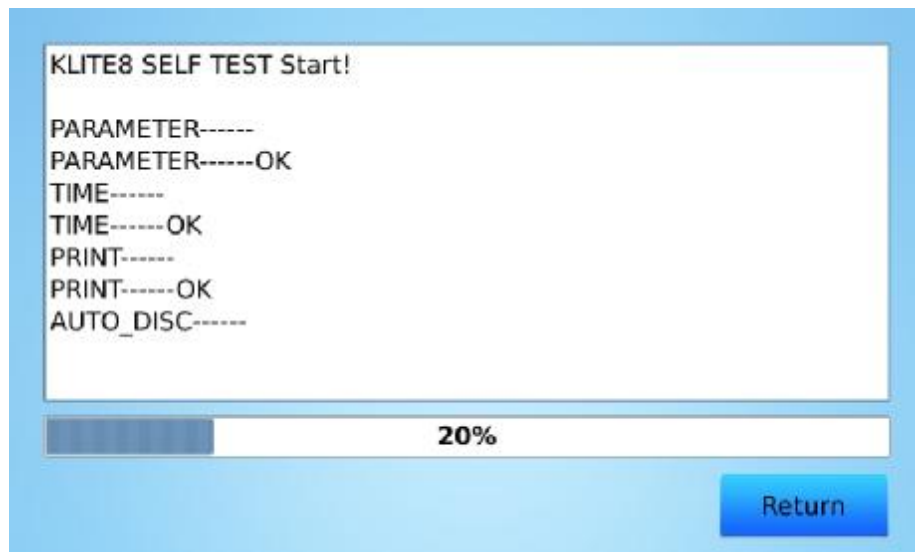


Tap “Reset” button to set slope 1 and intercept 0;

5) Tap “Statistics” button to calculate each level’s CV.

### 6.9.6 Self Test

Tap “Self Test” button to check on important parts automatically. If the self test is OK, the analyzer will return to main menu automatically. If not, please remove all troubles according to the hint on the screen.



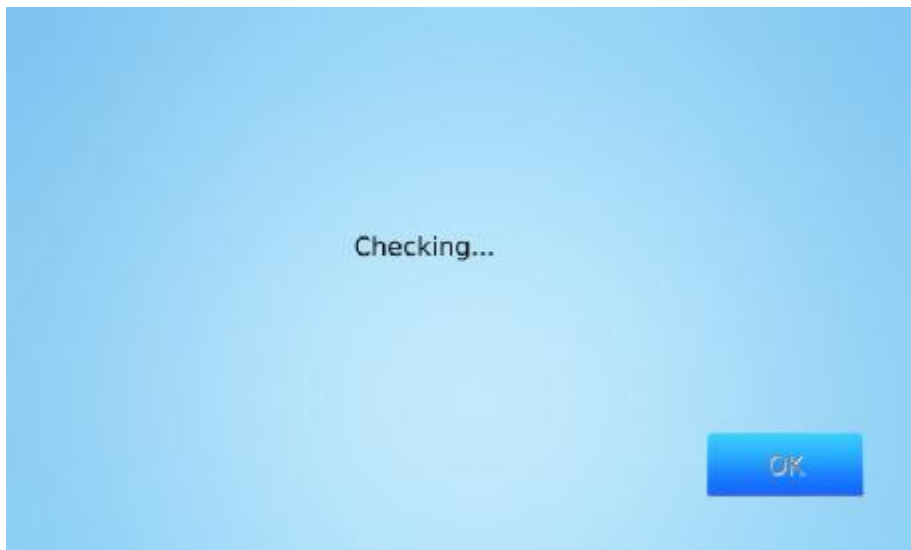
### 6.9.7 Touch panel calibration

Tap “Touch panel calibration” button to calibrate the touch panel.

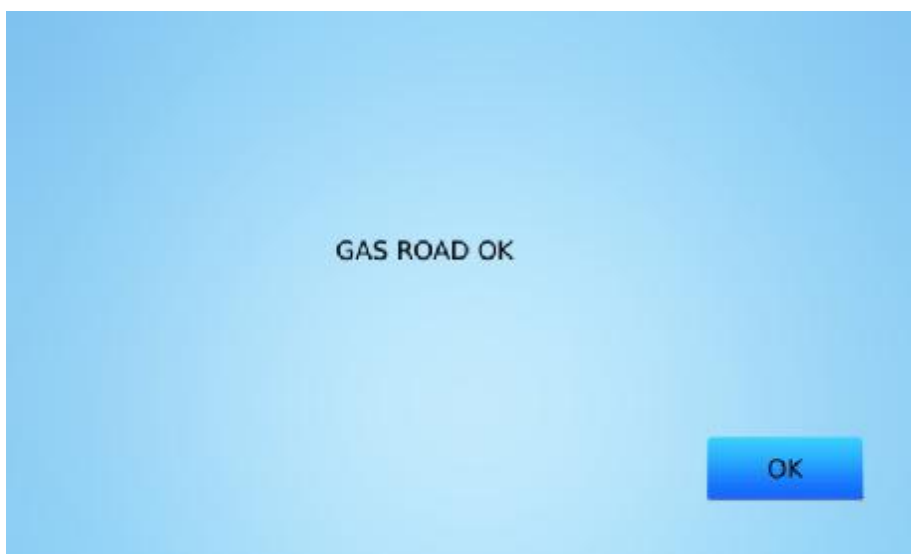


## 6.9.8 Clogged Check

Tap “Clogged Check” button to check out whether the TCO<sub>2</sub> gas circuit is clogged or not.



If it is ok , system will show as below:



If it is clogged , system will show as below, and TCO<sub>2</sub> is not available:

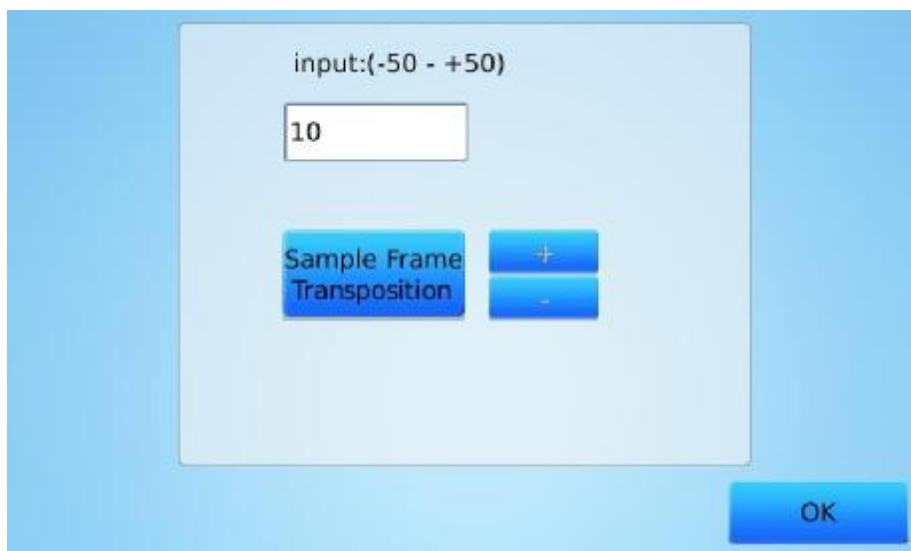


## 6.9.9 Tools

For customer service staff .

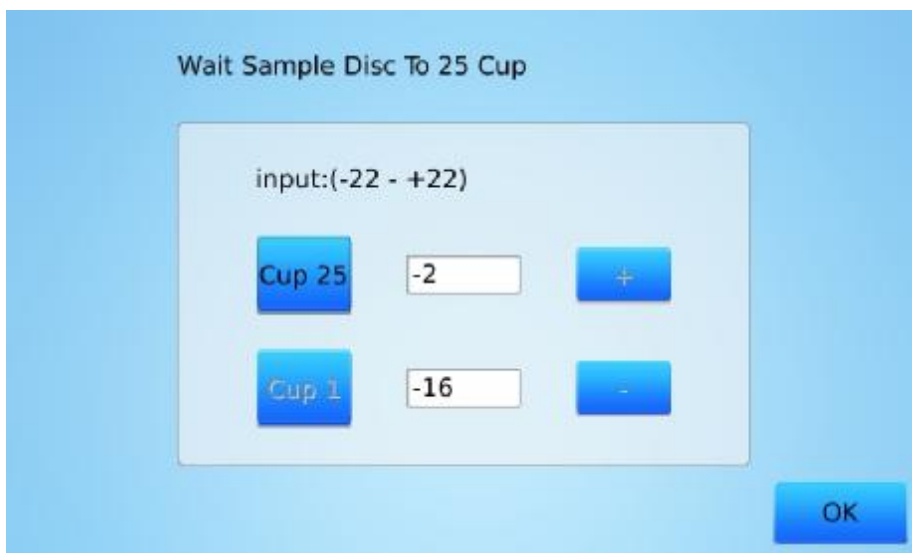
## 6.9.10 Sample Needle Adjust

Tap “Sample Needle Adjust” button to adjust the probe if its position is shifted. Press “Sample Frame Transposition” button and then press “+” or “-” button to make the probe align the center of its dock.



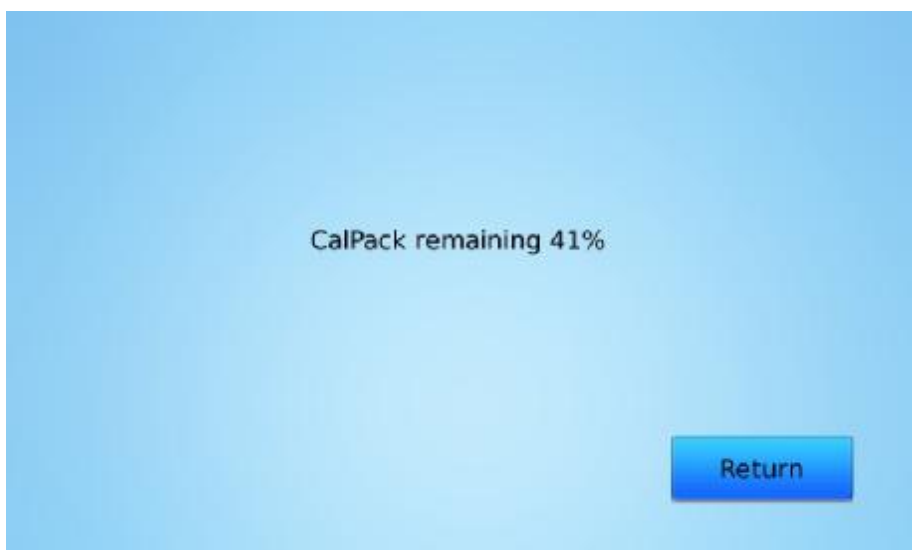
### 6.9.11 Sample Tray Adjust

Tap “Sample Tray Adjust” button to adjust the sample tray if its position is shifted. First position 25# is adjusted, press “+” or “-” button to make the probe to align the center of 25# .Then adjust position 1#. Press OK to save.



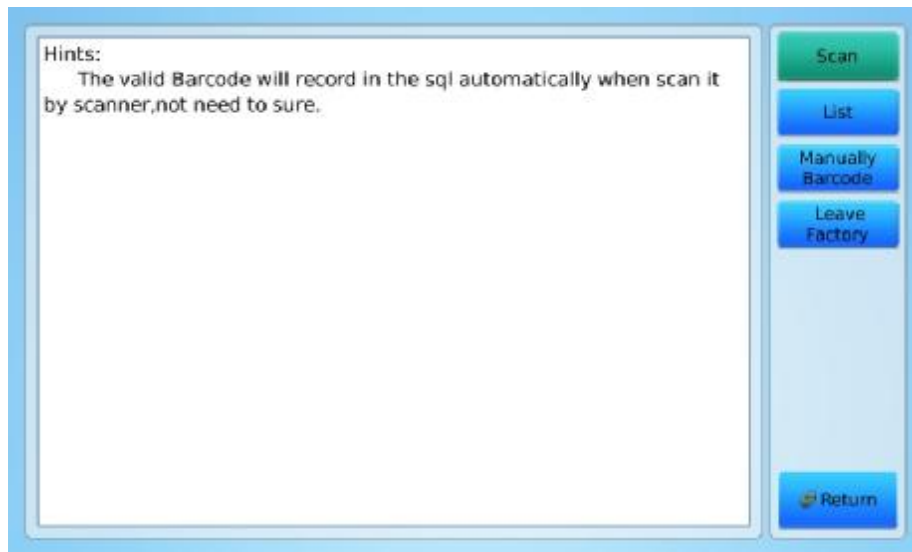
### 6.9.12 Cal Pack Used

Tap “Cal Pack Used” button to check Cal A remaining.



## 6.10 Consumables Management

1. Tap “Consumables Management” at the main menu:



2. Please refer to chapter 6.9.3 “Help”, or Tap “Manually Barcode” button to input the barcode if there is problem with the barcode scanner.



3. Tap “List” button to check state of current consumables.

	OpenDate	Expiration Date	Manufacture Date	Batch Number	Serial
K	2015-05-29	2016-05-23	2015-04...	1601	00002
Na	2015-05-29	2016-05-23	2015-04...	1601	00002
Cl	2015-05-29	2016-05-23	2015-04...	1601	00002
Ca	2015-05-29	2016-05-23	2015-04...	1601	00002
pH	2015-05-29	2016-05-23	2015-04...	1601	00002
Li	2015-05-29	2016-05-23	2015-04...	1601	00002
REF	2015-05-29	2016-05-23	2015-04...	1601	00002
<b>CAL Pack</b>	2015-07-02	2015-07-07	2015-01...	1234	00004
Pump Tube	2015-05-29	2016-05-23	2015-04...	1601	00002

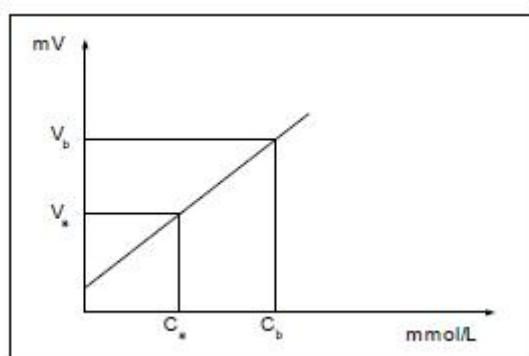
Scan
List
Manually Barcode
Leave Factory
Return

# Chapter 7 Calibration

## 7.1 General information

Calibration defines both points of Cal A and Cal B. When calibration is passed, the concentration in an unknown sample can be calculated from the two points via Nernst equation. The voltage (mV) difference between Cal B and Cal A should fall within the requirement to ensure linearity range of electrodes.

The response relationship between voltage and ion concentration is shown as below



Generally, if the slope of measured parameters by a electrode (or sensitivity) and drift rate (output electrode signal of the parameter) is known, the unknown value can be calculated by measuring the electrode. Electrode calibration is a process to obtain slope and drift rate from the output signal of the electrode associated with liquid concentration. Two-point calibration solution is used by this analyzer to achieve this goal.

## 7.2 One point calibration

One point calibration can associate mV values with ion concentration of Cal A. It defines the first point of two point calibration. It is also used to check the status of electrodes after two point calibrations is passed.

The step of one point calibration is as follow:



Calibration 1 Finish 00:44

	Voltage	Value	Unit	Slope	Status
K	=74.34	4.00	mmol/L		PASS
Na	=83.44	140.00	mmol/L		PASS
Cl	=94.02	100.00	mmol/L		PASS
Ca	=44.88	1.25	mmol/L		PASS
Li	=49.38	0.30	mmol/L		PASS
pH	=75.82	7.40			PASS
TCO2					

[Return](#)

1. Tap “1 Point Calibration” button at the submenu of calibration.
2. The analyzer will aspirate calibrator automatically.
3. The calibration result will be printed after one pint calibration is done.
4. The analyzer will aspirate flush solution automatically to flush the Flow path.
5. When the flush is done, system will return to the main menu automatically or wait for the further command from the operator

There are four possibilities for one point calibration

Pass	The system will display the corresponding concentration of Cal A and return to the main menu.
Unstable	Unstable mV value. The system will also alarm voltage value is unstable
Drift	When two mV values are beyond a certain range, the system will alarm the electrode drift. The abnormal electrode channel will be displayed at the



	bottom of the screen.
OR: mV out of range	If the electrode mV value exceeds the set range, the system will prompt the mV is out of range. Please refer to the following instructions for the range of each electrode.

Notice:

“Cal A”: “A1” here means the first one point calibration

“02:01”: Calibration time

“Voltage”: mV value of the electrode

“Value”: The concentration of ion, unit mmol/L.

“Status”: Status of calibration, show “PASS” when the calibration passes or “FAIL” when the calibration fails.

## 7.3 Two point calibration

Two point calibration is necessary before testing or QC on  $\text{Li}^+$ ,  $\text{K}^+$ ,  $\text{Na}^+$ ,  $\text{Ca}^{2+}$ , pH,  $\text{Cl}^-$ , Two point calibration includes calibration A and B.



	Voltage	Value	Unit	Slope	Status
K	=92.27	8.00	mmol/L	17.93	PASS
Na	=77.27	110.00	mmol/L	-6.05	PASS
Cl	=99.92	70.00	mmol/L	5.98	PASS
Ca	=52.85	2.50	mmol/L	7.97	PASS
Li	=54.88	1.20	mmol/L	5.66	PASS
pH	=95.59	7.00		19.80	PASS
TCO2					

Return

1. Tap “two point calibration” button at the submenu of calibration;
2. The analyzer will do Cal A (the same as one point calibration);
3. When the Cal A passes, the analyzer will do Cal B automatically;
4. The analyzer will aspirate Cal B to perform the calibration;
5. The calibration result will be printed after two point calibration is done;
6. The analyzer will aspirate flush solution automatically to flush the flow path;

7. When the flush is done, system will return to the main menu automatically or wait for the further command from the operator.


There are four possibilities for one point calibration

Pass	The system will display the corresponding concentration of Cal A /B and return to the main menu. The system is ready for test
Unstable	Unstable mv value. The system will also alarm voltage value is unstable
Drift	When two mV values are beyond a certain range, the system will alarm the electrode drift. The abnormal electrode channel will be displayed at the bottom of the screen.
OR: mV out of range	If the electrode mV value exceeds the set range, the system will prompt the mV is out of range. Please refer to the following instructions for the range of each electrode.
Slope Abnomal	Difference on MV between Cal B and Cal A is called slope. If the difference exceeds the prescribed range, it is called the slope abnormal. Please refer to the following instructions.

## 7.4 Li\_K Value Adjustment

This menu is applicable to perform Lithium calibration only.

1. Perform ISE Two point calibration. Continue to next step if it is passed with one trial only.
2. Enter “Main Menu→Servers→QC Calibrate→QC Test”, test QC level1/level2/level3. If Na is in the range, then continue to next step. If Na is out of range, then perform Na correlation as section 6.7.9 and 6.9.5.
3. 4. Feed selective coefficient calibrator (for Li+) to the #25 cup, enter Calibration and select Li\_K test.
5. After 3 times of repeated K test, the result of K is automatically printed out and update the Li\_K in “Correlation Coefficient ” menu.

	<p>! Li is affected by the status of Na electrode. Make sure Na is stable and in the range when Li has problem.</p> <p>! K test must be done after maintenance of Li and Na electrode.</p>
---	--

## 7.5 TCO<sub>2</sub> Calibration

1. Tap “**TCO<sub>2</sub> Calibration**” button to enter TCO<sub>2</sub> calibration menu

2. The analyzer will aspirate TCO<sub>2</sub> standard solution to the reaction cup to perform the calibration on TCO<sub>2</sub>
3. Once TCO<sub>2</sub> calibration passes, the result will be displayed and printed automatically
4. The analyzer will aspirate flush solution automatically to flush the flow path.
5. When the flush is done, system will return to the previous menu automatically.

Calibration TCO <sub>2</sub> Finish					
	Voltage	Value	Unit	Slope	Status
K					
Na					
Cl					
Ca					
Li					
pH					
TCO <sub>2</sub>	=39.20		mv		PASS

Return

## 7.6 ISE+ TCO<sub>2</sub> Calibration

ISE + TCO<sub>2</sub> Calibration will be two point calibration on ISE and TCO<sub>2</sub> calibration. The analyzer must perform ISE + TCO<sub>2</sub> calibration before test or QC.

1. Tap “ISE+TCO<sub>2</sub> Calibration” button to enter ISE+TCO<sub>2</sub> calibration menu;
2. The analyzer will perform two pint calibration on ISE as 7.3 section;
3. When two point calibration passes, the analyzer will perform TCO<sub>2</sub> calibration;
4. The analyzer will aspirate flush solution automatically to flush the flow path;

Calibration Finish					00:29
	Voltage	Value	Unit	Slope	Status
K	=91.29	8.00	mmol/L		PASS
Na	=76.99	110.00	mmol/L		PASS
Cl	=99.41	70.00	mmol/L		PASS
Ca	=52.15	2.50	mmol/L		PASS
Li	=54.57	1.20	mmol/L		PASS
pH	=95.00	7.00			PASS
TCO2	=38.95		mv		PASS

Return

## 7.7 Calibration Frequency

This analyzer supports automatic calibration function, which is to keep and monitor electrode condition. The system can be set up in each calibration interval by every 60 minutes, 120 minutes, 180 minutes, or 240 minutes.

The steps to set calibration frequency is as follow, tap “System Setup” button at main menu:



Tap “Calibration Intervals” button:

Calibration Interv

☒ 60 Minutes
 ☐ 120 Minutes
 ☐ 180 Minutes
 ☐ 240 Minutes

Sleep Time

start 0 : 0

end 0 : 1

Li-K value calibration Interval

After 7 days to run k value calibration

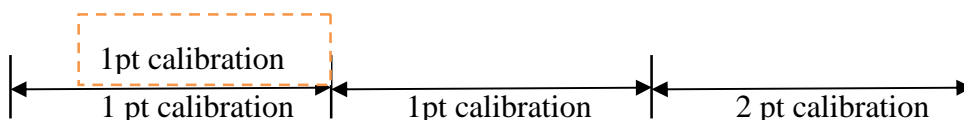
OK Return

3. Choose the calibration interval by 60 minutes, 120 minutes, 180 minutes or 240 minutes.

4. Tap “confirm” button to save

5. Automatic calibration frequency is as follow:

There will be one two pint calibration following every two one point calibrations as the picture below.



	<p>In the automatic calibration mode, two-point calibration automatically will be performed after every two point calibrations</p>
--	--

## 7.8 Calibration Results

1. Tap “ISE CAL Results” or “TCO<sub>2</sub> CAL Results” button at “Data Management” menu to enter calibration result search interface:

Calibration Data

Date Range: 2015 . 06 . 25 -- 2015 . 06 . 28 Search

	Date	Time	Cal Type	K_vol	Na_vol	Cl_vol	Ca_vol	pH_vol
1	2015-06-28	23:27	A-1	77.70	86.05	96.84	46.41	95.27
2	2015-06-28	22:25	B-1	96.05	79.88	102.66	54.38	113.59
3	2015-06-28	22:24	A-1	77.27	85.70	96.56	45.98	94.38
4	2015-06-28	21:23	A-1	77.46	85.86	96.64	46.09	94.06
5	2015-06-28	20:22	A-1	77.54	85.94	96.76	46.21	93.55
6	2015-06-28	19:20	B-1	95.86	79.18	102.42	54.18	111.88
7	2015-06-28	19:19	A-1	77.11	84.96	96.37	45.78	92.58

More |<< < > >>| Return

Delete  
Delete All  
Empty DB

Calibration Data

Date Range: 2015 . 06 . 26 -- 2015 . 06 . 26 Search

	Date	Time	Cal Type	TCO2_vol
2	2015-06-26	14:59	TCO2-1	36.75
3	2015-06-26	14:35	TCO2-1	36.88
4	2015-06-26	14:14	TCO2-1	37.61
5	2015-06-26	12:08	TCO2-1	37.36
6	2015-06-26	10:04	TCO2-1	37.43
7	2015-06-26	07:05	TCO2-3	37.36
8	2015-06-26	07:03	TCO2-2	37.85
9	2015-06-26	07:02	TCO2-1	39.62

More |<< < > >>| Return

Delete  
Delete All  
Empty DB

- Input calibration time and search relevant data.
- Tap "extensions" button at the lower part of the interface. It will display the operation keys at the right side.  
A user can select delete or delete the current one to perform relevant operation.  
Select "empty database" to delete all calibration record
- Tap "more" button to check more calibration data or to print these calibration results.

Calibration type	Description
A1,2, or 3	The first, second or third attempt on Cal A
B1,2, or 3	The first, second or third attempt on Cal B

# Chapter 8 Patient Sample Analysis

The sample analysis of this analyzer only needs three steps. The following describes only the analysis on sample but does not involve any sample type. The sample analyses on different types are nearly the same except for some minor differences.

## 8.1 Sample collection

1. Prepare heparinized sample tube. Heparin concentration should be about 50-80IU/ ml.



If heparin is not enough, it may lead to a coagulation, which may cause liquid blockage. If heparin sodium is more than enough, the test results on  $\text{cNa}^+$  and  $\text{cCa}^{2+}$  will be greatly influenced.

2. Use blood sample tube to collect samples



The minimum sample volume shall be 1.0 ml as this analyzer needs at least 80  $\mu\text{L}$  to do a test.

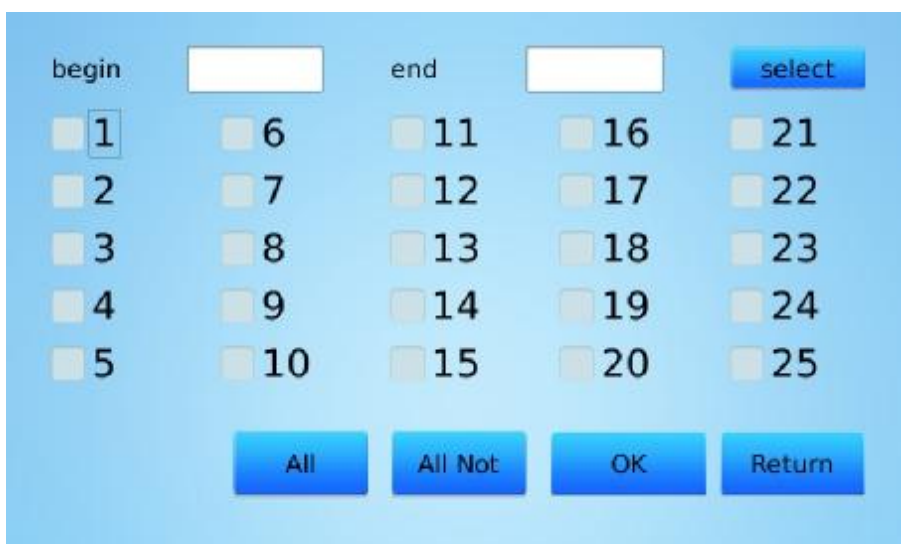
3. After collection , the samples shall be fully mixed with anticoagulant immediately. Use both hands to rotate and shake the sample tube gently to achieve this. According to the standard procedure, correct label must be stick to the tube after such mixing.

## 8.2 Steps of Sample Analysis

- 1) Tap the “Test” button of the main menu. The analyzer will enter the test menu as the picture below, select the testing parameter. Tap the sample number on the screen, then the color turn blue (White indicates that there is no sample; Pink indicates that the sample is testing now; Blue indicates that the sample is not tested yet; Grey indicates that the sample has been tested).



2) Also you can tap the button to select sample number, as below:



3) Place the sample into the right position and tap “Go” button directly. The sample will be aspirated into the measuring chamber. After the test, the result will be printed automatically. Also, you can check the results by tapping the sample number.

## 8.3 Test Results

Tap “Test results” button at data management menu to enter test results search interface:



Patient ID:

Date Range: 2015 . 04 . 01 -- 2015 . 07 . 01


	Date	Time	HL7 Send ID	HL7 Send Status
1	2015-06-26	15:21:39		
2	2015-06-26	15:19:14		
3	2015-06-26	15:16:48		
4	2015-06-26	15:14:27		
5	2015-06-26	15:12:43		
6	2015-06-26	15:10:10		
7	2015-06-26	15:07:32		
8	2015-06-26	15:03:43		

1. The upper side of the interface is the search field. The user can search by time period and "Sample ID" (Patient ID). The middle part is to display test results. The lower part is for function keys.
2. Input sample ID or test date then tap "search" button to search relevant data.
3. Tap "more" button to check more details like basic information, test results, A5 test report, analysis report, edit, etc.

# Chapter 9 Trouble Shooting

This section covers the trouble shooting procedures of the instrument. The instrument can perform self test when power up. It will detect most of the problem except electrodes.

## 9.1 Normal Troubles and Solutions

	<ul style="list-style-type: none"><li>I the instrument is not the control material factory production of corrected in the measured sample of some projects may be biased, need to re adjust the project machine, belonging to the matrix effect is a normal phenomenon.</li><li>I to ensure the measurement results are accurate, the user shall regularly conduct quality control measure, usually once a day, in addition to the use of the company's quality control liquid and a variety of quality control serum, the standard of quality control liquid cannot use similar instrument equipped with measurement, because of some additives other standard solution which may cause unnecessary damage of electrode.</li><li>I As <math>\text{Li}^+</math> electrode test is modified by the <math>\text{Na}^+</math>, when the <math>\text{Na}^+</math> electrode is abnormal, of the test results <math>\text{Li}^+</math> electrodes is not reliable.</li></ul>
---	---

## 9.2 Electrode

The electrode may have some faults during testing on samples, especially complex samples. It will affect the measurement accuracy or even can not be measured at all. Please make correct judgment according to the fault phenomena, troubleshooting in time, make the instrument to maintain normal operation when there is electrode failure.

### 9.2.1 Drifting

Activation time is not enough	Increased activation time
Electrode has the slight leakage	To replace the new electrode
Concentration change on Refilling solutions	Replace the refilling solution & Enhance the seal
Reference electrode core coating goes off	Replace the reference electrode core

## 9.2.2 Unstable

- |                            |                                |
|----------------------------|--------------------------------|
| 1) Electrode loose contact | Wipe each contact with alcohol |
| 2) Unstable power supply   | Install a regulator            |

## 9.2.3 Slow reaction and low slope

- |                               |  |
|-------------------------------|--|
| 1) Electrode pollution        | Do de-protein, conditioning to clean the electrode |
| 2) Sensitive membrane damaged | Replace a new electrode                            |

## 9.3 A simple method to check respondent circuit channel of each electrode

9.3.1 To change the position of the normal electrode (such as  $\text{Cl}^-$ ) and unstable (mV variably) electrode (such as  $\text{K}^+$ ) between each other. Do a calibration and observe the display screen.

9.3.2 K display (the actual measured  $\text{Cl}^-$ ):

If the mV value stability indicating  $\text{K}^+$  circuit is no problem, there may be a problem with  $\text{K}^+$  electrode.

If the mV value is not stable description of  $\text{K}^+$  circuit problem, there can be no problem with  $\text{K}^+$  electrode.

## 9.4 Only one unstable electrode

Solution:

A. to do de-protein ( $\text{K}^+$ ,  $\text{Cl}^-$ ,  $\text{Ca}^{2+}$  electrode) or conditioning ( $\text{Na}^+$ , pH electrode)

B. to exchange the position of two electrodes, refer to the "common fault handling"

If the problem can not be settled, please contact customer service department of Cornley for guidance and assistance

## 9.5 Two or more unstable electrodes

The solution:

A. De-protein or conditioning;

B. Replace new calibration standard solution;

C. Check reference electrode: whether there is leakage, bubble, not clean, silver bar peeling coating, or no liquid;

D. Check the external power supply: whether the grounding or the regulator is installed well.

## **9.6 Longer balance time on $\text{Li}^+$ 、 $\text{K}^+$ 、 $\text{Cl}^-$ 、 $\text{Ca}^{2+}$ electrodes**

Possible contamination, do de-protein immediately.

## **9.7 Longer balance time on $\text{Na}^+$ 、pH**

Possible contamination, do conditioning immediately.

## **9.8 Problems on Flow Path**

Self Test will conduct a comprehensive inspection of each flow path. If there is fault main menu will be recorded, the three photosensitive detection of OP1, OP2, OP3 two groups of voltage value displayed a group of absolute voltage, a group of water jump voltage, jumping more than 10mV in normal work, less than 10mV solution check fault. If there is no water jump for circuit fault, anhydrous as flow path fault. Please check carefully the interface without plugging for flow path fault.

## **9.9 Slope out of range**

Metamorphic standard solution, showed turbid, precipitation, to replace the new standard solution; electrode contamination must be to de-protein or conditioning.

## **9.10 Problems on Repeatability**

Electrode: eliminate the bubble in the bubble near the sensing membrane electrode.

The sample mixed with bubble: find out reason, be removed.

Reason: the test samples prepared with the new quality control samples or fresh serum.

## **9.11 Problems on Accuracy**

Interference of other substances in the sample: pay attention to sampling method.

Standard concentration change: to replace a new calibration standard solution.

Protein, lipid, deviation and flame photometer, may this deviation will be corrected according to ion electrode method for quasi.

Correct parameter adjustment.

## **9.12 Problems on QC**

The analyzer is designed for fast and accurate measurement of human blood. Advanced technology that has good accuracy and repeatability in the linear range is quite wide.

To ensure that your analysis report has indisputable accuracy, you should regularly carry out quality control measure, usually once a day, in addition to the use of the company's quality control liquor, quality control and reagent please don't measure other types of analyzer are used, because the control material and reagent in the face of some additives may cause damage to the electrode.

## **9.13 Problems on Fuse**

Confirm the fuse has burned out, need to perform following replacement:

Turn off the power switch, unplug the power plug;

A convex mark in the power supply socket analyzer on the cover using a screwdriver, lever out the fuse socket outward force;

Remove the fuse burned out;

Install new fuse.

## **9.14 No flush or flow slowly**

The flush solution is out: to replace a new reagent pack.

Electrode dislocation or not installed by pressing wrench compression, so that measuring the pipeline does not seal: this can be seen when cleaning with a cleaning liquid overflow on the electrode surface. Need to be installed and tightened electrode.

Cleaning pump weak or damaged: replace the pump.

Cleaning pipeline damaged or blocked: piecewise check syringe, replace the defective pipeline.

Cleaning the pump does not turn: required by the electrical technicians to inspect the relevant circuit.

## **9.15 No Cal A or Cal B**

Error message "No Cal A" (or " No Cal B"), and returns to sleep.

Electrode dislocation or not installed by pressing wrench compression, so that measuring pipeline is not sealed: re electrode installed correctly and fasteners.

A suction pump is weak or damaged: replace the pump.

The suction pipeline damaged or blocked: piecewise check syringe, replace the defective pipeline.

## **9.16 No sample when sampling**

Have a careful check according to the instruction. If the problem can not be settled, please contact Cornley for further guidance.

## **9.17 Problems on Pump Tubes**

In case of any of the following circumstances, it means the pump tube shall be replaced  
Over the shelf life

Pipe sticking together.

Pump tube aging.

Pipe rupture.

## **9.18 Loose Connector**

The power supply interface loosening: analyzer cannot test.

Reagent: interface loosening caused interface showed no reagent.

As for the above problem needs to check whether the interface loosening, if yes, then connect the interfaces well.

# Chapter 10 Maintenance

This section includes the recommended maintenance procedures for the instrument. The frequency of preventive maintenance operations is based on average workload of 20 to 30 samples per day with a normal instrument use. Facilities with heavier workloads should schedule maintenance operations more frequently.

Wear disposable gloves to avoid contact with potentially infectious materials while maintaining the instrument.

## 10.1 Daily maintenance

The maintenance operations described here are recommended to be performed everyday just before or after routine measurements.

1. Clean the probe and sample tray
2. Clean surface of the instrument.
3. Do TCO<sup>2+</sup> 2 PT calibration first to check the instrument first. After calibration is passed, test a sample to check.
4. Near day off, do deproteinization or cleaning to maintain electrodes and reaction cell if necessary.

## 10.2 Weekly maintenance

The maintenance operations described here are recommended to be performed every week at the end of the routine measurements.

1. Sterilize exterior and interior surface and aspiration probe tie-in
2. Take out reference electrode and shake it for serial time to avoid crystal formation.
3. Cleaning the flow path to prevent blockage.
4. Check the multiplexer if there is any leakage.
5. Check TCO<sub>2</sub> , Cal A if it is not enough.
6. Test middle level QC, adjust slope and intercept accordingly.
7. Perform deproteinization and cleaning to maintain electrode and reaction cell.

8. Clean Flow flow path with syringe. Hard pushing can break the membrane. Careful cautions should be taken when sterilizing probe to avoid injury and potential infections.

### 10.3 Monthly maintenance

1. Check the solution level of  $K^+$ ,  $Na^+$ ,  $Cl^-$  electrodes. Replace the refill solution of  $K^+$ ,  $Na^+$ ,  $Cl^-$  electrodes if it is less than 2/3.

For  $K^+$ ,  $Na^+$ ,  $Cl^-$ ,  $Ca^{2+}$  and pH electrodes, empty the remaining refill solution before filling new.

2. Correct coefficient factors (slope and intercept) with high/middle/low level QC.

3. Take out the reference electrode, remove crystal if there is too much. Refill if the solution is not enough.

4. Clean the entire flow path to avoid blockage

### 10.4 Yearly Maintenance

To do a completed inspection for the instrument every year.

### 10.5 As necessary

1. Never switch off the analyzer

2. Never mix old and new reagents together

3. Serum must be centrifuged within one hour after the collection of blood sample

4. Do not change the slope or interception frequently. Minor changes are OK for routine checks.

5. No direct strong light on multiplexer.

6. The instrument may be abnormal if the operation or maintenance is not done strictly according to this manual.

7. Only the trained engineer can do maintenance and fix for the instrument. All spare parts for such maintenance and fix must be original from Cornley.

8. If the analyzer must be stopped with any reason, the flow path must be washed and emptied.

The calibration standard solutions must be handled according to guidance of 6.9.1.



9. To prevent the clot in flow path, please 1) The liquid level of the serum in the tube must be over 10mm; 2) Please separate the protein fibers from the serum samples.

## **10.6 Shelf life**








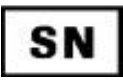




Storage shelf life: three years









Designed usage shelf life: five years

## **10.7 Transportation and storage**

This analyzer allows the use of common traffic tools. But need to prevent the severe impact, vibration, and rain splash during transportation process. Transportation requirements must be included in the contract. Analyzer packaging should be stored indoors with ambient temperature  $-20^{\circ}\text{C}\sim+55^{\circ}\text{C}$ , relative humidity of not more than 80%, non corrosive gas with good ventilation. For the long-term storages, the analyzer is required to be power-on once a month and dehumidification at the same time.

## Appendix A Symbols

	IVD product
	CE mark
	Biological contamination risk
	Alert
	Notice
	This way up
	Please consult the manual
	Serial number of the analyzer
	Electronics waste
	Possible injury for hand
	Warning of high temperature
	Risk of electric shock

	Laser
	EC representative
	Manufacture date
	Manufacturer
	Keep away from rain
	Keep away from sunlight
	Only three layers at the most
	Fragile