PR series

Electrolytes analyzer

User Manual

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Revised history

Version	Date	Description	Author
Version 3.20	03/25/10	Software update	
Version 4.00	03/17/11	Software update	
Version 4.01	12/21/11	CE and Li Support	
Version 4.02	09/17/12	Without packing list	
Version 4.03	02/19/16	Software update	

CONTENTS

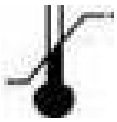
Preface

1. Using this manual

This manual provides the information and procedures necessary to operate and maintain the system. It is designed to meet the needs of medical personnel who use the system on a daily basis and perform routine maintenance and troubleshooting.

2. Understanding the symbols

This section describes the symbols that may appear on the exterior of the system. These symbols provide you with either important information or warning for proper operations.

CE	Complies with IVD directive 98/79/EC
IVD	In vitro diagnostic Medical devices
	Biohazard Warning
	Caution to alter the user to possible personnel injury or damage to the instrument.
	Note provides specific information in the form of recommendation, pre-requirements etc.
	Temperature limitation of storage
LOT	Batch code
	Place upward
	Consult instructions for uses

	Serial NO
	Expiration date
	Manufactured date
	Manufacturer

3. Cautions and hazards

3.1 Operator's qualifications

	This instrument should be operated by skilled or trained medical personnel. It is crucial for the hospital or organization that employs this instrument to carry out a reasonable service/maintenance plan. Ignorance of this warning may result in function failure or shorten its life expectancy. Only operate the instrument under the specified condition listed in this manual, Otherwise, the system may not work normally or even damage is caused to the instrument.

3.2 Safety precautions

	Blood sample and blood products are potential source of infectious diseases. Special care should be taken to avoid possible infections and contamination when handling those sample and operating the system. Gloves and protective clothing are always required.

3.3 Disposals of waste solution, waste bottle, used gloves

	Waste solution and waste bottle which may contain or contact with bio hazardous materials should be disposed in compliance with national or local regulations. (Bio hazardous, dangerous solution)

3.4. Cleaning and sterilization maintenance

It is suggested that operators should strictly comply with national or local regulations as well as the following:

	Clean the surface with blenching water of low concentration. Sterile the surface with hydrogen peroxide solution of 2%.
	Never use organic solution to clean or sterile the surface.
	Always wear disposal gloves to avoid potential bio hazardous infections.

4. Technical assistance

Technical assistance is available over telephone and email. Please send email to sales@cornley.com /support@cornley.com or contact us by +0086-755-86330866. If you are interested in our products family, please go to our website: http://www.cornley.com for more information.

1 General introduction

1.1 Application area

The instrument is intended for measuring ion concentration of potassium, sodium, chloride, in the serum, plasma and whole blood, and potassium, sodium and chloride in the urine.

The instrument is designed to be fast, efficient and easy use. You can easily operate this system through keypad.

1.2 System description

This system mainly consists of probe, LCD display, keypad, measuring chamber, multiplexer, pump, printer, etc.

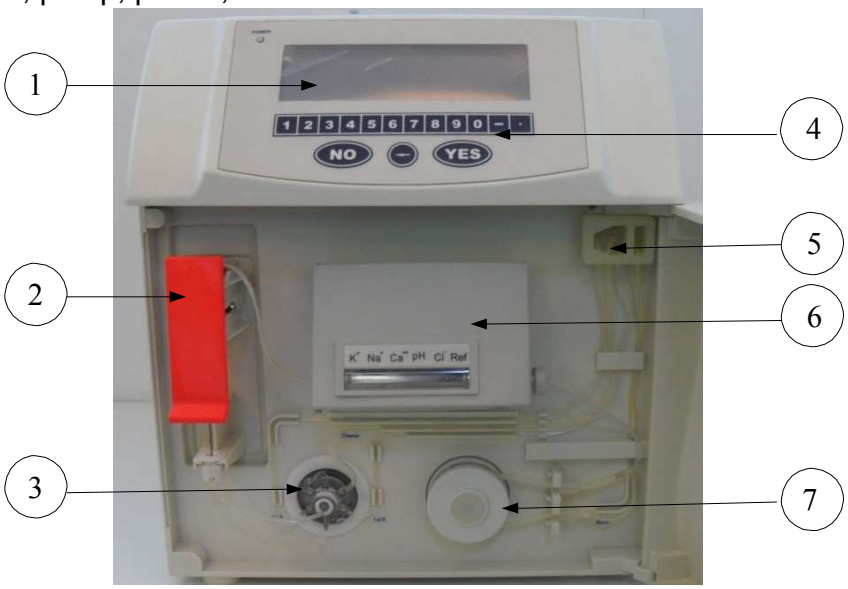


Fig. 1.1: Front view

1. LCD
2. Probe
3. Multiplexer
4. Keypad
5. Reagent pack connector
6. Measuring chamber
7. Peristaltic pump

Fig. 1.2: Back view

1. RS232 port
2. Power switch
3. Power socket

1.3 Specifications

This section provides the requirements, specifications and typical performance of the instrument.

Dimension

	length(mm)	Width(mm)	Height(mm)
Main unit	300	260	360

Weight

Main unit	7.5kg

Power requirements and consumption

Power supply	AC100~240V
Consumption	100VA
Fuse	2×F3.15L 250VAC

Operating environment

Ambient temperature	5~40ºC
Relative humidity	Up to 85% non condensing

Storage and transportation conditions:

Temperature	-20ºC~+60ºC
Humidity	Up to 95% non condensing

Sample volume

Typical	120μL(ISE)
Minimum	65μL(ISE)

Sample type

Type	Whole blood, Serum, Plasma, Urine

Screen

Type	LCD
Resolution	240×64 pixel

Printer

Type	Thermal printer
Resolution	240×128 pixel
Full graphics	8 dots/mm
Printing speed	15mm/s
Paper width	57.5mm

Measured parameters

Parameters	Measuring range	Resolution
Potassium ion(K^+)	0.30—10.00mmol/L	0.01mmol/L
Sodium ion(Na^+)	20.0—200.0mmol/L	0.1mmol/L
Chloride ion(Cl^-)	20.0—200.0mmol/L	0.1mmol/L
Calcium(Ca^{2+})	0.30—5.00mmol/L	0.01mmol/L
Lithium(Li^+)	0.00—3.00mmol/L	0.01mmol/L
pH	6.0—9.0	0..01

1.4 Model differences

The model family consists of 3 models.

Model	Configurations
3 Parameters	K/Na/Cl
4 Parameters	K/Na/Cl/Li
5 Parameters	K/Na/Cl/Ca/pH

This manual is drafted on the base of 3 parameters. Most of its contents can be applied to 4 parameters and 5 parameters except the following differences:

1.4.1 For 4 parameters only

1. All menus concerned with K/Na/Cl will be replaced by K/Na/Cl/Li, such as calibration test,report, etc.
2. Under **QC**>>**K TEST**, it is special for Lithium correction.

1.4.2 For 5 parameters only

1. All menus concerned with K/Na/Cl will be replaced by and K/Na/Cl/Ca/pH , such as calibration, test,etc.
2. TCa, iCa, nCa and pH will be printed out on the report
3. Under **Service**>>**Unit**, Ca is displayed.
4. Under **Setup**>>**Printer option**, pH option is added.
5. Temperature correction is added.

   Since pH is related to temperature and Ca is affected by pH (nCa≈iCa when pH=7.40), it is necessary to compensate the temperature in order to get correct Ca value. Please follow below procedures to setup temperature.

   a) Power off the analyzer and open its rear cover.
   b) Power up the analyzer for at least 30 minutes.
   c) Enter **SETUP**, press key *-, No, No, 1, 1, 9* to enable temperature compensation. The system then prompts to enter the value of current room temperature with message "T_Room=_____".
   d) Test current room temperature with thermometer and enter the value with numeric keys.
   e) Press *YES* to save.
   f) Close rear cover and power up for at least 30 minutes.
   g) The measured temperature will display at the right bottom of main menu.
   h) After temperature setup, the analyzer will compensate pH to 37ºC and get correct nCa value (inaccuracy <2ºC).

	The temperature should be adjusted again if the variation of room temperature exceeds 10ºC.

	pH is use for Ca correction only. It can not be served as clinical application.

2 Installation

	Always wear disposal gloves to avoid biohazardous infections when handling or operating this instrument.

2.1 Operating environment

The environment which is going to install the instrument shall comply with the following requirements:

6. Temperature: 5-40ºC.
7. Relative humidity: ≤80% (without condensate).
8. Power supply: 100-220V~50Hz/60Hz.
9. The earth of the socket shall be well grounded and keep way the instruments from possible electromagnetic interference.
10. Working area: L*W (1.5*0.6) and at least 0.5m far from other instruments.
11. Others: Avoid sunlight irradiation, erosive gas, great temperature change and dust.

	The instrument is intended for indoor use only.

2.2 Unpacking

Unpack and remove the instrument and the accessories from the cartoon. Place them on a solid work table and check them with packing list. If any missing or damage is found, please contact our distributors.

Please keep the carton and poly foam for future repacking in case of movement or repairing.

2.3 Electrodes Installation

2.3.1 Preparation

a) Reference electrode

1. Take out the reference electrode.
2. Remove the tape on both sides the covers the hole.
3. Install O ring on both sides.

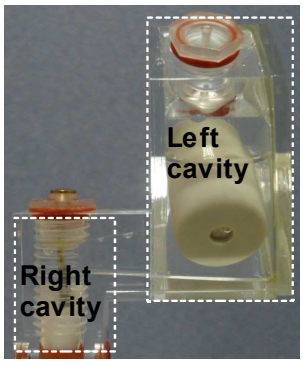


Fig. 2.1: Reference electrode

4. Use a syringe and aspirate refill solution for reference (20ml).Then inject it into reference electrode from the hole on the right cavity. The solution surface should reach at least 1/3 of the internal capsule.
5. Flip the bottom if there are any air bubbles above membrane area on the left cavity.

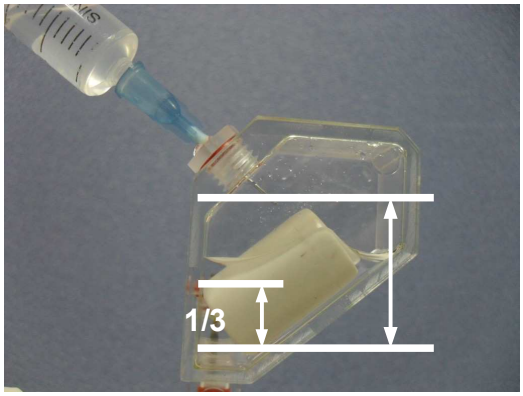


Fig. 2.2: Refill reference electrode

⚠	1. Refill solution can be added directly. No need to replace. 2. It is normal if there is crystal formation in left cavity. 3. It is recommended to take out and shake the REF each week to prevent crystal formation inside left cavity. 4. Reference is the common terminal for all electrodes.

⚠	Refill solution for ISE is totally different from refill solution for REF. Never mix use those two solutions under any circumstances.

b) ISE electrodes

1. Take out electrodes from the box.
2. Replace refill solution if it is less than 1/2 height of internal cavity.
3. Follow the below procedure to replace refill solution of electrodes.

   a) Screw out the electrode head. Empty original refill solution.

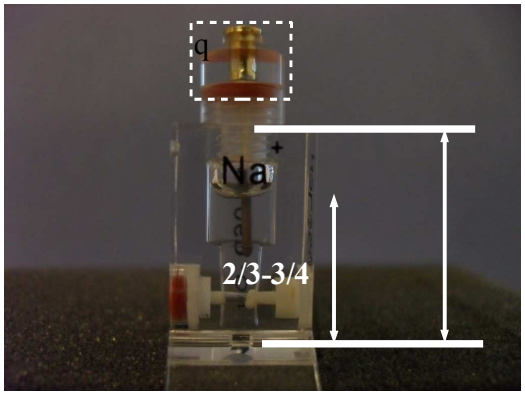


Fig. 2.3: Screw out electrode head

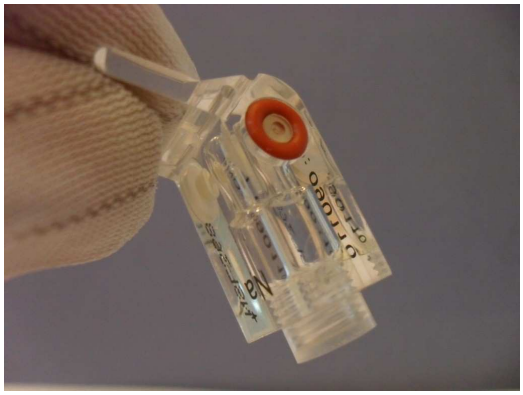


Fig. 2.4: Empty original solution

b) Cut it open one vial of refill solution for ISE. Aspirate it with a syringe.

c) Insert syringe inside the electrode and lean the needle against the internal cavity. Then inject slowly. Until the level reaches 2/3 height of internal cavity.

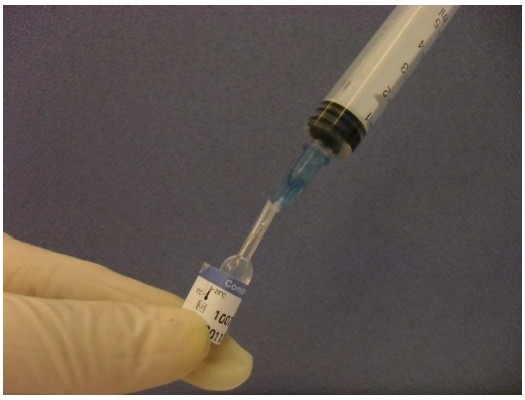


Fig. 2.5: Aspirate refill solution

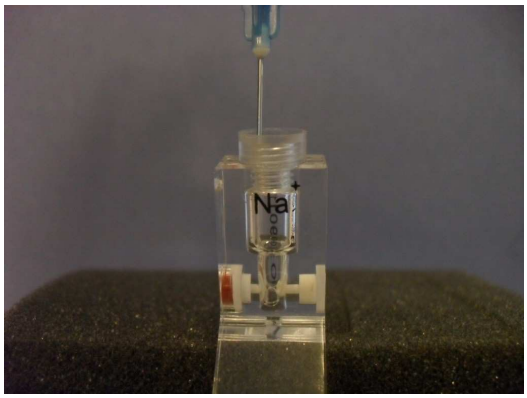


Fig. 2.6: Inject refill solution

d) Dry the screw hole of electrode with tissue.

e) Screw in the electrode head. Wipe dry the surface of electrode.

f) Flip the bottom to exclude air bubbles.

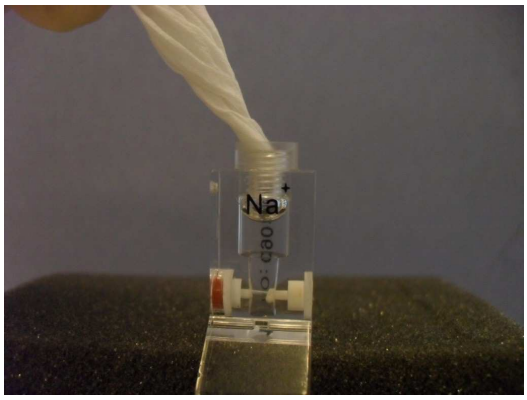


Fig. 2.7: Dry screw hole

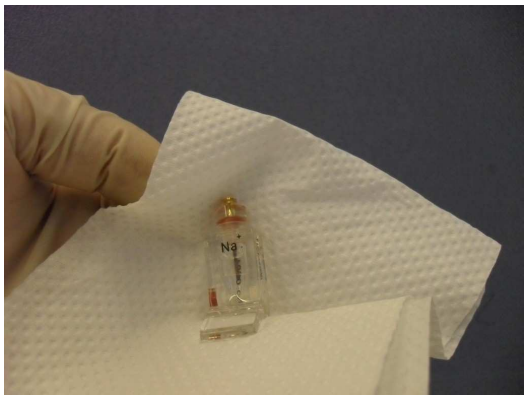


Fig. 2.8: Wipe dry surface

⚠	1. Empty the remaining refill solution before adding new. 2. The refill solution level should be around 2/3 to 3/4 height of internal cavity. Otherwise the internal pressure can break the membrane. 3. Check the condition of the O ring. Missing or broken will cause sample leakage. 4. There is a small slot on the electrode head to balance the pressure. Make sure it is dry before screwing in. 5. Replace refill solution of ISE for every 3 months.

	Refill solution for Lithium is different from refill solution for ISE. Never mixes use those two solutions under any circumstances.

2.3.2 Installation

1. Open the cover of the instrument. Open the door of measuring chamber.
2. Pull out and twist the knob of measuring chamber to release it.
3. Wipe dry the internal surface of measuring chamber by tissue.
4. Install electrode one by one. First lift up then push forward until it is positioned.

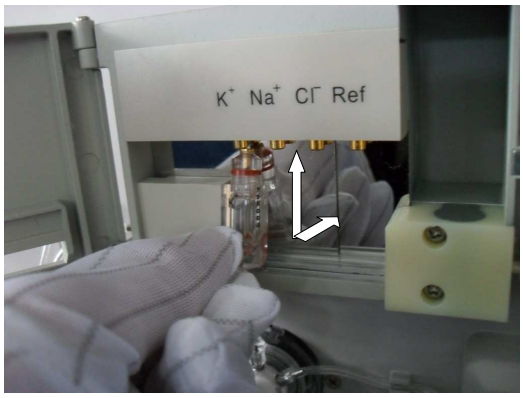


Fig. 2.9: Install electrode

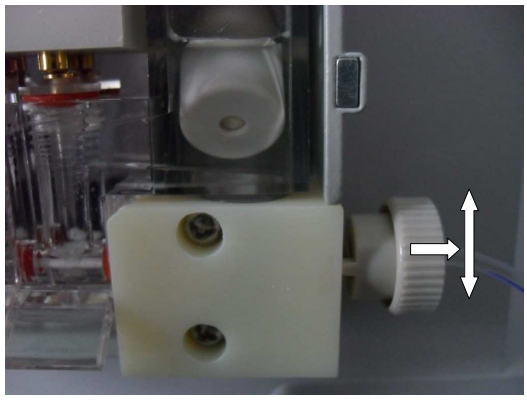


Fig. 2.10: Release lock knob

5. Level them with thumb by pressing hard.
6. Return lock knob.
7. Close the door of measuring chamber.

Fig. 2.11: Level electrode

	1. Clean the surface of measuring chamber and the electrodes first. 2. Missed or broken O ring can cause blockage or leakage. 3. Before taking out electrode, first lift up probe, then manually rotate pump to empty the pathway. Otherwise the remaining liquid can leak to the measuring chamber. 4. The tension of knob can be adjusted by screwing in and out the knob.

2.4 Pump tube installation

1. Connect tubes on both ends.
2. Insert one end into the slot.
3. Stretch the pump tube, then roll it around the wheel and insert another end into the slot .

Fig. 2.12: Connect pump tube

Fig. 2.13: Insert both ends

2.5 Reagent pack installation

1. Open the front door and disassemble the connector from old reagent pack if there is one.
2. Tear off the tape on the new reagent pack, Remove the protective tie-in.
3. Insert the reagent pack into the analyzer as right figure shown.
4. Insert silicon connector into reagent pack.
5. Close the front door.
6. Cover old reagent back with protective tie-in.

Fig. 2.14: install reagent pack

	Used reagent pack which may contain or contact with biohazardous materials should be disposed in accordance with local regulations of government or Lab.

2.6 Printer paper installation

1. Press open button on the printer to open the cover.
2. Remove old paper roll.
3. Insert the paper into the slot. Keep printable side downwards. (This side can be easily marked by nail).
4. Close the cover.
5. Press LF to feed paper.

Fig. 2.15: Install paper

2.7 Power on

1. Before powering on the instrument, make sure the voltage of power supply matches the requirement listed on rear label.
2. Insert the power cord into the socket of the instrument.
3. Plug another end of power cord into a grounded outlet.
4. Turn the switch on the back.

	1. An ungrounded power supply can lead to drift problem of all electrodes. 2.High power instrument with the same outlet can interfere with the instrument.

2.8 Self test

After power on, self test will be performed first to check its essential functions. A series of test will be performed. If one of tests is failed, error message will be prompted and the system is stopped.

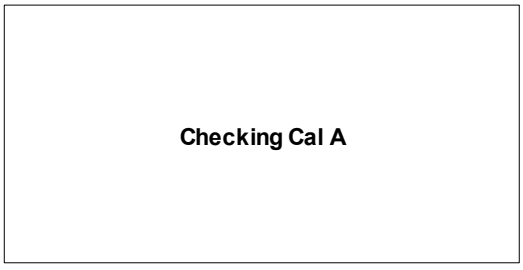


Fig. 2.16: Self test

Battery and sample sensor are checked first. Then Cal A and B are aspirated respectively to measuring chamber to check. Clock is tested finally.

	If self test is failed for a second time, power off the instrument and start troubleshooting. Please refer to the section of troubleshooting.

	Hold any key to skip self test after power on.

2.9 Auto calibration

Auto calibration starts automatically after self test is passed successfully.

The first time after power up, two successful cycles of calibration are required. The first calibration establishes a history data and the second calibration compares with the previous one to decide the status of electrodes.

The first passed Cal A shows in the right figure. The first pass shows no concentration.

The number in upper right corner is a 30 second down-counter. It stops counting when the response of electrodes is stable.

```
==============Cal A================28

K    =                        70.49 mv
Na   =                        73.23 mv
Cl   =                        67.80 mv

===============DONE!================
```

Fig. 2.17: First pass of Cal A

When Cal A is passed, then Cal B starts automatically.

The second passed Cal B shows the concentration of Cal B solution.

```
==============Cal B================28

K    =   8.00    mmol/L       83.45 mv
Na   = 110.00    mmol/L       68.00 mv
Cl   =  70.00    mmol/L       77.30 mv

===============DONE!================
```

Fig. 2.18: Second pass of Cal B

	For new electrodes, if the problem of drift is happened, feed fresh serum to activate electrode for 30 minutes, then check again.

2.10 Shut down

2.10.1 Within 24 hour

If the instrument will be needed within 24 hours, switch the instrument off directly.

2.10.2 Beyond 24 hour

If the instrument will be needed longer than 24 hours, perform the following procedures:

1. Perform Stop Use under **Service**>>**Stop use**.
2. Remove reagent pack from its housing and cover the protective insert.
3. Remove Electrodes from measuring chamber and place it into box.
4. Release pump tube.
5. Place reagent pack in a safety place.
6. Clean the surface of instrument and place it into carton box.

3 Operation

3.1 Main menu

There are 5 sub menus under main menu.

1. **Test**
2. **Calibration**
3. **Setup**
4. **Maintenance**
5. **Service**

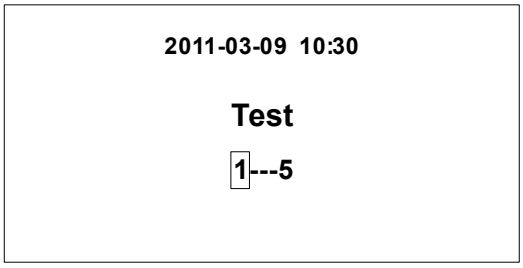


Fig. 3.1: Main menu

The first line shows system date and time. The second line shows the name of current menu. The number in the third line indicates the No. of menu. Current No. is highlighted. Press this number can direct enter this menu.

3.2 Menu operation

There are 3 command keys,10 digital keys, 1 dot and 1 minus key to operate this system.

←	Exit current menu or return upper menu.
YES	Confirm selection or move to next item.
NO	Exit or skip current items or menu.
1-9	Digital input/option command/shortcut of menu.

The menu operation is quite easy by using above keys. Normal operations are listed below:

1. Use *NO* key to skip to next menu, use ← to return upper menu , press *YES* to confirm.
2. Use shortcut to enter a menu. For example, press *1 1* to directly enter serum test under main menu.
3. Use digital key to select option or toggle option.
4. Use *YES* to move to next items under certain menu, use → to clear, use← to move previous(for example, under Reference range).
5. Use keys prompted displayed at the bottom.

3.3 Calibration

Electrodes need calibration to associate the response of electrode (in mV) with the known concentration of ion in the calibration solution. The Nernst equation shows that mv is proportional to the logarithm of concentration. If two mvs from two different known concentrations are measured, then an unknown concentration of ion in the sample can be calculated once its mv is measured.

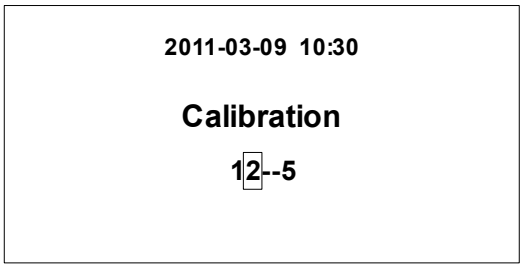


Fig. 3.2: Calibration

⚠	In this system, each calibration will try 3 times if it is failed. If the third trial is failed, the system will stop and ask for recalibration. Press *YES* to continue, or press *NO* to exit. Electrodes as well as the problem will be displayed on LCD if the calibration is failed. Please refer to troubleshooting or contact the service engineer for more help.

3.3.1 1 Point Calibration

1 PT calibration can associate mv values with ion concentration of Cal A. It defines the first point of two point calibration. 1 PT calibration is also used to check the status of electrodes after two point calibrations is passed. In this case Cal B is presumed to be fixed and only Cal A is required.

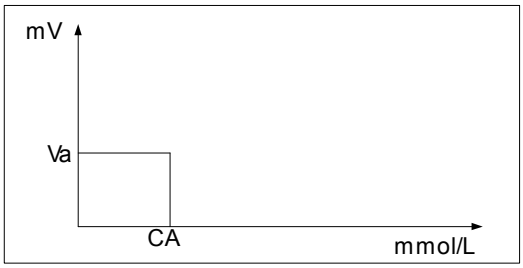


Fig. 3.3: 1 PT calibration

1. Select **1 Point Calibration**, then press *YES* to start 1 PT calibration.
2. Then Cal A solution is aspirated and moved to measuring chamber for test.
3. Once it is finished, the concentration of Cal A solution will be displayed on the LCD.

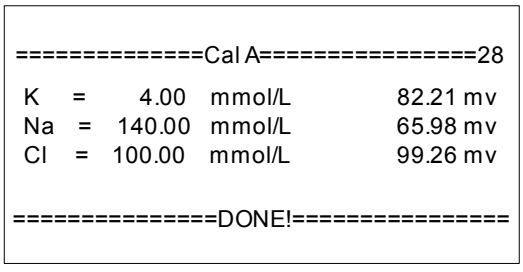


Fig. 3.4: 1 PT calibration is passed

⚠	1. The number showed on the upper right corner is a down counter (30s). 2. The second column shows equal mark(=) when mv reading is stable. 3. The third column indicates respective concentrations of Cal A. 4. The fifth column shows the measured mV values from Cal A.

There are 4 possible results from 1 point calibration.

Pass	When it is passed, concentration of Cal A will be displayed and system returns to main menu.
Unstable	Electrodes can not reach stable when down-counter is finished.
Drift	The mV difference from two consecutive tests exceeds the limit. It means electrode is unstable.
Over Range	MV exceeds the limit of electrodes. It also means a failed electrode or channel.

3.3.2 2 Point Calibration

2 PT calibration defines both points of Cal A and Cal B. When 2 point calibration is passed, the concentration in an unknown sample can be calculated from the two points via Nernst equation. The mv difference between Cal B and Cal A should fall within the requirement to ensure linearity range of electrodes.

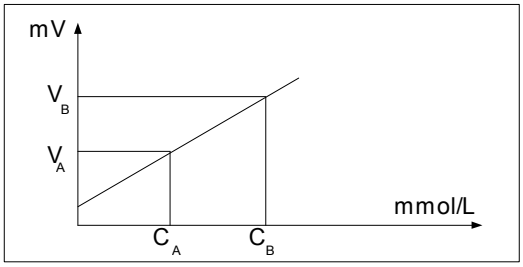


Fig. 3.5: 2 PT calibration

2 PT calibration includes two steps: Cal A (1 PT calibration) and Cal B. When both calibrations are passed, the 2 PT calibrations are passed.

1. Select **2 Point calibration**, press *YES* to start.
2. Cal A will start first. That is 1 PT calibration. After Cal A is passed, the instrument will start Cal B automatically. Then Cal B solution is aspirated and sent to measuring chamber for test.

```
==============Cal B================28

K   =   8.00     mmol/L        83.45 mv
Na  = 110.00     mmol/L        68.00 mv
Cl  =  70.00     mmol/L        77.30 mv

===============DONE!================
```

Fig. 3.6: 2 PT calibration

3. After Cal B is passed, concentration of Cal B solution will be displayed on the LCD. There are five possible results from this calibration.

Pass	When it is passed, concentration of Cal B will be displayed and system returns to main menu.
Unstable	Electrodes can not reach stable when down-counter is finished.
Drift	The mv difference from two consecutive tests exceeds the limit of 0.5 mv. It means electrode is unstable. The failed electrode is displayed at the bottom of screen.
Over Range	Mv exceeds the limit of electrodes. It also means a failed electrode or channel.
Abnormal	The Value of Cal B-Cal A is out of limited range. It means that linearity range of electrode can not assure its performance.

2 PT Calibration will be auto started after every 2 times of 1 PT calibration.

3.4 Test

There are 4 menus to test sample.

1. **Serum**
2. **Whole blood**
3. **Urine**
4. **QC test**

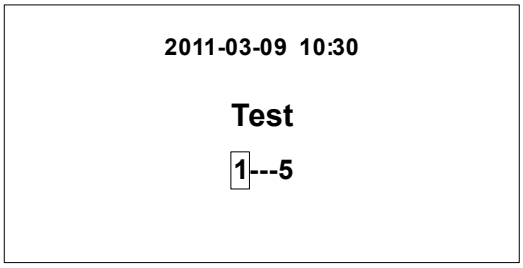


Fig. 3.7: Test

Always wear gloves to avoid bio-hazardous infections while performing all the tests concerned.

3.4.1 Serum test

Serum sample can be tested under **Serum** menu.

1. Enter **Serum** menu under **Test** menu.

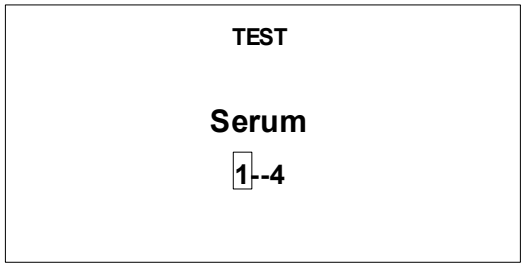


Fig. 3.8: Serum test

2. Input a serial number by press *1*.
3. Lift up probe and feed serum sample. Then press *YES* to aspirate.

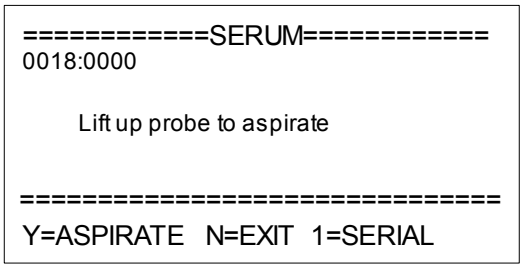


Fig. 3.9: Serum test

4. When the test finished, the result shows on the LCD and the report will be printed out.
5. After all test are finished, Cal A is aspirated to flush the pathway.

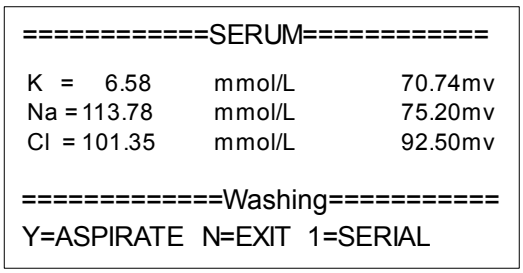


Fig. 3.10: Serum test result

	↑ or ↓ will be printed after the result if normal range of one item is exceeded

3.4.2 Whole blood test

Whole blood sample can be tested under this menu.

1. Enter **Whole blood** test.
2. The test procedures for whole blood test are the same as serum test. Please refer to serum test.

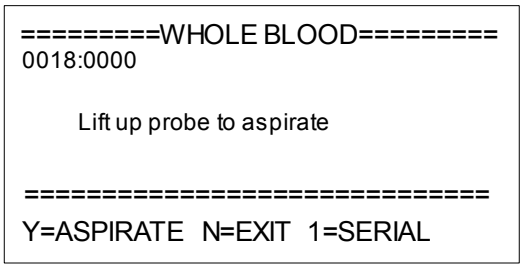


Fig. 3.11: Whole blood test

	Extra flushing is required after whole blood test to avoid blockage.

3.4.3 Urine test

Urine sample can be tested under this menu.

1. Select **Urine** test.
2. Dilute the urine sample with Cal A in 1:4 first.
3. The following procedures are the same as **Serum** Test

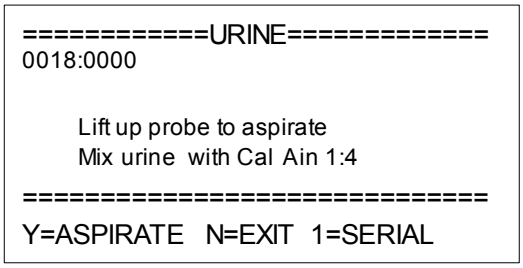


Fig. 3.12: Urine test

	1. Only K, Na, Cl are tested for urine sample. 2. Urine shall be collected from 24 hours and the test is an average value against 24 hours. 3. Urine sample must be diluted with Cal A first. The ratio for dilution is 1:4. One part of urine adds into 4 part of Cal A. The instrument will calculate and give the result automatically.

3.4.4 QC test

This menu is applicable to perform quality control test.

1. Enter **QC test**.
2. There are six options under this menu.
   1-3: Start to test QC level 1/2/3.
   4-6: Setup Level 1/2/3 range.

```
============QC test===========

     1 QC Level 1        4 Level 1 range
     2 QC Level 2        5 Level 2 range
     3 QC Level 3        6 Level 3 range

==============================
1-6=SELECT  NO=EXIT
```

Fig. 3.13: QC text

3. Setup level range and test QC level accordingly.
   There are two commands to show data.
   1: Show statics data (mean, SD)
   2: Show single record.

```
===========QC Level 1==========

NO. 0004

    Lift up probe to aspirate

==============================
Y=ASPIRATE  N=EXIT  1=STAT 2=READ
```

Fig. 3.14: QC test level 1

	When QC test is used to calculate Coefficient factor, history data must be cleared first. That means QC test starts from 0001.

3.4.5 K test (For lithium only)

This menu is applicable to perform Lithium calibration.

1. Perform **QC test** as **3.4.4** for 3 levels, continue next step only after Na is passed.

2. Enter **QC test** and select **K test.**

3. Feed elective coefficient calibrator (for Li^+) to the probe as required. When finished test, the result will be shown as right.

```
==============K TEST================

0001                              28
K   =   8.00      mmol/L      83.45 mv
Na  =  110.00     mmol/L      68.00 mv
Cl  =   70.00     mmol/L      77.30 mv
Li  =    2.00     mmol/L      86.20 mv

===============DONE!================
```

Fig. 3.15: K TEST

4. After 3 times of repeated K test, the result of K is automatically printed out and the analyzer returns to main menu.

	Li is affected by the status of Na electrode. Make sure Na is stable when Li has problem.

3.5 Maintenance

The performance of electrodes will decrease with the increasing tests of samples. Routine maintenance is essential to maintain electrodes and prolong their lifetime.

There are 4 menus under **Maintenance** menu.

1. **Deproteinize**
2. **Conditioning**
3. **Cleaning**
4. **Flush**

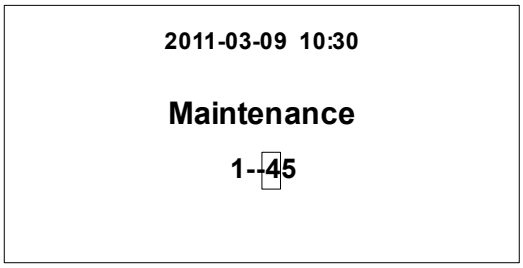


Fig. 3.16: Maintenance

3.5.1 Deproteinize

This is a routine maintenance procedure required for electrodes.

The protein or fat in the samples can clot on the surface of membrane and reduce the performance of electrodes. The deproteinize procedure can remove those protein or fat and maintain the electrodes. The requirement for such maintenance is based on sample load. For example, every 60 samples or every 10 days to perform one deproteinize when the instrument gives message to maintain electrodes. The interval between maintenance can be set under **SERVICE**>> **Maintenance interval**.

1. Enter **Deproteinize.**
2. Prepare the deproteinizer. Take out one pair of enzyme and dilutor. Add the dilutor into the enzyme. Shake the vial for several times then wait for 2 minutes until the enzyme power is completely dissolved (clear solution).
3. Lift up probe and press *YES* to aspirate.
4. The whole procedure will last 30 minutes. Press *NO* to stop if an early exit is desired.
5. 2 PT calibration is performed automatically after exiting **Deproteinize**.

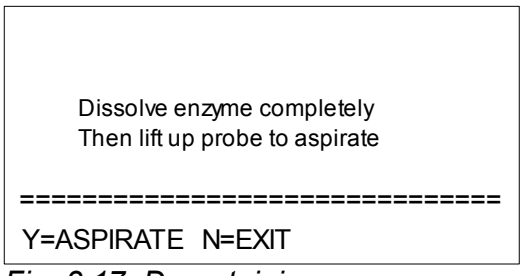


Fig. 3.17: Deproteinize

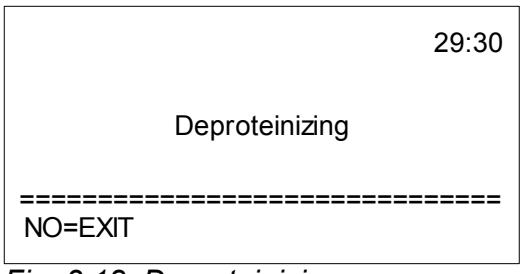


Fig. 3.18: Deproteinizing

	Feed fresh serum instead of deproteinizer under **Deproteinize** when activating new electrodes.

3.5.2 Conditioning

Conditioning is only effective to Na and pH electrodes. Perform it only when Na and pH have problem.

1. Enter **Conditioning**.
2. Take out one piece of conditioner and feed it to the probe. Then press *YES* to aspirate.
3. The conditioning procedure takes 5 minutes. Press *NO* to stop and if an early exit is desired.
4. 2 PT calibration is performed automatically after exiting **Conditioning**.

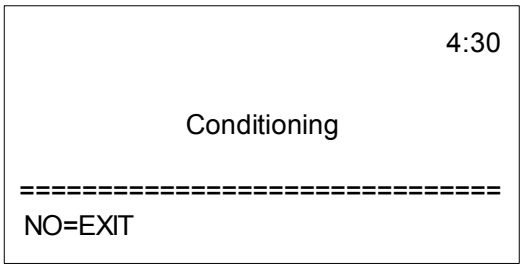


Fig. 3.19: Conditioning

3.5.3 Flush

When whole blood or urine is tested, extra flush is required.

1. Enter **Flush**.
2. Cal A is aspirated to flush the pathway.

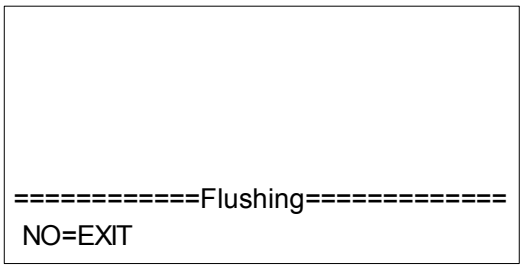


Fig. 3.20: Flush

3.5.4 Cleaning

Perform cleaning when electrode has abnormal problem or membrane is dyed. It can also help to clean electrodes and liquid pathway to prevent them from blockage or clot.

1. Enter **Cleaning**.
2. Cleaning solution is aspirated to clean electrodes.
3. Cleaning lasts 2 minutes. Press *NO* to exit if an early stop is wanted.
4. After exiting, 2 PT calibrations will start automatically.

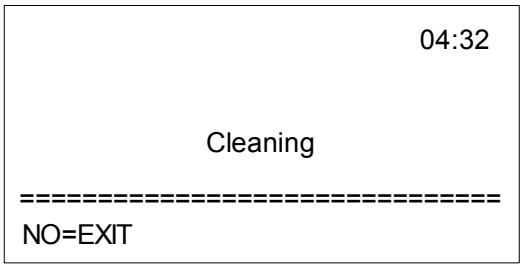


Fig. 3.21: Cleaning

3.6 Setup

There are ten menus under **Setup** menu.

1. **Time**
2. **Reference range**
3. **Maintenance interval**
4. **Select channel**
5. **Sample Volume**
6. **Coefficient factor**
7. **Printer option**
8. **LCD contrast**
9. **Unit**

Fig. 3.22: Setup

3.6.1 Time

1. Enter **Time** setup.
2. Input date and time accordingly.
3. The system can maintain the date automatically by its on board battery. Stay power on to recharge the battery or replace a new one.

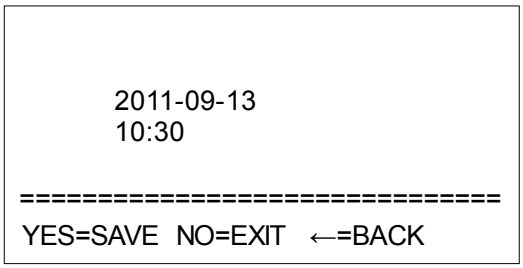


Fig. 3.23: Time setup

3.6.2 Reference range

This sets up the reference range of electrolytes

1. Enter **Reference range** setup.
2. Input low limit and high limit of each electrode.
3. Press *YES* to save.

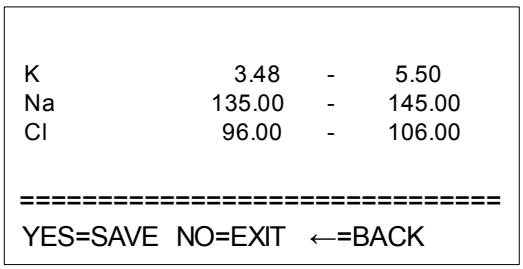


Fig. 3.24: Reference range

3.6.3 Maintenance interval

The performance of electrodes can decrease with increasing tests of samples. The electrodes require routine deproteinize or cleaning to assure its performance. The menu can setup up the interval between mainteance.

1. Enter **Maintenance interval** setup.
2. Input days and tests for Deproteinize. When either condition is met, Need de-proteinize is prompted.
3. Input number of days for Cleaning. When this condition is met, Need cleaning is prompted.
4. Press *YES* to save.

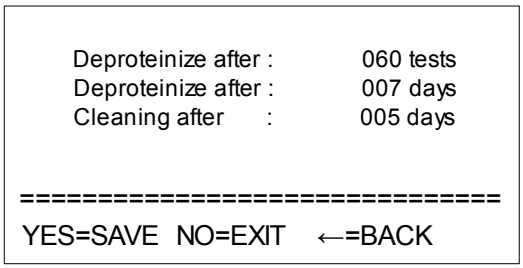


Fig. 3.25: Maintenance interval

3.6.4 Select channel

A channel can be turned off when it is failed. The test can be continued with other channels.

1. Enter **Select channel**.
2. Setup each channel by using 1-3. Press *YES* to save.

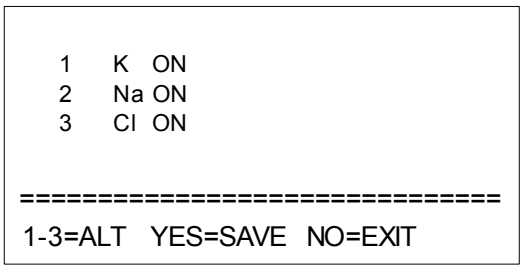


Fig. 3.26: Select channel

⚠	Calibration will be performed if one channel is re turned on.

3.6.5 Sample volume

This can adjust the aspiration volume when pump tube is aging. It proves 5 levels of adjustment.

1. Select **Sample volume**.
2. Press *1* to increase. Press *2* to decrease.
3. Press *YES* to save.

   3 is roughly corresponding to 130-150 µl and each step has 20µl difference.

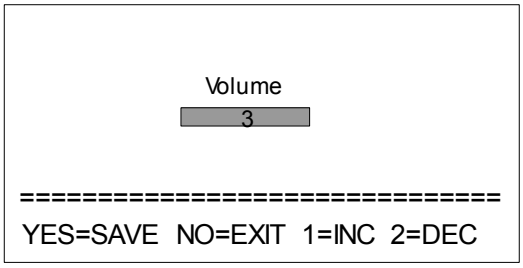


Fig. 3.27: Sample volume

⚠	Adjust the volume for every 3 months to compensate the aged pump tube.

3.6.6 Coefficient factor

The instrument supports to correct the electrodes when the result is different from standard values

1. Select **Coefficient factor**.
2. The first column is slope, and the second one is intercept. The password for editing is *55*.

   ←: Reset slope and intercept to 1.00 and 0.00

   1: Input slope and intercept directly.

   2: Calculate intercept and slope according to QC data in **QC test**. The next menu is shown as right figure to input target value when cal is selected.

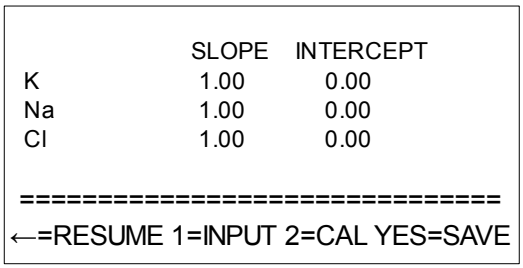


Fig. 3.28: Coefficient factor

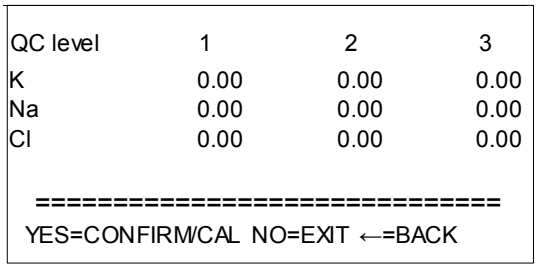


Fig. 3.29: Input target value

1. Only K, Na, Cl, Ca can be calculated.
2. The calculation adopts results from QC level 1/2/3. The history data must be cleared first before starting QC test (No. starts from 0001).

3.6.7 Printer option

This menu controls the setup of printer.

1. Select **Printer option**.
2. There are two options to control the printer and test report.

   Printer : Turn printer on or off.

   Reference range: Select to print reference range on the report or not.

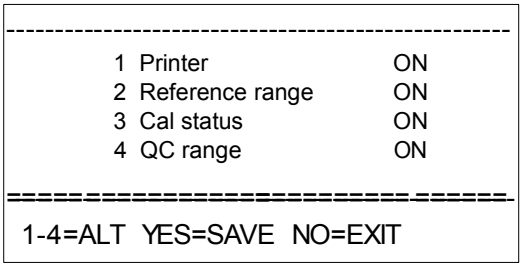


Fig. 3.30: Printer option

   Calstatus: Enable or disable auto Cal status print.

   QCrange: Enable or disable QC range print when QC test.

3.6.8 LCD contrast

This can adjust the contrast of LCD.

1. Enter **LCD contrast**.
2. Adjust the contrast accordingly
3. Press *YES* to save.

Fig. 3.31: LCD contrast

3.6.9 Unit

This controls unit of test result.

1. Enter **Unit**.
2. Press corresponding digit to toggle between option.

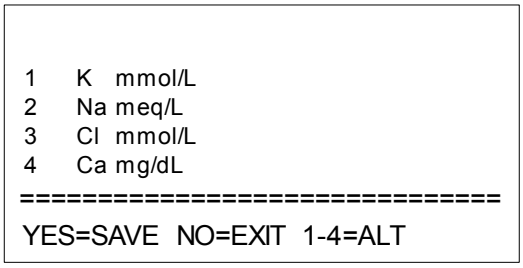


Fig. 3.32: Unit

	mmol/L is available for K Na Cl Ca. meq/l is available for K Na Cl. mg/dL is only available for Ca.

3.7 Service

There are 6 menus under service menu.

1. **Data retrieval**
2. **Calibration data**
3. **Data transfer**
4. **Stop use**
5. **Multiplexer check**
6. **Replace reagent**

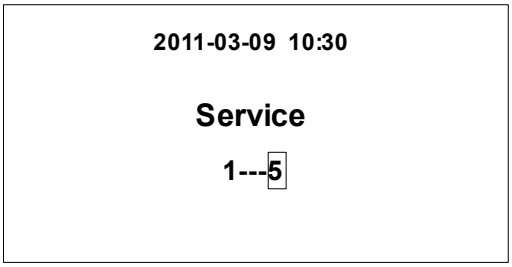


Fig. 3.33: Service

3.7.1 Data retrieval

1. Select **Data retrieval**.
2. Next input the searching rules either by date or by serial then press *YES* to search.
3. The result shows after searching.

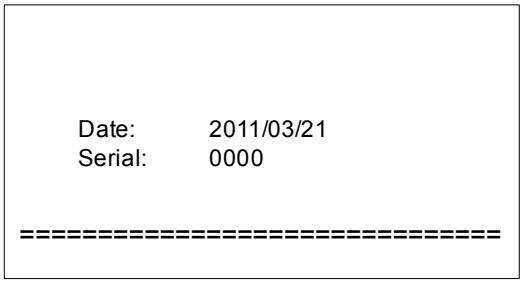


Fig. 3.34: Data retrieval

3.7.2 Calibration data

This menu provides information for troubleshooting. Calibration data can be used to judge the status of electrodes.

1. Select **Calibration data.**
2. Press *1* or *2* to skip between data.

3. The last 32 records can be reviewed. "B2" means the second trial of Cal B. "10:38" is the time when Cal B2 is carried out. The number after each electrode is mv value.

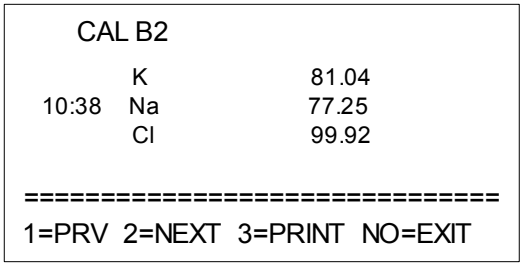


Fig. 3.35: Calibration data

3.7.3 Stop use

This function guides the operator to prepare for long time shut down or before transportation.

1. Select **Stop routine**.
2. Follow the instructions to flushing the pathway.
3. Remove the reagent pack and cover its protective insert.
4. Remove the electrodes from measuring chamber.
5. Screw out the head of reference electrode and empty its refilling solution

3.7.4 Data transfer

The instrument can transfer data to computer via RS232 serial cable.

1. Connect the instrument and the computer via serial cable using the port of RS232 on the back cover.
2. On the computer, select Start >> All program >> Accessories >> Communication >> HyperTerminal, setup the HyperTerminal as left down shown (*Fig. 3.36*).
3. Select **Data transfer** to start transmitting. This will dump all the history record into computer.

PROTOCOL	Serial
PORT	COM *
BAUD RATE	19200
DATA BITS	8
PARITY	None
STOP BITS	1

Fig.3.36: Protocol

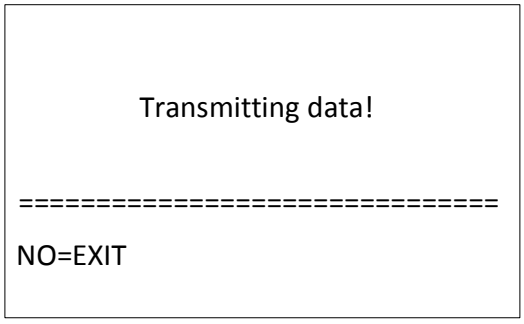


Fig.3.37: Data transfer

3.7.5 Replace reagent

This function guides the operator to replace new reagent pack.

1. Select **Replace reagent**.
2. Follow the instructions to replace the reagent pack.

	This operation is only necessary when reagent counter is activated

3.7.6 Multiplexer check

This function is used to troubleshoot multiplexer.

1. Select **Multiplexer check**.
2. There are four options at the bottom.
   1: Switch multiplexer to Cal A.
   2: Switch multiplexer to Cal B.
   3: Switch multiplexer to cleaning.
   4: Switch multiplexer to null.
3. Lift up probe.
   Select one option and inject DI water from connector to check corresponding flow path. Normally, DI water will come out from probe tie-in if there is no blockage.

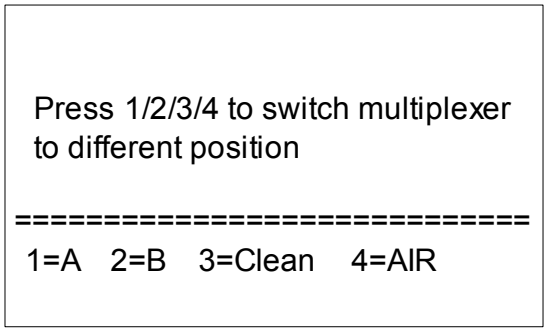


Fig. 3.38: Multiplexer check

4 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.

4.1 Sterilization

The purpose of sterilization is to minimize the danger` of infection when contacting with blood-contaminated parts.

The sterilization should be performed routinely.

It is recommended the operator comply with sterilization procedures and special requirement of lab.

	Only use liquid disinfector such as 2% hydrogen peroxide. Never use organic solution or alcohol to clean or sterilize the surface.

	Do not pour any liquid such as the disinfector directly on the surface, or it will cause electrical short circuit.

The following parts need to be sterilized periodically.

1. Probe
2. Liquid flow path
3. Display and keys

4.2 Daily maintenance

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

1. Clean the probe
2. Clean surface of the instrument.

3. Do 2 PT calibration first to check the instrument first. After calibration is passed, test a sample to check.
4. Near day off, do Deproteinize or cleaning to maintain electrodes if necessary.

4.3 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 several times to avoid crystal formation.
3. Cleaning the pathway to prevent blockage.
4. Check the multiplexer if there is any leakage.
5. Test middle level QC, adjust intercept and slope accordingly.
6. Perform Deproteinize and cleaning to maintain electrodes.
7. Clean liquid pathway by injecting DI water with a syringe. Avoid hard pushing from breaking the membrane.

	Careful cautions should be taken when sterilizing probe to avoid injury and potential infections.

4.4 Monthly maintenance

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

	For K^+, Na^+, Cl^-, Ca^{2+}, Li^+ 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 reference electrode, remove crystal if there is too much. Refill if the solution is not enough.
4. Clean all the pathway to avoid blockage.

4.5 Every 3 months

Replace refill solution for K^+, Na^+, Cl^-, Ca^{2+}, Li^+ and pH electrodes

Adjust sample volume of aspiration if it is not enough.

4.6 Every 6 months

1. Replace pump tube
2. Check O ring of electrode
3. Check connection of tube
4. Check the movement of multiplexer.

4.7 As necessary

1. Replace printer paper
2. Replace O rings
3. Perform Conditioning if Na^+ and pH electrode has problem.
4. Perform Deproteinize if K^+, Cl^+ ,Ca^{++}, Li^+ and pH has problem.
5. Perform Cleaning if Deproteinize is invalid.

5 Troubleshooting

This section covers the troubleshooting procedures of the instrument.

The instrument can perform self test when power up. It will detect most of the problem except electrodes.

5.1 Self test and liquid pathway problem

Problem	Possible causes	Measures
Multiplexer error	Sensor is broken	Need replacement
Sample sensor error	Need adjustment	Adjust R39 or R65
	Lens inside lock knob is polluted	Take out the lens and clean
	Sensor is broken	Need replacement
No Cal A No Cal B No Cleaning solution	Reagent pack is run out	Replace new one
	Reagent connector is loose	Re insert the connector
	Electrodes is not installed correctly	Level the electrode
	Knob of measuring chamber is open	Pull out and twist to lock
	O ring of electrodes is broken	Replace O ring
	Blockage in the multiplexer	Pull out by two handles &clean
	Leakage in the liquid pathway.	Check by injecting water
	Blockage in the probe	Clean
	Blockage in the waste tube	Clean by injecting water

5.2 Electrodes problem

If the problem happens with

5.2.1 Only one electrode

Problem	Possible causes	Measures
OR	Refill solution is less than 3/4	Empty and replace new
	Coat of internal core is broken	Replace new electrode
	Incomplete installation	Press and level with thumb
	Air bubble above membrane	Fillip and exclude
Abnormal	Membrane is polluted	Deproteinize or cleaning
	Electrodecase is cracked	Replacenewelectrode
	Internal core is broken	Replace new electrode
	Lifetime is exhausted	Replace new electrode
Drift	Need activation (only for new)	Activate with fresh serum for 30 mins

Problem	Possible causes	Measures
Drift	Liquid on the surface	Take out and clean
	Incomplete installation	Press and level with thumb
	Insufficient refill solution	Replace new refill solution
	Rusty electrode head	Replace new electrode
	Air bubbles above membrane	Fillip and exclude
Li problem	Na electrode problem	Maintain Na Li
	electrode problem	Maintain Li
	Inaccurate K value	Perform K Test

5.2.2 More than two electrodes

Problem	Possible causes	Measures
Drift or Abnormal or OR	Poor grounded power supply	Connect earth
	Air bubble in REF electrode	Exclude air bubble
	Crystal formation in REF	Clean
	REF is unstable	Replace
	Liquid in the measuring chamber	Take out electrodes and clean allsurface
	O ring is missing or broken	Replace new
	Membrane is polluted	Deproteinize or cleaning
	Blockage in the liquid flowpath	Check with syringe
	Leakage in the liquid flowpath	Check with syringe
	Air bubble in the liquid pathway	Check leakage or blockage

5.3 High or low test result

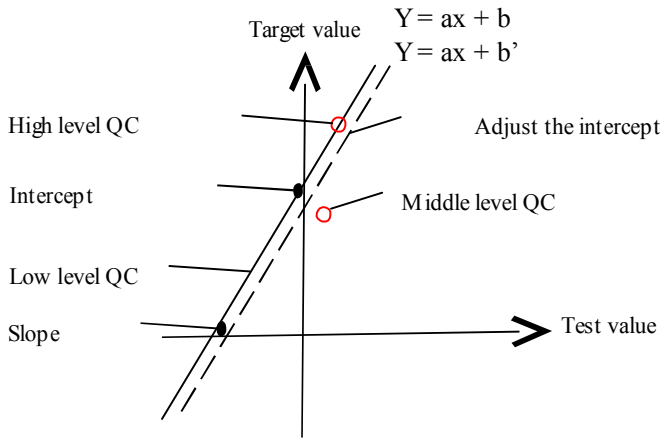
The high or low test result may caused by coefficient factors. The electrode requires correction to match standard value through coefficient factor. The performance of electrode is affected by the protein or fat clot of samples. It is recommended to do routine QC test to monitor this affection. Once the result is higher or lower than normal level, it is required to correct the electrode by adjusting coefficient factor.

$$SLOPE \quad \frac{Y_H \quad Y_L}{X_H \quad X_L}$$

INTERCEPT=Y_H-SLOPEX_H Or Y_L-SLOPE*X_L*

Where: Y_H, Y_L is the target value of the High level, Low level QC

X_H, X_L is the average test value excluding the highest and lowest test value.



The program in the **Setup>>Coefficient factor** is used to change slope and intercept values to provide best correlation with Linearity Quality Control materials

The following procedure should be utilized to determine slope and intercept values:

Prepare the Linearity Control Materials as recommended.(High, Middle, Low level provided by the same manufacturer).

1. Select **Setup>>Coefficient factor** to enter. Select ← to reset the values. (slope =1.0, intercept = 0.0 , Password: 55). Press *YES* to save.
2. Enter **QC test** and select level 1, clear the history data, the serial No should be started from 0001.
3. Enter **QC test** and select level 2, clear the history data, the serial No should be started from 0001.
4. Test QC level 2 at least 5 times.
5. Enter **QC test** and select level 3, clear the history data, the serial No should be started from 0001.
6. Test QC level 3 at least 5 times.
7. Select **Setup>>Coefficient factor**. Press *2* to select calculation.
8. Input expected value of QC level1/2/3, Press *YES* to continue.
9. The calculated coefficient factor will display on the LCD. Press *YES* to save.
10. Enter **QC test** and select level 2, test QC level 2 to check.
11. If the result is still a little lower or elevated, just fine adjust intercept accordingly. After adjustment, recheck with QC level 2.

A Annex

A.1 Sample collection and storage

There is complete sample handling and storage information in the standard Clinical Chemistry procedures published by NCCLS. This section only lists a few of them. Please refer to them for more details.

	Wear disposal gloves to avoid potential infections during these operations

A.1.1 Whole blood

Blood from artery vessels, vein and capillary vessel can all be used for test with this analyzer. Whole blood samples should be drawn carefully to avoid hemolysis. Elevated potassium values may indicate a hemolyzed sample; if hemolysis is suspected, a new sample should be drawn and analyzed. Finger stick methods should be avoided since they can result in elevated potassium values.

1. Collect the samples by venipuncture into a lithium-Heparin evacuated blood collection tube. Do not use AMMONIUM HEPARIN, EDTA or NaF tubes. Note the time of collection.
2. Mix the sample by inverting and rotating the tube. Do not shake.
3. Analyze the sample within one hour of collection. Beyond this time elevated potassium may be obtained.

	For the same sample, there is a difference of about 3mmol/L Cl^- ion between blood (serum) and whole blood. Salicylate (and its derivatives) and bromide inside the sample can increase the Cl reading. The sample may be polluted by perchlorate, cyanide sulfate, iodide or nitrate.

A.1.2 Serum

1. Collect the sample by venipuncture into an untreated tube. Fill the tube to at least 2/3 of the total volume. Note the time of collection.
2. Let the sample stand for 20-30 minutes to wait for clot formation.
3. Rim the clot with an applicator stick, then centrifuge the tube for 10-15 minutes and

remove the serum to a clean sample tube.

4. Serum may be analyzed immediately. If immediate analysis is inapplicable, then the sample should be stored at 4ºC for 24 hours or frozen at -20ºC for up to one week. Samples must be brought to room temperature and mixed well prior to analysis.
5. In order to obtain accurate results, samples should be free of any clots, fibrin, etc., which would obstruct sample flow and affect results. The use of a serum clearing agent is strongly recommended.

	If a serum separator tube is utilized, care must be taken to avoid inserting the Probe into the gel layer. This can create obstructions in the Probe and electrodes. Plasma samples offer no advantage over whole blood samples for stat analysis. If the sample is to be stored, serum specimens are preferable.

A.1.3 Plasma

1. Collect the specimen by venipuncture into a Lithium-Heparin evacuated blood collection tube. The heparin level should not exceed 15 U per ml of tube volume. Normally total 1000 unit is recommended
2. Do not use AMMONIUM HEPARIN, EDTA or NaF tubes. Note the time of collection.
3. Centrifuge the sample within one hour of collection. Carefully remove the top plasma layer fro analysis. Use a syringe fitted with a blunt-tipped needle for this procedure.
4. Analyze plasma sample within 4 hours of collection. Refrigerated samples must be brought to room temperature and centrifuged prior to analysis.

A.1.4 Urine

1. Follow standard clinical procedures for collection of random and 24-hour urine sample.
2. Refrigerate urine sample until time of analysis.
3. Centrifuge urine samples to remove cellular matter, crystals, etc.
4. Dilute the urine sample with one part of the urine to 4 parts of Cal A. Urine must be diluted. Do not attempt to analyze undiluted urine.

A.2 mv range for electrodes

	Normal range (mV)	mV(CAL B) – mV(CAL A)
K	45 ~ 140	12 ~ 21.0
Na	45 ~ 120	-4.2 ~ -7.3
Cl	50 ~ 120	5.4 ~ 10.8
Ca	35 ~ 100	6.6 ~ 10.5
pH	70 ~ 170	16 ~ 28
Li	50 ~ 150	5.0 ~ 9.0

When response potential of the electrode is outside the normal range, the system prompts OR error.

When potential difference of Cal B-Cal A falls beyond above limit, the system prompts abnormal error.

A.3 Interference factors

There are some medicines or factors that can affect the value of electrodes. The following are some examples and their effect.

Medicine	Effect Heparinate
anticoagulant	K↑, Na↑, Ca↓
Hemolysis	K↑, Ca↓
Contaminated container	K↑, Na↑, Cl↑, Ca↑
Salvolatile	K↑, Na↑, Ca↓
Nystatin	K↑, Ca↓
Amphoterisin	K↑, Ca↓
Procaine	K↓, Ca↓
Lidocaine	K↓, Ca↓
Bromide	Cl↑
Iodide	Cl↑
Nitrate	Cl↑
Thiocyanate	Cl↑, Ca↓
Salicylate	Cl↑, Ca↓

Other than above factors, electromagnetic interference, irradiation of strong light, degraded calibrate, additives and preservatives in the QC materials, imperfection of the grounding, unstable power supply, dry out of electrode refill solution, chloride layer falling off the silver stick of the electrode or corrosion and moist of grounding points are all the inducements to imperfection in calibration and testing.

A.4 Reference Range for adult

A.4.1 Electrolytes in serum and blood

	Reference Range	Unit
pH(37ºC)	7.35 ~7.45	
Sodium(Na^+)	136~146	mmol/L
Potassium(K^+)	3.5~5.1	mmol/L
Chloride(Cl^-)	98~106	mmol/L
Calcium Ionized(Ca^{++})	1.12~1.23	mmol/L
TCO_2	23~29	mmol/L

A.4.2 Electrolytes in urine

The normal range of electrolytes in urine is shown in below.

	Range	Unit
K^+	25 ~ 100	mmol/24hour
Na^+	130 ~ 145	mmol/24hour
Cl^-	110 ~ 250	mmol/24hour

Note: The unit is mmol/24 hour. Since electrolytes in urine vary greatly in one day, the range is an average concentration of all urine collected from one patient in 24 hours.

A.4.3 Table of Critical values

A critical value is a value at such variance with normal as to represent a path physiological state which is life threatening unless some action is taken immediately and for which an appropriate action is possible. It is the laboratory's responsibility to communicate these values immediately and flawlessly to the responsible clinicians. Each laboratory should determine its own critical values. The above values are stated for reference purposes only.

Analyte	Value	Possible Effect
pH	<7.2	Complex interwoven patterns of acidosis, alkalosis and anoxemia
	>7.6	Complex interwoven patterns of acidosis, alkalosis and anoxemia
Sodium(Na^+)	<120 mmol/L	Extremes of dehydration, vascular collapse, or edema, hypervolemia, heart failure
	>160 mmol/L	Extremes of dehydration, vascular collapse, or edema, hypervolemia, heart failure

Analyte	Value	Possible Effect
Potassium(K^+)	<2.5 mmol/L	Muscle weakness, paralysis, cardiac arrhythmias
Chloride(Cl^-)	<80 mmol/L	Over hydration, congestive failure, chronic respiratory acidosis, metabolic alkalosis
	>115mmol/L	Dehydration, excessive infusion of normal saline
Calcium(Ca^{++})	None established	

A.5 Working principle

Ion-selective electrode is a kind of chemical sensor that converts the activity of a certain ion into an electric potential. It is only sensitive to one kind of ion in the solution. When the ion is selective by the sensor and an electric potential is established against the sensor. The relationship between activity and potential is expressed by Nernst equation

$$E=E_0+\frac{2.303RT}{nF}\log c_x f_x$$

Where:

E= electric potential of ion-selective electrode in the solution being measured

E_O= standard electrode potential of ion-selective electrode

n =electrovalence of the ion being measured

R=gas constant (8.314 J/K.mol)

T=absolute temperature (273+tºC)

F=Faraday constant (96487 c/mol)

C_x=concentration of the ion being measured

f_x=activity coefficient of the ion being measured

In given conditions such as room temperature, Nernst equation shows that electrode potential of ion-selective electrode is linear to the logarithm of the activity (or concentration) of the ion being measured.

There is one exception of lithium electrode. The sodium ion will also affect lithium electrode. A selective coefficient calibrator is used to minimize the interference of sodium.