PR Series

Electrolytes analyzer

Service Manual

Rev. 4.00·12/21/11

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Revised history

Version	Date	Description	Author
Version 3.20	03/25/10	Software update	Dong Lihai
Version 4.00	03/17/11	Software update	Dong Lihai
Version 4.01	12/21/11	CE and Li Support	Dong Lihai

CONTENTS

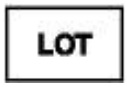
Preface

1. Using this manual

This manual provides the information and procedures necessary to maintain the system. It is designed to meet the needs of medical personnel who performs 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.

	In vitro diagnostic Medical devices
	Complies with IVD directive 98/79/EC
	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
	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: 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 Specifications

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

Method	ISE
Dimension	300*260*360mm
Weight	7.5kg
Power supply	AC100~240V/100VA
Fuse	2×F3.15L 250VAC
Operating temperature	5~40ºC,Up to 85% non condensing
Sample volume	Typical 120μL, minimum 65μL
Sample type	Whole blood, Serum, Plasma, Urine
Printer	Thermal, 57.5mm
Interface	RS232
LCD	240*64

Measured parameters

Parameters	Measuring range	Resolution	CV%
Potassium ion(K^+)	0.30—10.00mmol/L	0.01mmol/L	<1.0
Sodium ion(Na^+)	20.0—200.0mmol/L	0.1mmol/L	<1.0
Chloride ion(Cl^-)	20.0—200.0mmol/L	0.1mmol/L	<1.0
Calcium(Ca^{2+})	0.30-5.00mmol/L	0.01mmol/L	<1.5
pH	6.0—9	0..01	<1.0
Lithium(Li^+)	0.00—3.00mmol/L	0.01mmol/L	<1.0

2 Trouble shooting

2.1 Electrode problem

2.1.1 Drift

1. If the drift problem happens with two or more electrodes, most probably, it is caused by reference electrode or the flow path way.
   (a) Check power supply, if it is grounded, with stabilizer and no interference.
   (b) Check the tip of reference electrode, if there is any bubbles;
   (c) Check the refilling solution inside, if it is lower than 3/4 of internal cavity.
   (d) Check the fluid segment when calibration, if there is any bubbles ; if the fluid segment could be drawn to the measuring chamber.
   (e) Check the reagent pack, try with a new reagent pack.
   (f) Activate the electrodes with fresh serum, select **Maintenance**>> **De-proteinize**, and feed fresh serum to the probe, wait for 30 minutes to activate electrodes.
   (g) If drift problem is not fixed, please replace it with a new one or contact the service department immediately.
2. If drift problem happens with only one electrode, check as follows:
   (a) Check the tip of the electrode, if there is any bubbles;
   (b) For K^+, Ca^{2+}, Cl^- ,Li^+electrode, perform De-proteinize and check again; for Na^+, pH electrode, perform Conditioning and check again.
   (c) (Recommended)Activate the electrodes with fresh serum, select **Maintenance**>> **De-proteinize**, and feed fresh serum to the probe, wait for 30 minutes.
   (d) Perform cleaning. Enter Maintenance>>Cleaning, cleaning the electrode.

2.1.2 Abnormal problem

1. If the abnormal problem happens with two or more electrodes, most probably, it is caused by Reference electrode or the reagent pack.
2. If the abnormal problem happens with only one electrode, please check as below
   (a) Check the tip of the electrodes, if there is any bubbles.
   (b) Access **Service**>>**Calibration data** , select Print to check the mV value of CAL A and CAL B, check if the value could meet the following range:

Range	Cal A or Cal B			Cal B- Cal A	
K^+	45-140	mV		12-21.0	mV
Na^+	45-120	mV		-4.2 - -7.3	mV
Cl^-	50-120	mV		5.4-10.8	mV
Ca^{2+}	35-100	mV		6.6-10.5	mV
Li^+	50-150	mV		5.0-9.0	mV
pH	50-150	mV		16-28	mV

(c) For K^+, Ca^{2+}, Cl^- ,Li^+ electrode, perform De-proteinize cycle and check again; for Na^+, pH electrode, perform Conditioning cycle and check again.

(d) Perform cleaning cycle and check again.

(e) If still not fixed, please replace it with a new one or contact service department immediately.

2.1.3 OR problem

1. If the abnormal problem happens with two or more electrodes, most probably, it is caused by Reference electrode, grounding or flow pathway
2. If the abnormal problem happens with only one electrode, proceed as follows:

(a) To check the filling solution in it, if the level is lower than 2/3 of height of internal cavity. Most of the "OR" problem is caused by filling solution is not enough.

(b) To check the tip of the electrodes, if there is any bubbles.

2.1.4 Li electrode problem

Li is affected by Na electrode, if there is problem with Li, Na has to be checked first.

1. Check Na electrode if there is problem.
2. Perform QC test and correct Na to target value.
3. Perform K Test.
4. Maintain Li electrode ,check refilling solution, perform Deproteinize if appropriate.

2.1.5 High or low test result

When a new electrode is replaced or an electrode is found that the value is higher or lower than normal value, the correlation factor shall be readjusted to get a correct value.

At least two levels of QC materials from the same manufacturer shall be provided to do this correction. The difference between each level shall be as larger as possible. The minimum difference is showed below:

K:	2 ~ 4	mmol/L
Na:	30 ~ 60	mmol/L
Cl:	25 ~ 40	mmol/L
Ca	1.5 ~ 3	mmol/L
pH:	0.5 ~ 2.0	mmol/L

Notice: Randox® ISE QC serum are strongly recommended

There are two ways to get correlation factors, one is auto-calculated by the instrument, and the other one is manually calculated by operators. Here expected value is also called target value of QC materials. Measured value is the actual value measured from QC materials without correlation (Slope=1,intercept=0).

1. Auto calculation of correlation factors

(a) Run 1 point calibration and 2 point calibration prior to running QC test, and make sure it could pass only 1 time. The purpose is to ensure the electrodes in good condition.

(b) Reset slope and intercept, select **Setup**>>**Coefficient factor,** select Resume to clear slope and intercept, press *YES* to save. When finished, slope=1.0, intercept=0.0 (Password:55)

(c) Enter **QC test** and select level 1,clear the history data, the serial No should be started from 0001.

(d) Test QC level 1 at least 5 times.

(e) Repeat step 2-3 for level 2/3.

(f) Select **Setup**>>**Coefficient factor**. Press *2* to select calculation.

(g) Input expected value of QC level1/2/3, Press *YES* to continue.

(h) The calculated coefficient factor will display on the LCD. Press *YES* to save.

(i) Enter **QC test** and select level 2, test QC level 2 to check.

(j) If the result is still a little lower or elevated, just fine adjust intercept accordingly. After adjustment, recheck with QC level 2.

If only two levels of QC are available, just test it under QC level 1 and 2.

2. Manual calculation of correlation factors

(a) Enter Setup>>Test parameters program, select [Resume] to make slope=1.0 and

Perform 1 point calibration and 2 point calibration to check the status of the instrument, we must ensure the instrument is being good condition when proforming QC test.

(b) Reset slope and intercept, select **Setup>>Coefficient factor,** select Resume to clear slope and intercept, press *YES* to save. When finished, slope=1.0, intercept=0.0 (Password:55)

(c) Enter **QC test** and select level 1,

(d) Test QC level 1 at least 5 times.

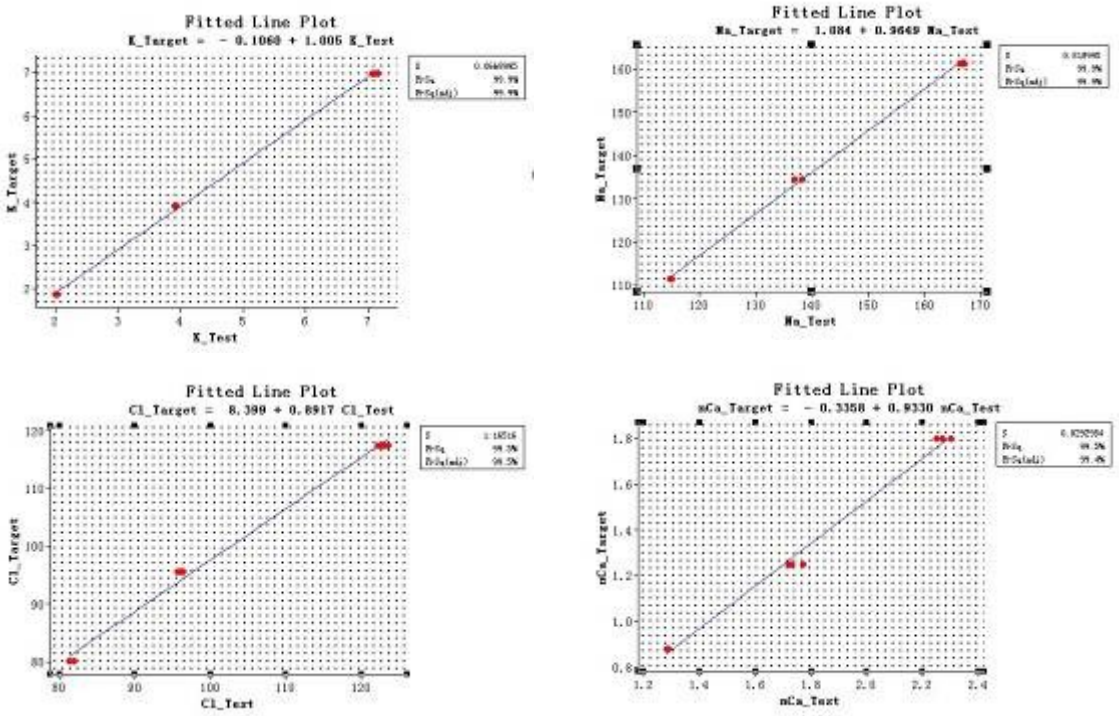
(e) Repeat step c to d for level 2/3.

(f) Input the QC data into EXCEL and use the function of SLOPE and INTERCEPT to calculate the slope and intercept.

Example

K_Test	K_Target	y=ax+b		
5.72	5.7	SLOPE	INTERCEPT	CORRELATION FACTORS
5.71	5.7	1.096444	-0.57389	0.999978
5.72	5.7	Note:		
5.73	5.7	Function available in EXCEL		
3.90	3.7	SLOPE(array y,array x)		
3.89	3.7	INTERCEPT(array y,array x)		
3.90	3.7	CORREL(array y,array x)		
3.90	3.7			
3.90	3.7			

(g) select **Setup>>Coefficient factor,** select Input to input slope and intercept from above calculation, press *YES* to save.



2.2 Aspiration failure

2.2.1 More than two solution

If the problem happens with Cal A/Cal B, even with serum, most probably, it is caused by sample pathway blockage or leakage.

(a) Check tube connections if there is any loose connection.

(b) check electrode O ring, if it is broken or missing (replace with a new one.).

(c) Check reagent pack connector, reinsert it to try.

(d) Check lock of measuring chamber if it is released.

(e) Check multiplexer, if there is crystal formation inside.

(f) Check if the membrane of electrodes is broken, if the membrane is broken (refilling solution may leak out, aspiration failure can be observed).

(g) Check subsection of liquid pathway for leakage or blockage by Injecting distilled water from reagent pack connector. For example.

From D to waste. Lift up probe, release pump tube, use a syringe and insert it from waste on the reagent connector, then slowly push the plunger. Observe if water comes out from probe.

From reagent pack to C. Lift up probe, enter **Service**>>**Multiplexer check**, select A/B or clean to switch multiplexer, then insert syringe into A/B or clean correspondingly on the reagent connector,slowly push plunger. Observe if water comes out from probe tie-in.

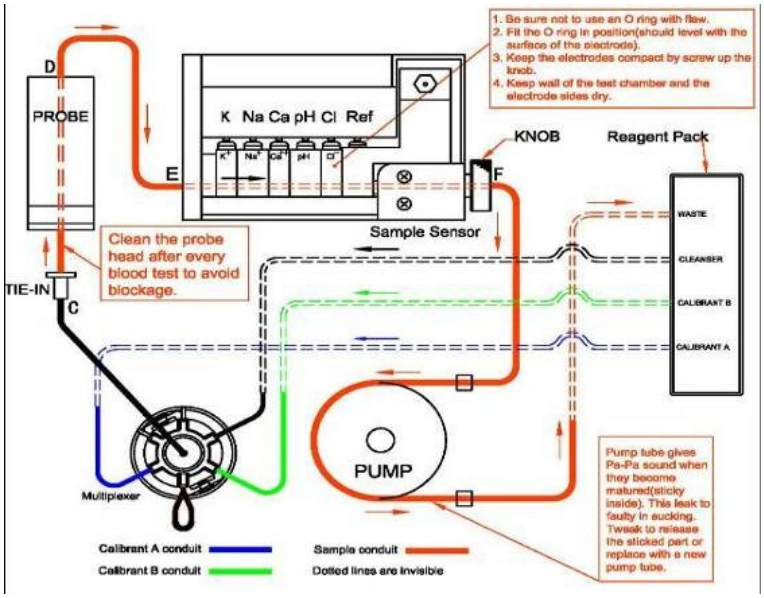


Fig. 2.1: Flowpath

2.2.2 Only one solution

If the problem only happens with only one solution, Cal A , Cal B or cleaning solution.

(a) Take out reagent pack and reinsert it into connector.

(b) Take out the reagent pack, connect the syringe to one end of pump tube, then insert another end to the outlet of Cal A or Cal B solution, draw the plunger to check if this solution is finished.

(c) Enter **Service**>>**Multiplexer check**, select different position, then rotate pump wheel manually. The solution should be observed from outlet of multiplexer if it works normally. Pull out the cover of multiplexer by pressing two handles to check if there is crystal formation inside.

2.3 Multiplexer problem

Multiplexer configures as flow control switch of the liquid: Cal A, Cal B, Clean solution. Only one solution is selected to be flowed out from the common outlet at any time. If the mutlitplexer has problem, the analyzer will prompts No Cal A or No Cal B failures.

There are two possible failures from the multiplexer

a) Electrical failure. It is caused by step motor or the sensor on multiplexer. The

problem of sensor can lead to wrong positioning.

b) Mechanical failure. When there is crystal inside or missing (broken) O ring, it can cause leakage or blockage of the pathway.

2.3.1 Electrical checking

(a) Open the cover, and measure the voltage of the Pin specified in below picture, it is the first Pin of the 4-way cable on the left.

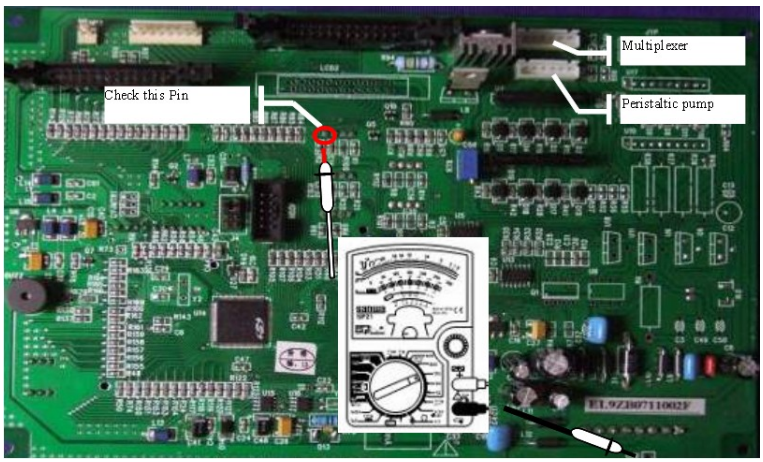


Fig.2.2: Multiplexer check

(b) Enter **Service**>>**Multiplexer check**, and skip the information, four choices are displayed at the bottom:"1→A(Cal A position); 2→B(Cal B); 3→Clean; 4→Air",observe the voltage change when switching between [1]/[2]/[3]/[4].

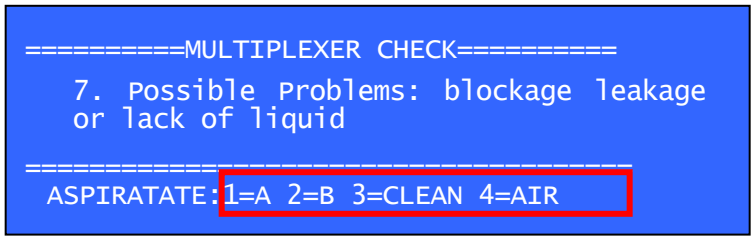


Fig. 2.3: Switch multiplexer

(c) If the multiplexer rotates to air position, the voltage of the first Pin should be more than 3.5V

(d) If the multiplexer rotates to Cal A/Cal B/Cleaning position, the voltage of the first Pin should be less than 1.0V

(e) If the given values are wrong, it should be the problem of sensor of the multiplexer; it is recommended to replace it with a new one.

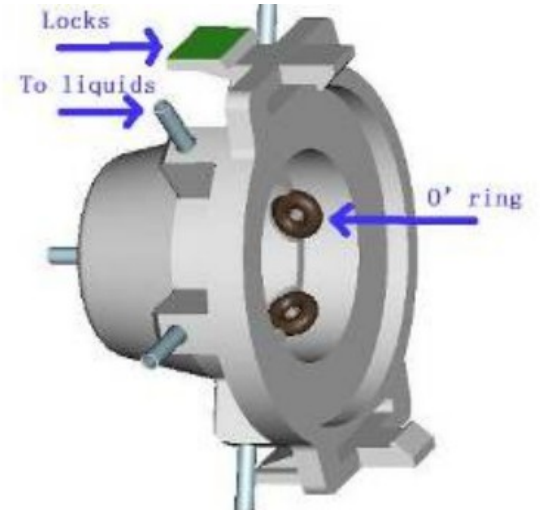
2.3.2 Mechanical checking

(a) Take out the multiplexer by pressing only two lockers

(b) Rotate the motor manually and check the position of the pointer.

(c) Observe the voltage change when the pointer is rotating around the position of the photo coupler(See section 2.3.1).

(d) Check the status of O ring, Clean the crystal if there is any.



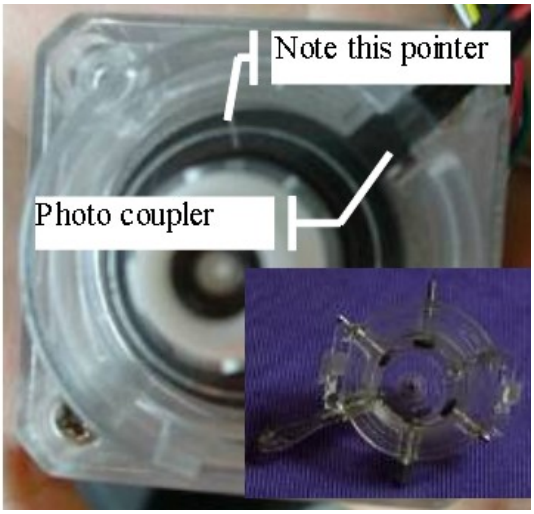


Fig. 2.4: Multiplexer check

2.4 Sample sensor problem

The sample sensor is place in the lock knob of measuring chamber. The problem of sample.sensor can cause No liquid found failure while the liquid is passing through the conduit.

2.4.1 Clean polluted sensor.

When the lens of sample sensor is polluted, there can be no liquid change found by the sensor. In this case, clean the hole with a thin roll of tissue.

Fig. 2.5: Clean lens

2.4.2 Adjustment of sample sensor.

When the sample sensor has problem or a new sample sensor is replaced, the system will prompt message to adjust R35 or R69.

Adjust R39 to 800mv when required.

Adjust R65 to 1.8V when required

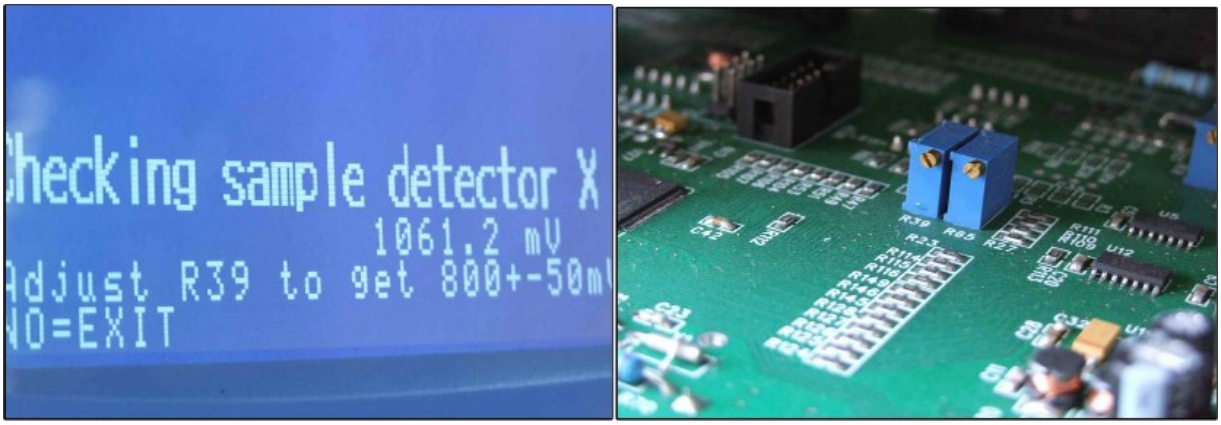


Fig. 2.6: Adjust R39/R65

2.5 Probe sensor problem

When the probe sensor has problem, calibration can pass successfully but can not find sample. In this case, the whole probe assembly should be replaced.

2.6 Door sensor problem

The door sensor will beep if the door of measuring is open. If it fails, the buzzer will beep long or no beep at all. Just check the magnetic block behind the door or replace a new measuring chamber.

2.7 LCD contrast adjustment

If software adjustment under **SETUP>>LCD CONTRAST** fails, there is another way to adjust the contrast. Find R78 on the mainboard and adjust it to the best contrast.

Note: The contrast of LCD varies with temperature.

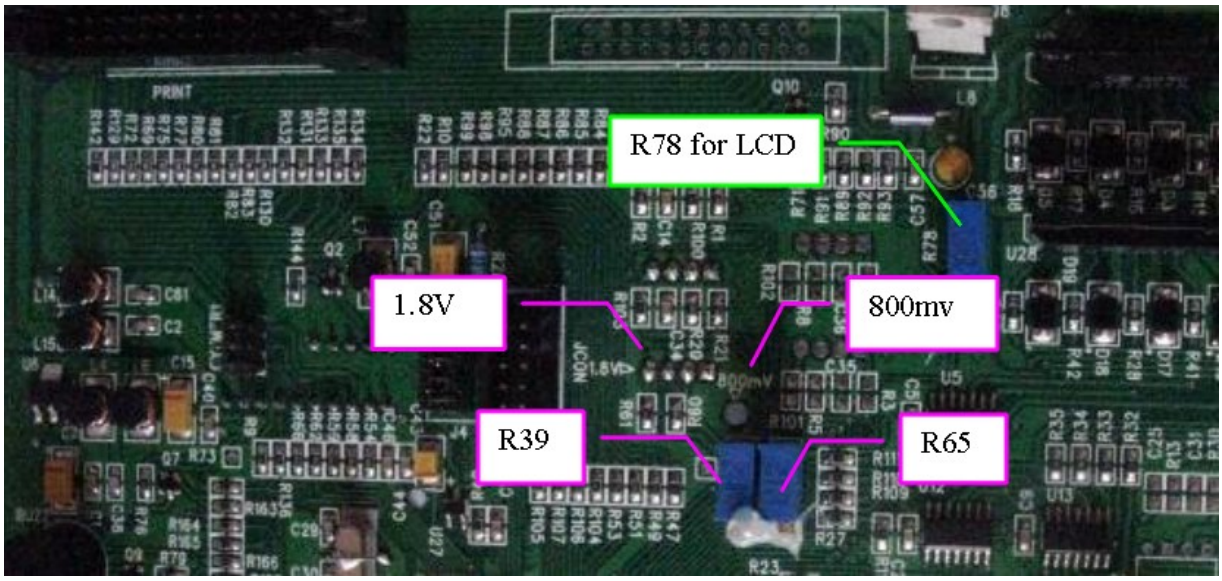


Fig. 2.7: LCD contrast

3 Factory Mode

3.1 Tca setting

1. Enter **Setup** and press - *NO NO 1 1 5*
2. System prompts with message "Turn TCa on/off"
3. Press *YES* or *NO* to enable or disable “TCa calculate” during sample measuring.

3.2 Total Test Quantity count setting

1. Enter **Setup** and press - *NO NO 1 1 6*.
2. System prompts with message "Reset to default or not"
3. Press *YES* or *NO* to reset all the parameters (including Test quantity, slope and intercept).

	The values of slope and intercept are erased as well. It is highly recommended to write down those values and reenter them after resetting.

3.3 Volume Test

1. Enter ->Setup and press - *NO NO 1 1 8*.
2. System prompts with message "Turn volume test on or not"
3. System prompts with message "Turn volume test on or not"
4. Press *YES* or *NO* to enable or disable 'the remaining volume statement’, the value of the remaining of the Cal A solution will be displayed at the bottom of the screen
5. Please enter **Service>>Replace reagent** and follow the messages prompted when replaced with a new reagent pack, in this case the system will come back to 100% after installed a new reagent pack.

	There can be some difference between the value displayed and the actual volume, because the remaining of the reagent pack is calculated by counting rounds of the peristaltic pump. New reagent pack must be replaced in the **SERVICE>> REPLACE REAGENT**, or the volume counter will not be reset.

3.4 Printer setup

Enter **Setup**>>**Printer setup**

Press 6 8 0 7 9 to adjust the Font size of the printer (T1, T2…D1, D2… appears on the right top of the screen)

3.5 Data transfer

Test results can be transferred to computer via RS232 port.

1. Turn off both the instrument and the PC to avoid static potential hazards.
2. Connect the instrument to the serial Port of PC via RS232 cable.
3. Start HyperTerminal by clicking on Start->Programs->Accessories -> Communications -> Hyper terminal'.
4. The first screen that appears is the 'New connection' dialog box. Here you can enter a name for this configuration of Hyper Terminal. Select an icon then press 'OK'.
5. The 'Connect To' dialog box appears. Ignore the first three boxes (these are for dial-up modem), In the last box 'Connect using' select the COM port that you will be using and press 'OK'.(The port number can be found by right click **My Computer> Manage >Device manager>Port**)
6. In the following 'COM properties' dialog box, set up the communication parameters for the COM port: Bits per second: 19200, data bits: 8, parity: none, stop bits 1, flow control: none. Press OK to save.

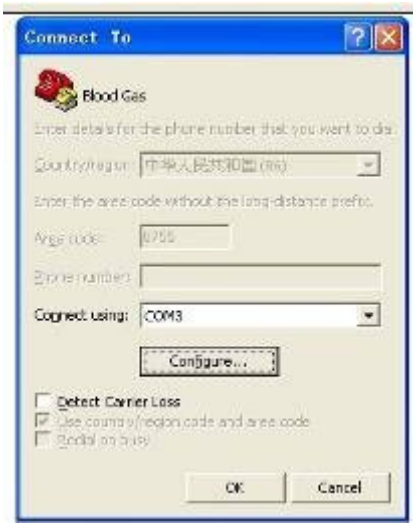


Fig. 3.1: Select COM port

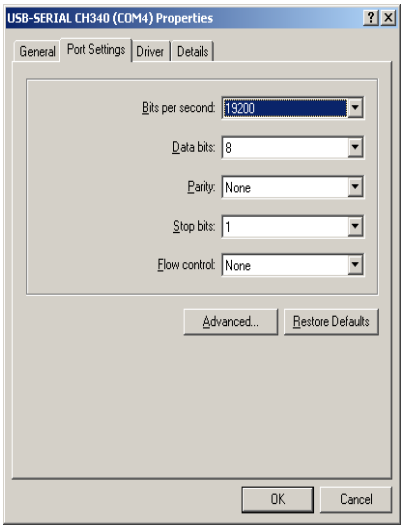


Fig. 3.2: Protocol

7. Then test results will be transferred to Hyper Terminal automatically after each test.

3.6 Software update

Software update needs the support of a programmer.

The update procedures include two steps: Download new software from computer to programmer, download new software from programmer to instrument.

3.6.1 Tools

1. Computer with serial COM(USB) and XP system 1PCS
2. Serial data cable(USB-to-Serial cable) 1PCS
3. Screwdriver 1PCS
4. Programmer with power adapter 1SET

3.6.2 Download to programmer

1. Connect the programmer to computer via RS232 cable.

Fig. 3.3: Serial port

Fig. 3.4: Serial cable

2. Connect the programmer to power adapter. Both Red and Green LED on the programmer should be on.
3. Unzip cornleysoftware package and click Cornleysoft.exe.

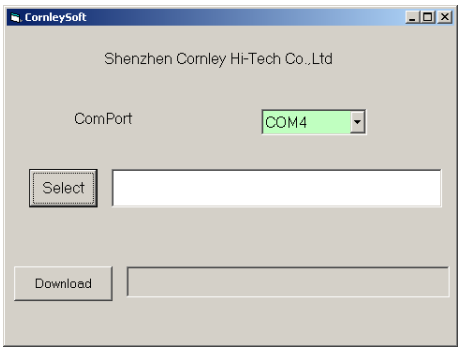


Fig. 3.5: Download interface

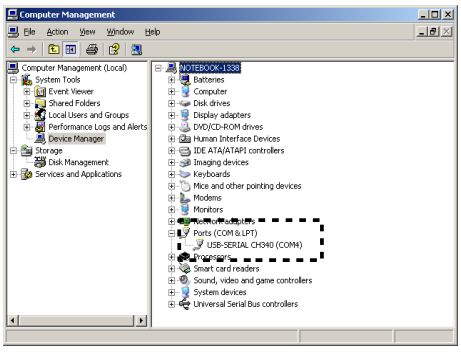


Fig. 3.6: COM port

4. Select COM port as shown on your computer by clicking **My Computer>>Manage>> Device Manager>>Ports**.
5. Press Select button to select code BIN file by browsing the file holder, click the proper

bin file then click Open.

6. Click DOWNLOAD to start download. The status bar shows the download progress. At the same time ,the Green LED on the programmer is flashing until finished.

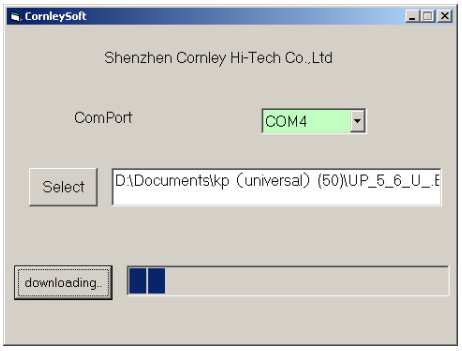


Fig. 3.7: Downloading

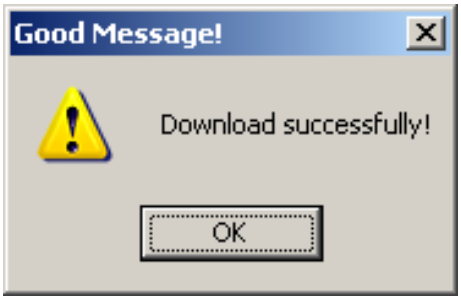


Fig. 3.8: Download is finished

7. When download is finished, a message of "Download successfully!" is displayed.
8. Disconnect the programmer with adapter and computer.

3.6.3 Download to instrument

1. Power off the instrument.
2. Open the back cover, Remove the 4 jumpers “J4” beside the “JCON”, otherwise it will protect against upgrading.
3. Connect the programmer to “JCON” on main board via the cable attached.

Fig. 3.9: JCON port and jumper

4. Power on the instrument.
5. Red and Green LED on the programmer should be on.
6. After several seconds (IMPORTANT), press the small button on the front panel of the programmer to start upgrade. The programmer will give one short beep immediately after pushing the button. The Green LED is off at the same time.

7. The programmer then gives two long beep sounds and the Green LED is on for a few seconds.
8. Several seconds later, the analyzer will give long BEEP BEEP,BEEP BEEP sounds to indicate successful resetting CPU on the instrument.
9. The programmer first gives one short sound and then more regular short beeps while upgrade. The Green LED is flashing all the time until download is finished. The upgrade process takes around 4 minutes. When it is finished, the programmer will give a long beep, then the analyzer restarts automatically..
10. Turn off the instrument and disconnect the programmer, Re-insert 4 jumper”J4”, resume the back cover,

4 Spare parts list

No	Description
1	Reagent Pack
2	Reagent connector
3	Electrode set (K/Na/Cl/Ref)
4	Electrode set(K/Na/Cl/Ca/pH/Ref)
5	pH Electrode
6	K Electrode
7	Na Electrode
8	Cl Electrode
9	Ca Electrode
10	Li Electrode
11	Big Reference Electrode
12	Small Reference Electrode
13	Electrode Conditioner/set (5 paces)
14	De-proteinizer (5 pcs) with Dilutor (5 pcs) /set
15	Refill Solution for ISE Electrodes/set (5 pcs)
16	Refill Solution for Ref Electrode (20ml/bottle)
17	Refill Solution for Li(20ml/bottle)
18	Selective Coefficient Calibrator (20ml/bottle)
19	Dilutor for Urine (20ml)
20	Probe tie-in
21	Auxiliary pump tube
22	Linearity Control Material(High/Middle/Low)
23	Print Paper
24	LCD module(YM24064F-1 P-1)
25	Printer(SP-RMDⅢ32PH)
26	O'ring of Multiplexer(1.07×1.27)
27	O'ring of Multiplexer(2.6×1.9)
28	O'ring of Electrodes (2.6×1.9)
29	Multiplexer(4 way)
30	Multiplexer(6 way)
31	Power supply module(with cable)
32	Main board (2.0 CE Marked)
33	Main board (1.6 Non CE Marked)
34	Key pad with led
35	Key pad
36	Peristaltic motor
37	Sample sensor (1.6 Non CE Marked)
38	Sample sensor(2.0 CE Marked)
39	Photo coupler for old multiplexer(MOC70T3)
40	Photo coupler for new multiplexer (Y306-01)
41	Probe Sensor 1.6 Non CE Marked
42	Probe Sensor 2.0 CE Marked

No	Description
43	Probe Assembly (1.6)
44	Probe Assembly (2.0)
45	Taike tube (G2.5×0.8)
46	Waste tube (G3×1.2)
47	Measuring chamber for K/Na/Cl Electrolytes Analyzer
48	Measuring chamber for K/Na/Cl/Ca/PH Electrolytes Analyzer