K-Lite8 series

Electrolytes/TCO2 Analyzer

Service Manual

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Table of Contents

1. Preface

1.1. About this manual

This manual contains all the information necessary to maintain or repair K-Lite8 series Electrolytes/TCO2 analyzer. Error messages are described in this manual and their possible causes and troubleshooting procedures are provided as well. User manual is the supplement of this manual and provides all detailed information about operating this system.

1.2. Symbols

The following table shows the symbols used in this manual or on the label.

	In Vitro diagnostic Medical Device
	Biohazard Warning
	Caution for electric shock
	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.
	Manufactured date
	Manufactured by
	Not for general waste

1.3. Safety information

The operation concerned in this manual should be performed by skilled/trained medical professionals only. The following safety rules must be kept in order to safety maintain and repair this system.

1.3.1. Electrical shock

The following rule should be strictly observed to avoid possible injuries when operating the analyzer.

	Unauthorized personnel is forbidden to open back cover of this instrument. Spilled reagent and sample may enter into the interior of the instrument and result in system failure or electric shock. They should not be placed on the top of the instrument.

1.3.2. Personal injuries

The following rule should be strictly observed to avoid possible injuries when operating the analyzer.

	Never put your hand or fingers into any opened component or touch the probe when the analyzer is under operation.

1.3.3. Biological hazards

The following rule should be observed to prevent possible biological hazards.

	Improper handling of specimen can lead to biological infections. Avoid any direct contact with specimens, reagents, controls, calibrators or wastes. Wear protective gloves, suits or protective goggles where appropriate.

1.3.4. Waste hazards

The following rule should be observed to prevent possible waste hazards.

	Used reagent pack which contains or contacts with biohazard materials should be disposed in compliance with regulations of local government or Lab. (Biohazard,

	dangerous solution)

1.3.5. Disposal of instrument

	Some chemical substance contained in the analyzer may be managed by local wasted regulation and disposal. Please refer to it for more details before the disposal of waste analyzer.

1.3.6. Cleaning and sterilization

	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 disposable gloves to avoid biohazard infections.

1.4. Technical assistance

Suggestions for improvement, additions, modifications, and corrections to the device are always welcomed. Please submit these at the official Cornley Website: www.cornley.com or send email to: sales@cornley.com /support@cornley.com .

2. General introduction

The instrument is intended for measuring ion concentration of potassium, sodium, calcium, chloride, lithium, pH and Total content of CO_2 in the serum, plasma and whole blood, and potassium, sodium and chloride in the urine.

The instrument is currently available in the following models.

1. Manual Sampling (without auto loader)

   K^+,Na^+,Cl^-,TCO_2

   K^+,Na^+,Cl^-,Ca^{2+},pH,TCO_2

   K^+,Na^+,Cl^-,Ca^{2+},Li^+,pH,TCO_2

   K^+,Na^+,Cl^-

   K^+,Na^+,Cl^-,Li^+

   K^+,Na^+,Cl^-,Ca^{2+},pH

   K^+,Na^+,Cl^-,Ca^{2+},Li^+,pH

2. Auto sampling (with auto loader)

   K^+,Na^+,Cl^-,TCO_2 +auto loader

   K^+,Na^+,Cl^-,Ca^{2+},pH,TCO_2 +auto loader

   K^+,Na^+,Cl^-,Ca^{2+},Li^+,pH,TCO_2+auto loader

   K^+,Na^+,Cl^-+auto loader

   K^+,Na^+,Cl^-,Li^++auto loader

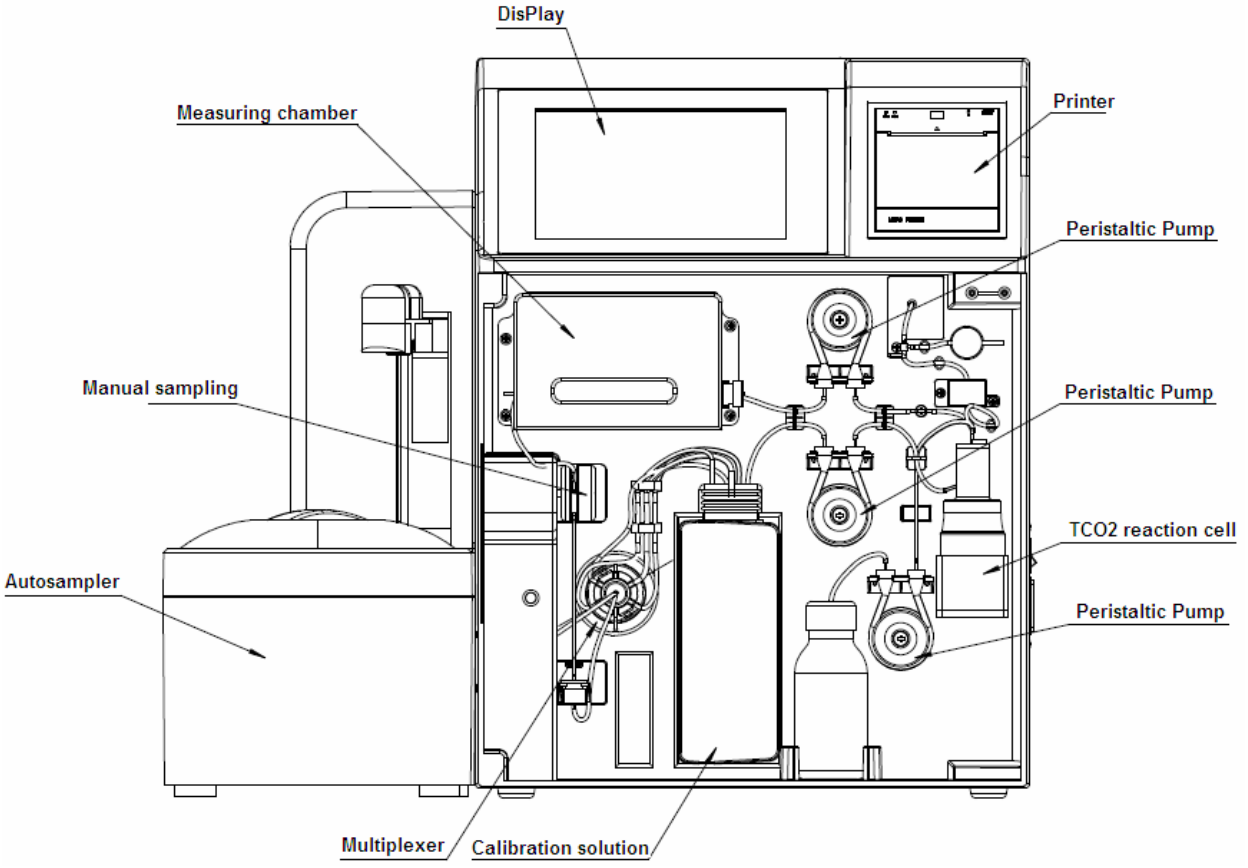
   K^+,Na^+,Cl^-,Ca^{2+},pH+auto loader

   K^+,Na^+,Cl^-,Ca^{2+},Li^+,pH+auto loader

2.1. General view

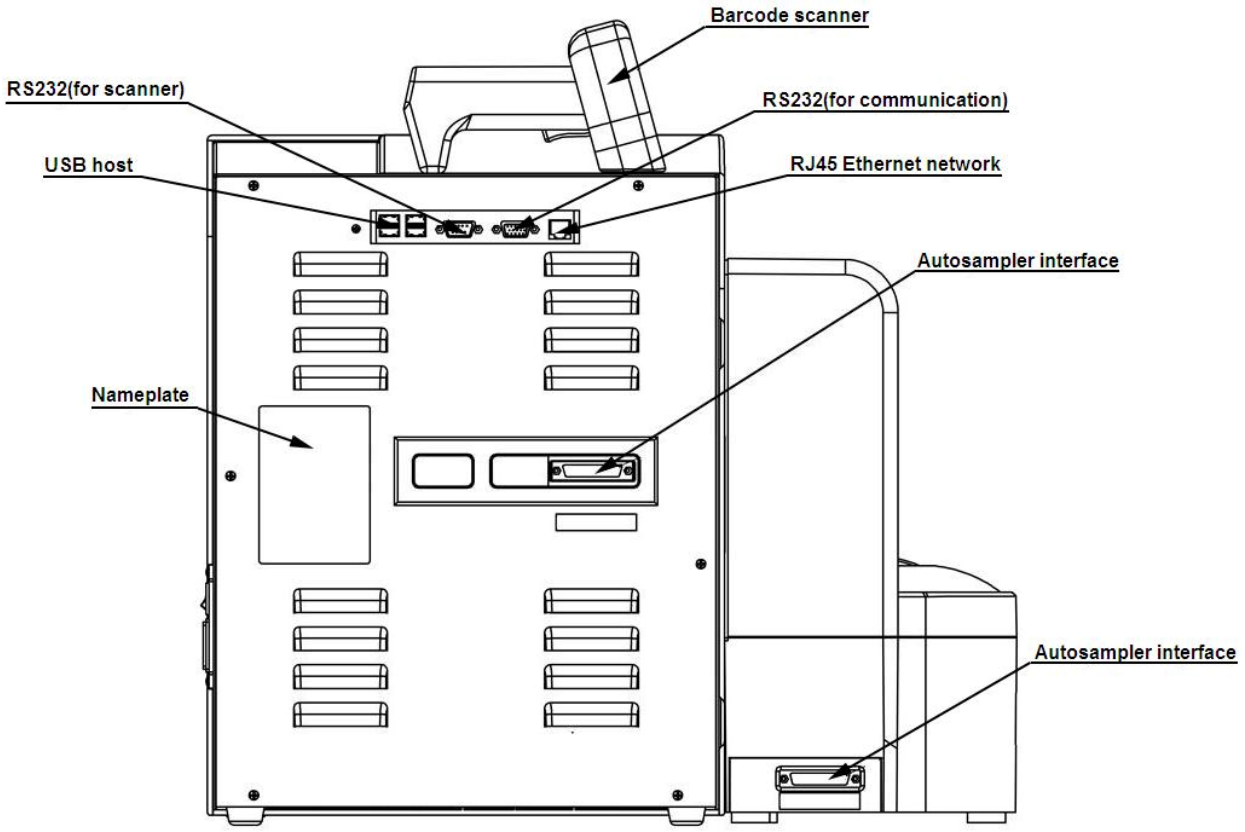
2.1.1. Front View

This system consists of manual probe assembly, display, measuring chamber, multiplexer, pump, printer, sample tray, etc.



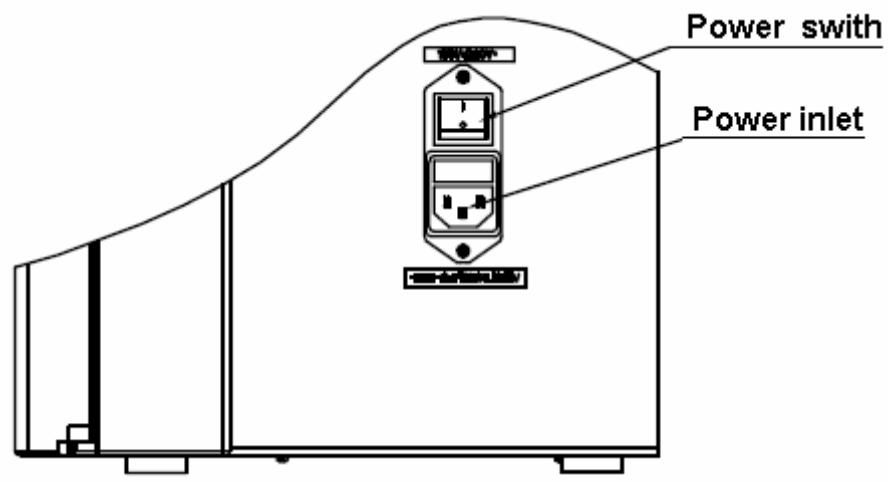
Part	Function
Display	Interface between operator and analyzer
Measuring chamber	The place to do test
Peristaltic Pump	Sample aspiration and waste drain
Calibration solution	The place for both reagent and waste
Manual sampling	Aspiration of samples and reagents
Autosampler	For automatic sampling
multiplexer	Control the flow of liquid
TCO_2 reaction cell	The place for sample and reaction solution to generate total dissolved CO_2
Printer	Print out test results and messages

2.1.2. Back view



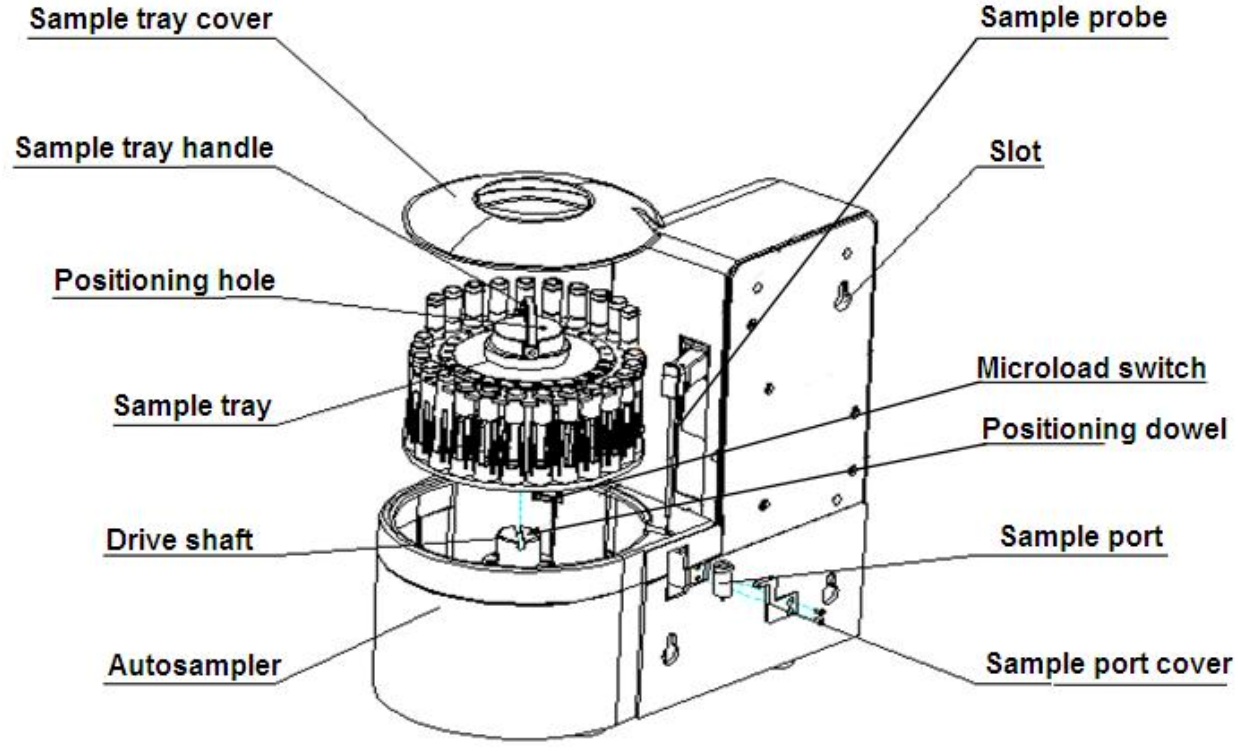
Part	Function
RS232 interface(scanner)	Slot for Barcode scanner
USB Port	For flash disk, mouse or standard keyboard
Nameplate	Describe the basic information and configuration of the analyzer
Barcode scanner	Slot for scanner, read barcode of consumable
RS232 interface(for communication)	May be used for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

2.1.3. Side view



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)



2.2. Specifications

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

Dimension

Item	length(mm)	Width(mm)	Height(mm)
Main unit	337	192	402
Auto loader	347	277	451

Weight

Main unit	17 kg
Auto loader	6.5 kg

Power requirements and consumption

Power supply	AC100~240V
Consumption	80VA
Fuse	2×F3.15L 250VAC

Operating environment

Ambient temperature	5~40ºC
Relative humidity	Up to 80% 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

Sample tray

Test speed	40 samples/hour
Support type	Cuvette or tube
Capacity	25 samples per tray

Measured parameters

Analytes	Measuring range	Resolution
Potassium ion(K^+)	0.50—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^+)	0-3.00mmol/L	0.01mmol/L
pH	6.00—9.00	0..01
TCO_2	6.0—50.0mmol/L	0.1mmol/L

3. Trouble shooting

The system will prompt electrode errors when one or several electrodes encounter problem. These errors include drift, abnormal and OR.

The electrode on this system can be divided into 2 groups: ISE electrodes and reference electrodes, ISE electrodes include K^+ ,Na^+ ,Cl^- ,Ca^{2+} , Li^+ ,pH. ISE electrodes depend on reference electrode.

The principle of TCO2 is based on differential pressure method. A pressure sensor is used to measure the pressure of TCO2 when it is released from the sample by reacting with reaction solution.

3.1. ISE Electrode problem

3.1.1. Definition

3.1.1.1. Drift

The mv difference between last and previous calibration from different calibration or between last trial and previous trial from same calibration falls outside of the limit. A drift electrode means that it is unstable.

Parameters	Drift limit[Cal A(B)3/2-Cal A(B)2/1]	
K^+ Na^+ Cl^- Ca^{2+}	<0.5	mV
pH	<1	mV

New electrode may take a few hours before reaching stable status. During this period, keep calibration by ignoring errors or activate electrodes with fresh serum for 30 minutes

3.1.1.2. Abnormal

The mV difference of Cal B-Cal A falls outside of the limit.

Parameters	Cal B - Cal A	
K^+	12 ~ 21.0	mV
Na^+	-4.2 ~ -7.3	mV

Cl^-	5.4 ~ 10.8	mV
Ca^{2+}	6.6 ~ 10.5	mV
pH	18 ~ 28	mV
Li^+	5.0 ~ 9.0	mV

3.1.1.3. Over Range(OR)

The mV of electrode falls outside of the limit.

Parameters	Cal A or Cal B	
K^+	45 ~ 140	mV
Na^+	45 ~ 120	mV
Cl^-	50 ~ 120	mV
Ca^{2+}	35 ~ 100	mV
pH	70 ~ 170	mV
Li^+	50 ~ 150	mv

3.1.2. More than one electrode

If the problem happens with more than one electrode, most probably, it is caused by reference electrode, or leakage or blockage in flow path way.

- Check power supply. It should be perfectly grounded, with stabilizer and no high-power instrument shall be used nearby.
- Check reference electrode. Any air bubble above membrane area can lead to problems for all electrode. Too much crystal formation above membrane can interfere conductivity. Try exclude air bubble and crystal when necessary.
- Check leakage and blockage in the flow path. Leakage or blockage can lead to aspiration failure when calibration. Bubbles can be observed within calibration solution when it is aspirated. The segment of Calibration solution inside measuring chamber should be bubble-free.
- Check if there is liquid leakage in the measuring chamber. Wipe dry electrodes and interior surface of measuring chamber, reinstall electrodes. Press down electrodes and level them with thumb. Check if the O ring of electrode or O ring of mini valve is missing.
- Activate electrodes with fresh serum.
  a) Select ISE De-proteinize under Maintenance
  b) Feed fresh serum to probe, press [Yes] to aspirate.
  c) After 30 minutes, perform calibration.
- Perform ISE Cleaning under Maintenance. This routine maintenance is required for every 60

samples or 5 days.

- Perform ISE De-proteinize under Maintenance. This routine maintenance is required for every 60 samples or 5 days.
- Try to replace new reagent pack if more than one electrode are abnormal.

3.1.3. One electrode only

3.1.3.1. Drift problem

- Check the tip of electrode, if there is any bubble. Tap the bottom to exclude bubble.
- For K^+, Ca^{2+}, Cl^- ,Li^+electrode, perform ISE De-proteinize cycle.
- For Na^+, pH electrode, perform ISE Conditioning cycle. Electrodes needs 30 minutes to become stable after maintenance.
- Activate the electrodes with fresh serum,
  a) Select ISE De-proteinize under Maintenance
  b) Feed fresh serum to probe, press [Yes] to aspirate.
  c) After 30 minutes, perform calibration.

3.1.3.2. Abnormal problem

- Check the tip of electrode, if there is any bubbles.
- Enter Service>>Calibration data retrieve program, select [Print] to check the mV value of CAL A and CAL B, check if the difference could fall within following range:
- For K^+, Ca^{2+}, Cl^- ,Li^+electrode, perform ISE De-proteinize cycle and check again;
- For Na^+, pH electrode, perform ISE conditioning cycle and check again.
- Perform ISE Cleaning under Maintenance. This routine maintenance is required for every 10 samples.
- If still not fixed, please replace a new one or contact service department immediately.

3.1.3.3. Over range problem

- Check the refilling solution inside electrode. Replace and refill it if it is less than half of internal cavity. Most OR problem is caused by less refilling solution.
- Check the tip of the electrodes, if there is any bubble. Tap the bottom to exclude bubble.
- Check internal AgCl bar inside electrode. White silver can be observed If its black coat is fallen.

3.2. TCO2 problem

3.2.1. Definition

3.2.1.1. Drift

The mv difference between last and previous calibration from different calibration or between last trial and previous trial from same calibration falls outside of the limit.

Parameters		Cal A(3/2)-Cal A(2/1)	
TCO_2	1		mV

3.2.1.2. Abnormal

The mv of calibration falls outside of the limit.

Parameters		Cal A	
TCO_2	5~60		mV

3.2.2. Drift problem

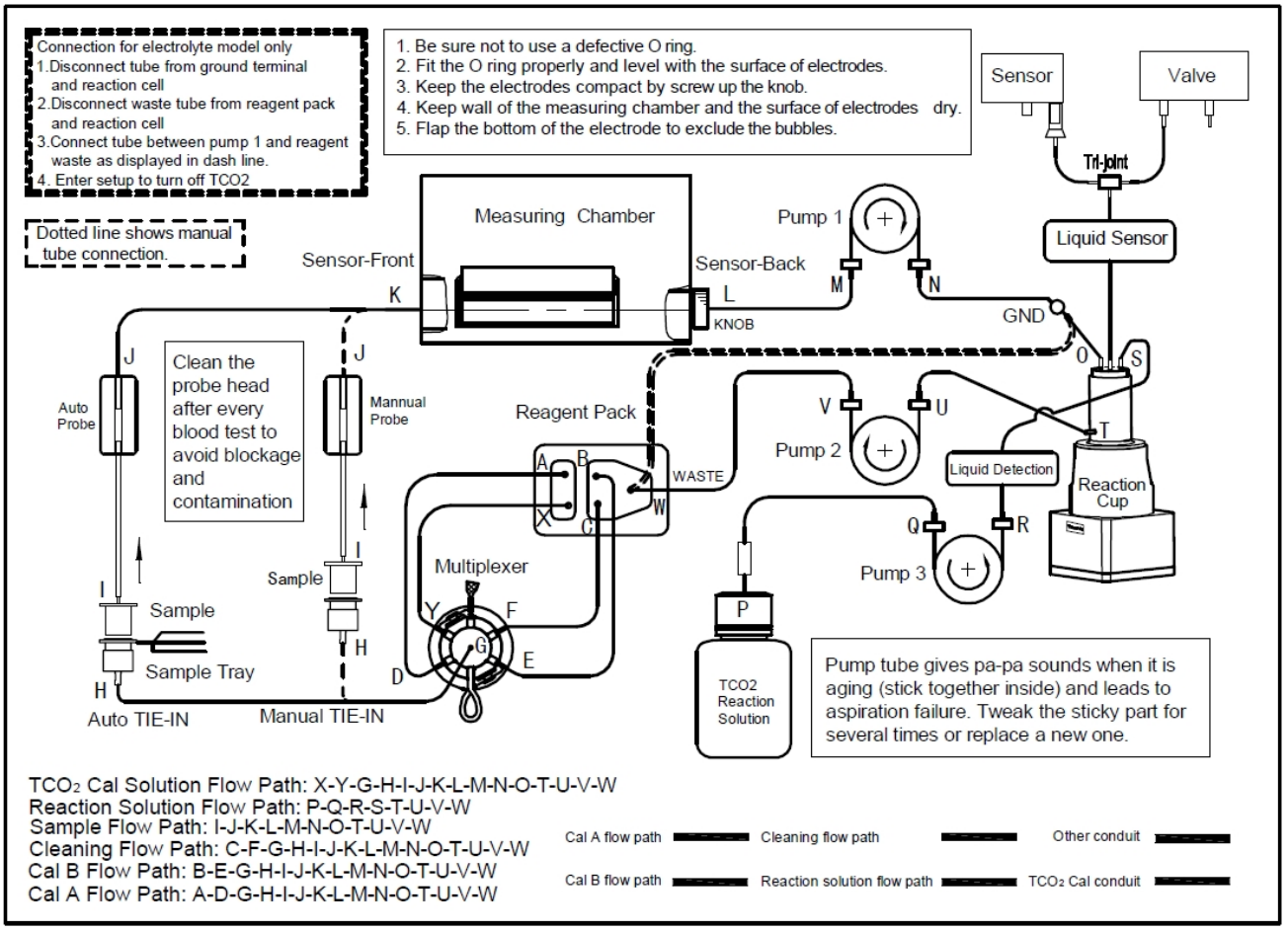
- Check if reaction cell is polluted. Perform TCO2 cleaning under Maintenance.
- Check if gas flow path is leaked.
- Check waste tube and pump if there is leakage or blockage

3.2.3. Abnormal problem

- Check if reaction cell is polluted. Perform TCO2 cleaning under Maintenance.
- Check if motor is working. Enter Service>>Help>>TCO2 motor&valve check, enable the motor to check.
- Check if belt is missing if there is no vibration while motor is OK,
- Check if reaction solution is finished or deteriorated.
- Check if TCO2 Cal A is finished or deteriorated (mv of calibration is above 19mv).
- Check waste tube and pump if there is leakage or blockage
- Check TCO2 valve if it is working. Enter Service>>Help>>TCO2 motor&valve check, enable the valve to check. Use a syringe where appropriate.

3.3. Flow path problem

3.3.1. Flow path



1) After a sample is sucked into the Measuring Chamber, there are Li^+, K^+, Na^+, Ca^{2+}, pH, Cl^-, Ref inside for seven electrodes. (each type electrode vary) in response to samples of the Li^+, K^+, Na^+, Ca^{2+}, pH,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_2 reaction cell, the HCO_3^- ion and the reaction solution are in the full reaction after mixing to generate CO_2. The pressure inside the TCO_2 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.

3.3.2. No Cal A, Cal B, Clean or TCO2 Cal A only

- Check flow path from A(B/C)-Multiplexer.
  1. Unplug tube from outlet of multiplexer.
  2. Unplug reagent pack connector. Use a syringe filled with DI water and insert it into hole A (or B/clean respectively)
  3. Enter Service>>Multiplexer check, switch multiplexer to A (or B/clean respectively). Push the plunger of syringe, water should be come out from Multiplexer. If it is failed, then check multiplexer as described in section 3.4.5.

- Check reagent pack. Unplug reagent pack connector. Use a syringe connected with a pump tube, connect it to the outlet pin of A/B/Clean on the reagent pack, pull the plunger to check if those solutions are finished.
- Reinsert reagent pack connector.

3.3.3. Multi-reagents failure

- Reinsert reagent pack connector.
- Check if pump tube is aged. If it is properly locked.
- Check flow path from A/B/Clean- Multiplexer as section 3.3.1
- Check flow path from Multiplexer – Reaction Cup

  Unplug tube from outlet of multiplexer and put it into DI water. Manually rotate Pump 1. The check is passed If water can be aspirated easily. If the check is failed, then continue to check as below
- Check flow path from K-L of Measuring Chamber.

Unplug tube from probe and put the tube into DI water. Manually rotate Pump 1. Observe if DI water flows smoothly through measuring chamber without any bubble.

If it is failed, reinstall electrodes, check the O ring on the side of electrode. Use a syringe connected with a pump tube, connect it to the tube from d, release pump tube from Pump 1, push the

plunger to check if there is blockage inside measuring chamber.

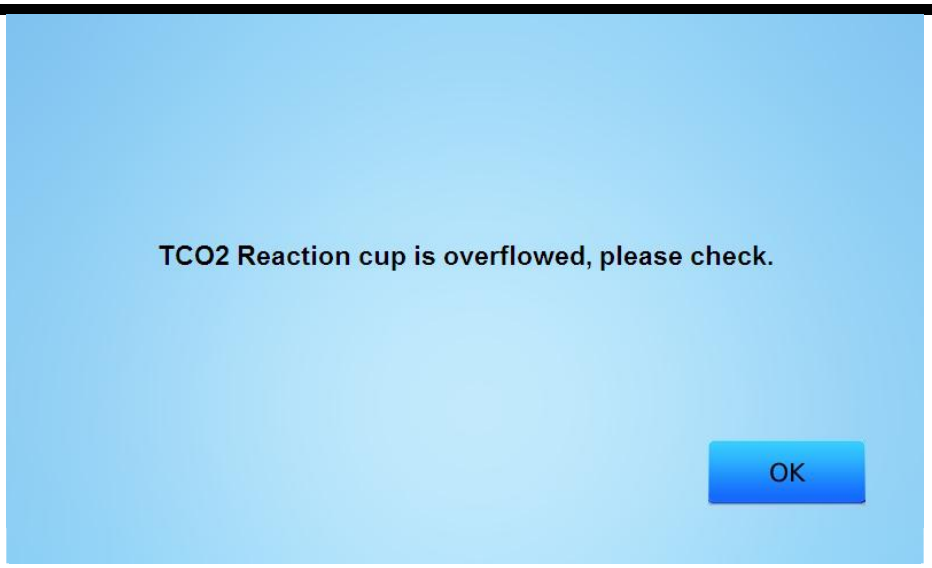
- Check flow path from Multiplexer to Measuring Chamber(K).
  1. Unplug tube from probe. Use a syringe connected with a pump tube, connect it to the tube from Measuring Chamber.
  2. Unplug tube from outlet of multiplexer.
  3. Push the plunger to check if there is blockage.
  4. Clean probe tie-in or probe with long needle if it is blocked.
- Check flow path from Measuring Chamber(L) to Waste.
  1. Release pump tube from Pump 1 and Pump 3.
  2. Unplug reagent pack connector.
  3. Unplug tube from Measuring Chamber(L). Use a syringe connected with a pump tube, connect it to the tube from Measuring Chamber(L).
  4. Try to push the plunger. Water should be come out from waste hole on the connector.
  5. If it is blocked, use a long needle to sort out blockage where appropriate.

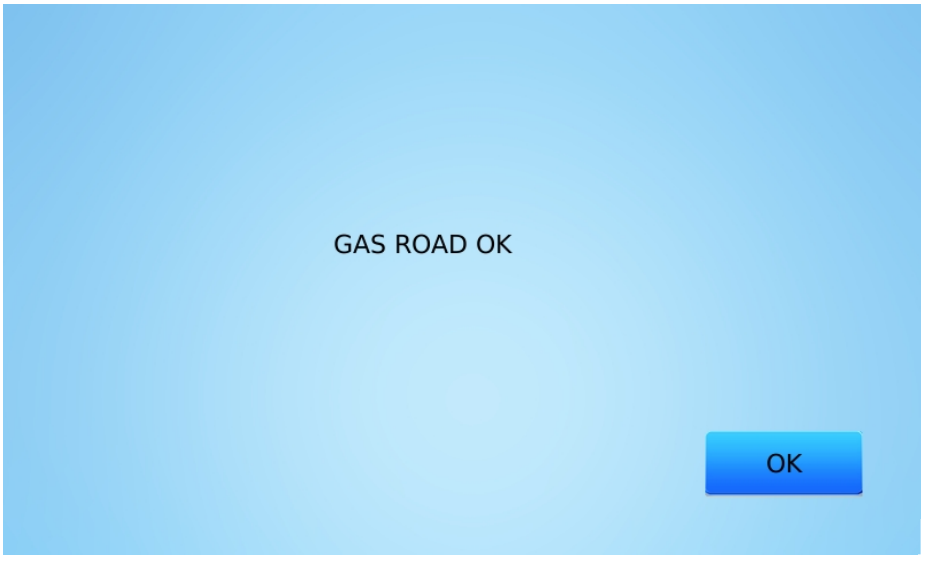
3.3.4. No reaction solution

- Check if reaction solution is finished.
- Check pump tube around pump Pump 3..
- If reaction solution is aspirated, then check reaction reagent sensor.
- If reaction solution can not be aspirated, then check flow path from TCO2 Reaction Solution(P) to Reaction Cup(S)
- Try a new aspiration pump tube.

3.3.5. Over flow of Reaction cell

Enter Service>> Clogged Check, Pump 3 will empty remaining liquid in the gas flow path automticlly.


TCO2 Reaction cup is overflowed, please check.
OK


GAS ROAD OK
OK