

Instruction for Cleaning Solution

【Product Name】

Cleaning Solution

【Package Specification】

50mL/bottle REF: 42005005

250mL/bottle REF: 42014005

【Intended Use】

Cleaning the tubes of electrolyte analyzer.

【Test Principle】

Not Applicable

【Main Composition】

Non-ionic surfactant with mass fraction of 0.1%, High intensive ionic buffer.

【Storage and Transportation】

Stable for 2 years when stored at 2-30 °C in the shade. The products should be transported with outer package.

【Applicable Instruments】

Electrolyte Analyzers

【Sample Requirements】

Not Applicable

【Test Methods】

Open the electrolyte analyzer's reagent room, carefully put in the corresponding reagent, connect the tubes of Standard A & B, and then close the reagent room. Turn on the power, the system enters the main menu, select "Calibrate", the instrument automatically aspirates Standard A & B and establishes the calibration curve. After calibration, click "Measure" to aspirate sample (Cleaning solution). For more Instrument operations, please refer to instructions for electrolyte reagent (ISE, Pressure Method) and electrolyte analyzer.

【Reference Range】

Not Applicable

【Interpretation of Test Results】

Not Applicable

【Calibration and QC】

Not Applicable

【Limitations of Testing Methods】

Not Applicable

【Performance Indicator】

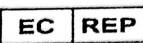
Not Applicable.

【Precaution】

1. This product is for in vitro diagnostic use only. Please refer to the instruction for usage.
2. Please seal it properly after using, to avoid long-time exposure in the air.
3. Avoid skin contact .Wear gloves when operating.
4. If the reagent is carelessly spattered onto the skin, eyes, etc., must wash with clean water, and if mistakenly swallowed, go to see a doctor immediately.
5. Do not use the solution when package is damaged.

【Icon Illustration】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Manufacturer
	Batch code

	Temperature limit
	Use-by date
	Authorized representative in the European Community
	Catalogue number
	Volume
	Main component
	CE Marking

【Training information】

Please refer to the service manual.

【Help information】

If you need help please contact after-sales.

【Trouble shooting】

Please contact after-sales.

【References】

Not Applicable

【Manufacturer】

Genrui Biotech Inc.
 Address: 4-10F, Building 3, Geya Technology Park, Guangming District,
 518106, Shenzhen, China
 Web: www.genrui-bio.com

【Medical Device Manufacturing Enterprise Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device
 Manufacturing Permit No. 20041046.

【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer
 Service and Support Center.

【Instruction Approved and Revised Date】Approved date: November 6th 2015Revised date: October 19th 2018

Wellkang Ltd
 16 Castle St, Dover,
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 (www.CE-marking.eu)

Instruction for Electrolyte Reagents (ISE, Pressure Method)

【Product Name】

Electrolyte Reagents

【Package Specification】

Packaging specifications are shown in Table 1 (Unit: mL):

Table 1

Type	STD A	STD B	STD C	CO ₂ STD	Buffer	REF
DS- I (NO.1)	400	90	0	0	0	42033001
DS- I (NO.2)	390	160	0	0	0	42034001
DS- I (NO.3)	390	160	0	0	0	42035001
DS- I (AB buffer)	390	80	0	0	80	42036001
DS- II (NO.1)	400	90	0	0	0	42037001
DS- II (NO.2)	390	160	0	0	0	42038001
DS- II (NO.3)	390	160	0	0	0	42039001
DS- II (AB buffer)	390	80	0	0	80	42040001
DS- III (NO.3)	390	80	80	0	0	42041001
DS- IV (NO.3)	390	80	80	0	0	42042001
DS- V	0	0	0	50	0	42043001
DS- C	0	0	400	0	0	42044001
GE-1	750	250	700	0	0	42047001
GE-2	750	250	0	0	0	42048001
GE-3	600	200	0	0	0	42049001
GE-4	600	200	600	0	0	42050001
GE-5	500	150	0	0	0	42051001
GE-6	500	150	500	0	0	42052001
GE-7	400	120	0	0	0	42053001
GE-8	400	120	400	0	0	42054001
GE-9	300	90	0	0	0	42055001
GE-10	300	90	300	0	0	42056001
DS-ISE	0	0	0	0	0	42045001
DS-Ref	0	0	0	0	0	42046001

【Intended Use】

It can be used with Electrolyte Analyzers by professionals, for the detection of potassium (K⁺), sodium (Na⁺), chloride (Cl⁻), calcium (Ca²⁺), magnesium (Mg²⁺), lithium (Li⁺), pH (pH value) and TCO₂ concentration in human serum. In addition, GE-1 and GE-2 also can concentration in human blood and urine.

【Test Principle】

ISE method: Use ISE (Ion Selective Electrode) technology to measure K⁺, Na⁺, Cl⁻, Ca²⁺, Li⁺, Mg²⁺ and pH in the sample. Test Standard A and B respectively to obtain two electrode potentials of known concentrations, and establish a calibration curve in the instrument programmed by these two potentials.

Measure the electrode potential of sample with unknown concentration and then calculate ion concentration (mmol/L) of unknown samples from the established calibration curve.

Pressure method: Compare the pressure value obtained by the reaction of Standard C and sample with that of Standard C and TCO₂ solution, to obtain TCO₂ content in the sample by calculation.

【Main Compositions】

Standard A: K⁺: 1.1%, Na⁺: 57.0%, Cl⁻: 40.5%, Ca²⁺: 0.5%, Li⁺: 0.4%, Mg²⁺: 0.5%.

Standard B: K⁺: 4.0%, Na⁺: 57.5%, Cl⁻: 36.5%, Ca²⁺: 1.3%, Li⁺: 0.3%, Mg²⁺: 0.4%.

Standard C (weak acid) and TCO₂ solution (carbonate).

Components of test kits with different batches cannot be interchanged for use

【Accessories Required But Not Provided】

None.

【Storage and Transportation】

Storage: Ambient temperature of 2-30°C, relative humidity of 20-85%, avoid direct sunlight.

Validity period: 24 months (sealed), 1 month (after opening).

GE-1&GE-2: 24 months (sealed), 50 days (after opening).

Please refer to the labels for production date.

【Applicable Instruments】

Applicable instruments	Test item
GE200, GE300, GE310, GE330, GE340, GE350, GE360	K ⁺ , Na ⁺ , Cl ⁻ , Ca ²⁺ , Li ⁺ , pH
GE320	K ⁺ , Na ⁺ , Cl ⁻ , Ca ²⁺ , Li ⁺ , pH, TCO ₂
GE500	K ⁺ , Na ⁺ , Cl ⁻ , Ca ²⁺ , Li ⁺ , Mg ²⁺ , pH,

【Sample Requirements】

The optimum sample is non-hemolyzed fresh serum. Samples should be analyzed within 5 hour at room temperature.

Whole blood: it is recommended to use no-additive evacuated or sodium heparin evacuated specimen collection tubes for whole blood or plasma samples. Whole blood samples should be analyzed within 60 minutes at room temperature and avoid hemolysis.

Urine sample: it is required to dilute the fresh urine samples with urine diluent at 1:10 before testing.

【Test Methods】

1. Open the electrolyte analyzer's reagent room, carefully put in the corresponding reagent, connect the tubes of Standard A & B or Reagent package, and then close the reagent room.
2. Turn on the power, the system enters the main menu, select "Calibrate", the instrument automatically aspirates Standard A & B and establishes the calibration curve. After calibration, click "Measure" to aspirate sample. After calculating the concentration, the instrument displays and prints it out. It is recommended to leave the analyzer on for 24 hours.
3. When using reagents at room temperature, it takes about 30-60 seconds to test one sample, if the sample is refrigerated, bring it to room temperature before analysis.
4. Use Standard A and Standard B to perform two-point calibration.
5. Test QC to do quality control before testing samples every day to ensure the reliability of test results. QC must not contain substances that interfere with ion selective electrodes and must be accurately diluted. Mean value of test results of the QC must be within the allowable range.
6. For more instrument operations, please see the operation manual of electrolyte analyzer.

【Reference Range】

Item	Serum or Blood	Urine
K ⁺	3.5-5.3 mmol/L	25-125 mmol/L
Na ⁺	135-148 mmol/L	130-260 mmol/L
Cl ⁻	98-107 mmol/L	170-255 mmol/L
Ca ²⁺	1.10-1.30 mmol/L	2.7-7.5 mmol/L
Li ⁺	0-0.7 mmol/L	N/A
Mg ²⁺	0.7-1.1 mmol/L	3.0-4.5 mmol/L
TCO ₂	22-29 mmol/L	N/A
pH	7.35-7.45	N/A

【Interpretation of Test Results】

1. Results are for clinicians' reference only. To draw a clinical conclusion, please also consider the patient's clinical symptoms and other test results.
2. Select calibrators and controls manufactured by qualified companies (such as Randox) to do calibration and quality control.

【Limitations of Test Method】

1. Using plasma that contains EDTA, heparin, sodium citrate and oxalate will result in increased sodium concentration and decreased calcium concentration in test results.
2. Sodium azide, salicylic acid and other drugs can cause increase in the chlorine concentration in test results.
3. ISE method can be used to measure ionized calcium only, total calcium cannot be measured directly (as concluded by test summary and technical exchange meeting). Diagnosis and treatment cannot rely on this test result only, but need to take the clinical history and other laboratory test results into account.

【Performance Indicators】

1. Analytical sensitivity

Minimum detection limit of Standard C $\leq 1.41\text{mmol/L}$

2. Linearity range

Linear regression coefficient of Standard A, B, C: $r \geq 0.990$

Linearity shall comply with requirements in Table 2.

3. Measurement range

Testing diluted urine range shall comply with requirements in Table 3.

4. Precision, Accuracy, Difference between batches

When testing control material, calibrator, certified reference serum with electrolyte reagents, the precision, accuracy, difference between batches of each item should be consistent with requirements in Table 2&3.

Table 2 Performance for serum and whole blood

Item	Linearity range	Accuracy (B)	Precision	Difference between batches
K ⁺	1.5-7.5mmol/L	$\leq 2.0\%$ or $\leq 0.15\text{mmol/L}$	$CV \leq 1.5\%$ or $SD \leq 0.08\text{mmol/L}$	$\leq 0.5\text{mmol/L}$
Na ⁺	100-180mmol/L	$\leq 2.0\%$ or $\leq 3.0\text{mmol/L}$	$CV \leq 1.5\%$ or $SD \leq 1.5\text{mmol/L}$	$\leq 10\text{mmol/L}$
Cl ⁻	80-160mmol/L	$\leq 2.0\%$ or $\leq 3.0\text{mmol/L}$	$CV \leq 1.5\%$ or $SD \leq 1.5\text{mmol/L}$	$\leq 10\text{mmol/L}$
iCa ²⁺	0.5-2.5mmol/L	$\leq 2.5\%$ or $\leq 0.12\text{mmol/L}$	$CV \leq 1.5\%$ or $SD \leq 0.06\text{mmol/L}$	$\leq 0.3\text{mmol/L}$
Li ⁺	0.5-2.5mmol/L	$\leq 2.5\%$ or $\leq 0.12\text{mmol/L}$	$CV \leq 1.5\%$ or $SD \leq 0.06\text{mmol/L}$	$\leq 0.3\text{mmol/L}$
Mg ²⁺	0.5-2.5mmol/L	$\leq 2.5\%$ or $\leq 0.12\text{mmol/L}$	$CV \leq 1.5\%$ or $SD \leq 0.06\text{mmol/L}$	$\leq 0.3\text{mmol/L}$
pH	6.8-7.6	$\leq 2.0\%$	$\leq 1.5\%$	≤ 0.15
CO ₂	10-60mmol/L	$\leq 2.0\%$	$\leq 1.5\%$	≤ 3.0

Table 3 Performance for diluted urine

Item	Measurement range	Accuracy (B)	Precision (CV)	Difference between batches
K ⁺	1-500 mmol/L	$\leq 10.0\%$	$\leq 5.0\%$	$\leq 10\text{mmol/L}$
Na ⁺	25-1000 mmol/L	$\leq 10.0\%$	$\leq 5.0\%$	$\leq 20\text{mmol/L}$
Cl ⁻	25-500 mmol/L	$\leq 10.0\%$	$\leq 5.0\%$	$\leq 20\text{mmol/L}$
iCa ²⁺	0.5-40.0 mmol/L	$\leq 10.0\%$	$\leq 5.0\%$	$\leq 1.5\text{mmol/L}$
Mg ²⁺	0.5-40.0 mmol/L	$\leq 10.0\%$	$\leq 5.0\%$	$\leq 1.5\text{mmol/L}$

【Precautions】

- The product should be used within its validity period, not mixed up with toxic, corrosive or contaminated goods. Stop using it if the package is damaged, or the solution is cloudy, moldy or precipitated.
- Ensure that all electrodes are immersed in Standard A & B when perform the calibration.
- Keep remaining reagents under seal for the pH and ions may change when exposed to the air.
- Avoid skin contact. Wear gloves when operating.
- If the reagent is carelessly spattered onto the skin, eyes, etc., flush with clean water immediately, and if mistakenly swallowed, seek medical advice.
- Waste from clinical use of this product should be disposed of in accordance with the relevant provisions of medical wastes.
- Do not mix different batches of reagents.
- Do not use the solution when package is damaged.

【Icon Illustration】

	Consult Instructions for use		Main component
	Batch code		Catalogue number
	Temperature limit		Humidity limit
	Date of manufacture		Use-by date
	Manufacturer		CE Marking
	Authorized representative in the European Community		In vitro diagnostic medical device
	Keep away from sunlight		Keep dry
	Contains sufficient for <n>tests		Volume

【Training information】

Please refer to the training manual.

【Help information】

If you need help please contact after sales.

【Trouble shooting】

Please contact after sales.

【References】

- Huang Ziqing. Introduction to the theory of electrolyte solution. Science press, 1983.08.
- Adrian Schreiber. Charite Universitäts medizin Berlin. Solving electrolyte disturbances with the Ehrlich reagent. HELIOS Klinikum Berlin, Franz Volhard Clinic, Berlin, Germany.
- Nephrology Dialysis Transplantation (Impact Factor: 3.37), 07/2003, 18(6): 1217-9.
- REN Biqiong, XU Guofeng, ZOU Guoying, ZHANG Yu, YU Qihua. Department of Clinical Laboratory, Hunan Province Second People's Hospital, Assessment of the effect of self-made electrolyte reagent in the electrolyte system of Dimension AR analyzer. Hunan Changsha 410007, China. Laboratory medicine 2006.06.
- United States Patent 6387646. Inventors: Kimata, Shinsuke (Tsuruga, JP), Mizuguchi, Katsuhiko (Tsuruga, JP), Kawamura, Yoshihisa (Tsuruga, JP). Reagent compositions for measuring electrolyte. Publication Date. 05.14.2002.
- National Guide to Clinical Laboratory Procedures (Third Edition). Department of Medical Administration in People's Republic of China. Ye Yingwu, etc., 2006.11.

【Manufacturer】



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【Medical Device Manufacturing Enterprise Permit Number】

GuangDong SFDA(State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046.

【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center.

【Instruction Approved and Revised Dates】

Approved date: November 6th 2015

Revised date: Oct 22th 2018



Wellkang Ltd
16 Castle St, Dover,
CT16 1PW, UK
(www.CE-marking.eu)

Instruction for PVC Electrode Activating Solution

【Product Name】

PVC Electrode Activating Solution.

【Package Specification】

50ml/bottle REF: 42005002

250ml/bottle REF: 42014002

【Intended Use】

Used for new electrode activation

【Test Principle】

Not Applicable

【Main Composition】

Ionic, non-ionic surface active agent.

【Storage and Transportation】

Stable for 2 years when stored at 2-30 °C in the shade. The products should be transported with outer package

【Applicable Instruments】

Electrolyte Analyzers

【Sample Requirements】

Not Applicable

【Test Methods】

Open the electrolyte analyzer's reagent room, carefully put in the corresponding reagent, connect the tubes of Standard A & B, and then close the reagent room. Turn on the power, the system enters the main menu, select "Calibrate", the instrument automatically aspirates Standard A & B and establishes the calibration curve. After calibration, click "Measure" to aspirate sample (PVC electrode activating solution). For more operation, please refer to instructions of electrolyte reagent (ISE, Pressure Method) and electrolyte analyzer

【Reference Range】

Not Applicable

【Interpretation of Test Results】

Not Applicable

【Calibration and QC】

Not Applicable

【Limitations of Testing Methods】

Not Applicable

【Performance Indicator】

Not Applicable

【Precaution】

1. This product is for in vitro diagnostic use only. Please refer to the instruction for usage.
2. Please seal it properly after using, avoid long-time exposure in the air.
3. The reagent should avoid contamination.
4. Avoid skin contact. Wear gloves when operating.
5. If the reagent is carelessly spattered onto the skin, eyes, etc., must wash with clean water. and if mistakenly swallowed, go to see a doctor immediately.
6. Do not use the solution when package is damaged.

【Icon Illustration】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Volume
	Batch code

	Temperature limit
	Use-by date
	Authorized representative in the European Community
	Catalogue number
	CE Marking
	Main component
	Manufacturer

【Training information】

Please refer to the service manual.

【Help information】

If you need help please contact after-sales.

【Trouble shooting】

Please contact after-sales

【References】

Not Applicable

【Manufacturer】

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District,

518108, Shenzhen, China

Web: www.genrui-bio.com

【Medical Device Manufacturing Enterprise Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046.

【Guarantee and Technical Support】

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【Instruction Approved and Revised Date】Approved date: November 6th 2015Revised date: October 19th 2018

Wellkang Ltd
16 Castle St, Dover,
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(www.CE-marking.eu)

Instruction for DS-Ref Ref. Filling Solution

【Product Name】

DS-Ref Ref. Filling Solution

【Package Specification】

10mL/bottle REF:42046001

【Intended Use】

Used as filling solution for reference electrode.

【Test Principle】

Not Applicable

【Main Composition】

Saturated KCl solution and Preservative.

【Storage and Transportation】

Stable for 2 years when stored at 2-30 °C in the shade. The products should be transported with outer package.

【Applicable Instruments】

Electrolyte Analyzers

【Sample Requirements】

Not Applicable

【Test Methods】

Fill Ref. filling solution into reference electrode. For more Instrument operations, please refer to electrolyte analyzer operation manual.

【Reference Range】

Not Applicable

【Interpretation of Test Results】

Not Applicable

【Calibration and QC】

Not Applicable

【Limitations of Testing Methods】

Not Applicable

【Performance Indicator】

Not Applicable

【Precaution】

1. Please seal it properly after using, to avoid long-time exposure in the air.
2. Avoid skin contact .Wear gloves when operating.
3. If the reagent is carelessly spattered onto the skin, eyes, etc., flush with clean water immediately, and if mistakenly swallowed, seek medical advice.
4. The best volume of solution for normal operation is 2/3 level of the intra-cavity.
5. Do not use the solution when package is damaged.

【Icon Illustration】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Manufacturer
	Batch code
	Temperature limit
	Use-by date
	Authorized representative in the European Community

	Catalogue number
	CE Marking
	Volume
	Main component

【Training information】

Please refer to the service manual.

【Help information】

If you need help please contact after-sales.

【Trouble shooting】

Please contact after-sales.

【References】

Not Applicable.

【Manufacturer】

Genrui Biotech Inc.

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【Medical Device Manufacturing Enterprise Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046.

【Guarantee and Technical Support】

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【Instruction Approved and Revised Date】Approved date: November 6th 2015Revised date: October 19th 2018

Wellkang Ltd
 16 Castle St, Dover,
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Instruction for Deproteinizer

【Product Name】

Deproteinizer

【Package Specification】

50mL/bottle REF: 42011003

【Intended Use】

Used for cleaning and maintenance of electrolyte analyzer tubes and electrodes.

【Test Principle】

Not Applicable.

【Main Composition】NaClO: ~1.0% Cl₂**【Accessories Required But Not Provided】**

None.

【Storage and Transportation】

Stable for 2 years when stored at 2-30℃ in the shade that avoid light, and 2 months after opening.

The products should be transported with outer package

【Applicable Instruments】

Electrolyte Analyzers.

【Sample Requirements】

Not Applicable.

【Test Methods】

- Weekly cleaning after sample test, press the "Maintain" - "Cleaning" - "Deprotein" or "Tube" to cleaning the electrolyte analyzer tubes and electrodes. When finished cleaning, press the "Activating" to aspirate PVC electrode activate solution. the procedure will be completed automatically.
- When test times up to "Set Deprotein times", the instrument will warn "Pls. Aspirate deproteinized solution", put Deproteinizer under the probe, press "Enter", when hearing a "Di" sound, remove the solution quickly. Deprotein procedure will be completed automatically. And then, using "Activation solution" for "the cleanser" cleaning, the procedure also will be completed automatically. Final, press the "Maintain" enter the "ADC" and press "STD A", allow the electrode memberance to be soaked in reagents for about 30 minutes. When it finished, do calibration for one time or more till the calibration result is stable.

【Reference Range】

Not Applicable.

【Interpretation of Test Results】

Not Applicable.

【Calibration and QC】

Not Applicable.

【Limitations of Testing Methods】

Not Applicable.

【Performance Indicator】

Not Applicable.

【Precaution】

- The product should be used within its validity period and avoid light storage. Stop using it if the package is damaged.
- When finished deprotein cleaning, it's better to use "activation solution" to activating electrode. It's not to test sample until the calibration result is stable.
- The deproteinization process may cause electrodes drift, use the QC serum or fresh serum to activate the electrodes and repeat the calibration procedure until the electrodes are stable.
- The product not allow stay in electrode probe or electrolyte analyzer tubes for a long time that more than the time of deprotein procedure.
- If the reagent is carelessly spattered onto the skin, eyes, etc., must wash with clean water, and if mistakenly swallowed, go to see a doctor immediately.

【Icon Illustration】

	Date of manufacture		Manufacturer
	In vitro diagnostic medical device		Volume
	CE Marking		Catalogue number
	Batch code		Main component
	Use-by date		Temperature limit
	Authorized representative in the European Community		

【Training information】

Please refer to the training manual.

【Help information】

Please contact after sales.

【Trouble shooting】

Please contact after sales.

【References】

Not Applicable.

【Manufacturer】

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

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After-sales Service Unit: Genrui Biotech Inc.

【Medical Device Manufacturing Enterprise Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046.

【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center.

【Instruction Approved and Revised Date】Approved date: December 5th 2018Revised date: December 5th 2018

Wellkang Ltd
 16 Castle St, Dover,
 CT16 1PW, UK
 (www.CE-marking.eu)

Instruction for DS-ISE ISE Filling Solution

【Product Name】

DS-ISE ISE Filling Solution

【Package Specification】

10mL/bottle REF:42045001

【Intended Use】Used as filling solution for ion electrodes(K⁺, Na⁺, Cl⁻, Ca²⁺, Li⁺, pH).**【Test Principle】**

Not Applicable.

【Main Composition】

KCl0.04%,

NaCl0.6%,

CaCl₂0.033%,

pH regulator

preservative

【Storage and Transportation】

Stable for 2 years when stored at 2-30 °C in the shade. The products should be transported with outer package.

【Applicable Instruments】

Electrolyte Analyzers

【Sample Requirements】

Not Applicable

【Test Methods】

Fill ISE filling solution into ion electrode. For more operations, please refer to electrolyte analyzer operation manual.

【Reference Range】

Not Applicable

【Interpretation of Test Results】

Not Applicable

【Calibration and QC】

Not Applicable

【Limitations of Testing Methods】

Not Applicable

【Performance Indicator】

Not Applicable

【Precaution】

1. Please seal it properly after using, to avoid long-time exposure in the air.
2. Avoid skin contact .Wear gloves when operating.
3. If the reagent is carelessly spattered onto the skin, eyes, etc., flush with clean water immediately, and if mistakenly swallowed, seek medical advice.
4. The best volume of solution for normal operation is 2/3 level of the intra-cavity.
5. Do not use the solution when package is damaged.

【Icon Illustration】

Label	Meaning
	Date of manufacture
IVD	In vitro diagnostic medical device
	Manufacturer
LOT	Batch code
	Temperature limit

	Use-by date
EC REP	Authorized representative in the European Community
REF	Catalogue number
CE	CE Marking
	Volume
	Main component

【Training information】

Please refer to the service manual.

【Help information】

If you need help please contact after-sales.

【Trouble shooting】

Please contact after-sales.

【References】

Not Applicable

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Instruction for DS-ISE ISE Filling Solution

【Product Name】

DS-ISE ISE Filling Solution

【Package Specification】

10mL/bottle REF:42045001

【Intended Use】Used as filling solution for ion electrodes(K^+ , Na^+ , Cl^- , Ca^{2+} , Li^+ , pH).**【Test Principle】**

Not Applicable.

【Main Composition】

KCl0.04%,

NaCl0.6%,

CaCl₂0.033%,

pH regulator

preservative

【Storage and Transportation】

Stable for 2 years when stored at 2-30 °C in the shade. The products should be transported with outer package.

【Applicable Instruments】

Electrolyte Analyzers

【Sample Requirements】

Not Applicable

【Test Methods】

Fill ISE filling solution into ion electrode. For more operations, please refer to electrolyte analyzer operation manual.

【Reference Range】

Not Applicable

【Interpretation of Test Results】

Not Applicable

【Calibration and QC】

Not Applicable

【Limitations of Testing Methods】

Not Applicable

【Performance Indicator】

Not Applicable

【Precaution】

1. Please seal it properly after using, to avoid long-time exposure in the air.
2. Avoid skin contact .Wear gloves when operating.
3. If the reagent is carelessly spattered onto the skin, eyes, etc., flush with clean water immediately, and if mistakenly swallowed, seek medical advice.
4. The best volume of solution for normal operation is 2/3 level of the intra-cavity.
5. Do not use the solution when package is damaged.

【Icon Illustration】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Manufacturer
	Batch code
	Temperature limit

	Use-by date
	Authorized representative in the European Community
	Catalogue number
	CE Marking
	Volume
	Main component

【Training information】

Please refer to the service manual.

【Help information】

If you need help please contact after-sales.

【Trouble shooting】

Please contact after-sales.

【References】

Not Applicable

【Manufacturer】

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District,

518106, Shenzhen, China

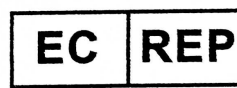
Web: www.genrui-bio.com

【Medical Device Manufacturing Enterprise Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046.

【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center.

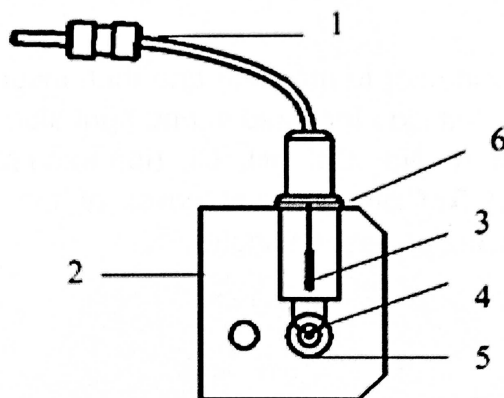
【Instruction Approved and Revised Date】Approved date: November 6th 2015Revised date: October 19th 2018

Wellkang Ltd
 16 Castle St, Dover,
 CT16 1PW, UK
 (www.CE-marking.eu)

Electrolyte Analyzer Installation Guide

Part I Installation procedure

Structure of Electrode

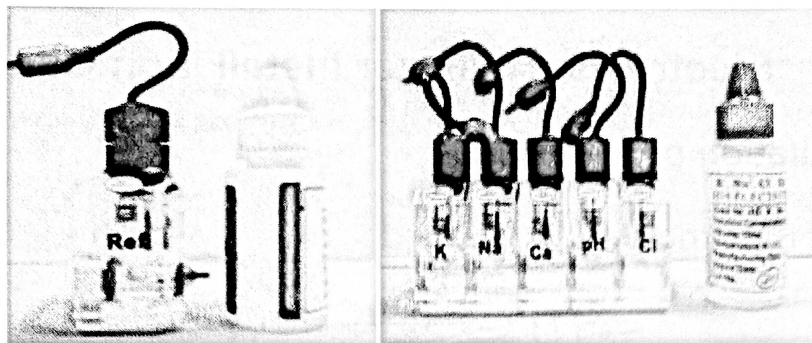


1. Electrode connector
2. Electrode body
3. Ag/AgCl inner electrode
4. Ion selective membrane
5. O-ring
6. O-ring

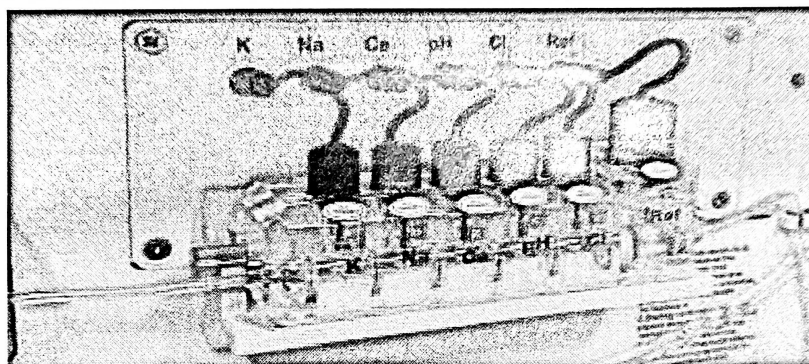
1. Add filling solution into 2/3-3/4 of the electrode chamber, then screw the conductive pole, make sure there is no bubble among the filling solution.

Note: There are two filling solutions with different color bottle cap. The blue one is used for filling the K, Na, Ca, pH, Cl electrode chamber, the white one is used for ISE Ref.

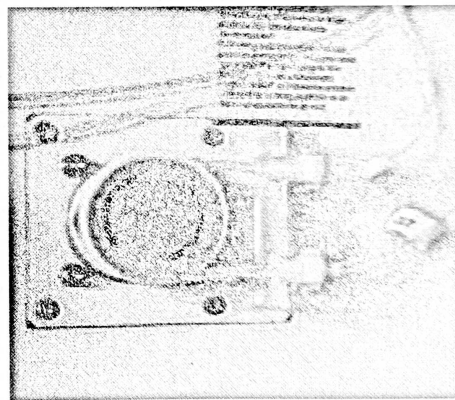
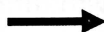
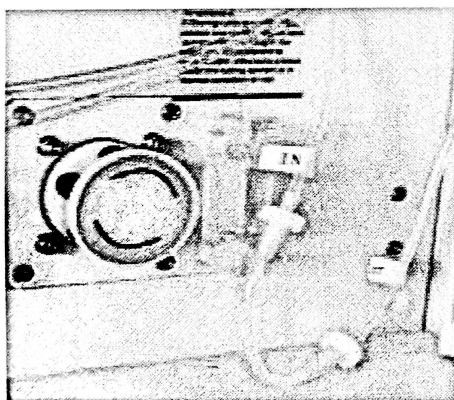




2. Connect electrode connector to machine and then insert the tube to the both ends of the electrode body, left side for liquid in and right side for liquid out. There are six sockets with sign of K, Na, Ca, pH, Cl, (for example only, please refer your instrument electrode) Ref on the front cover of the panel. Plug the electrode connector into the socket correspondingly.



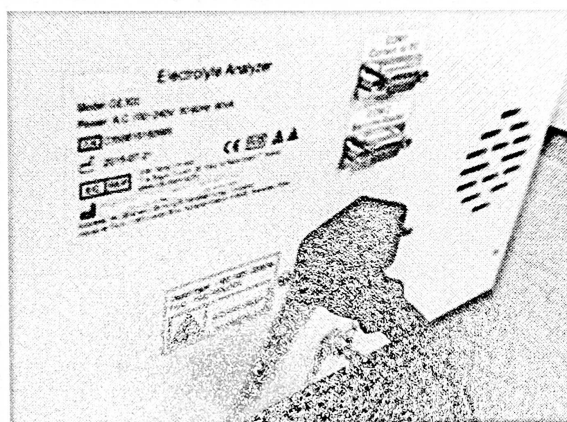
3. Connect the tube on the peristaltic pump. Please pay attention to the pump tube installation direction.



4. Insert reagent tube to the reagent container, then put them into the reagent chamber. Pay attention to the reagent card of the A/B standard solution facing inside and then close reagent door.

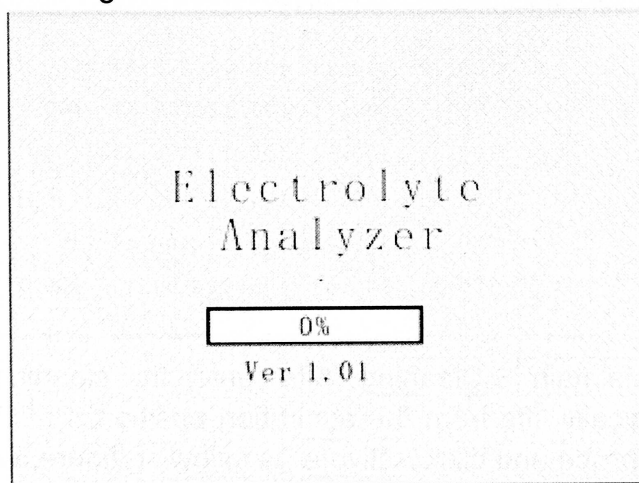


5. Connect the power cord. If the grounding is not very good (grounding wire and zero wire voltage is higher than 0.5V DC), please connect the grounding cable to the grounding pole as the following picture and connect the other end to the ground of the lab.



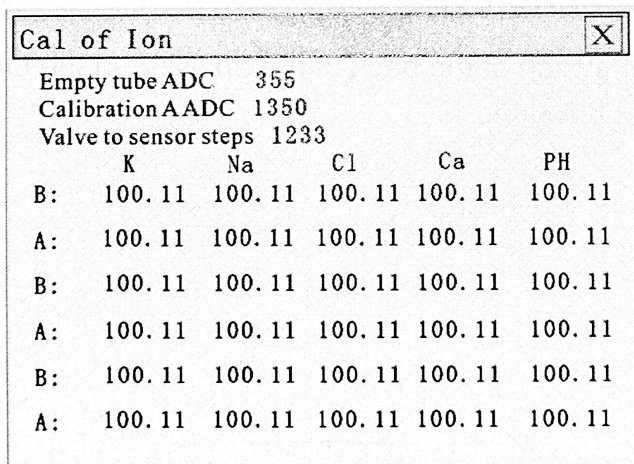
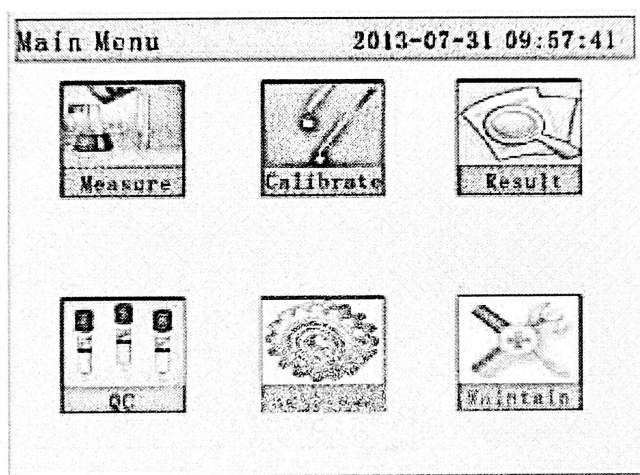
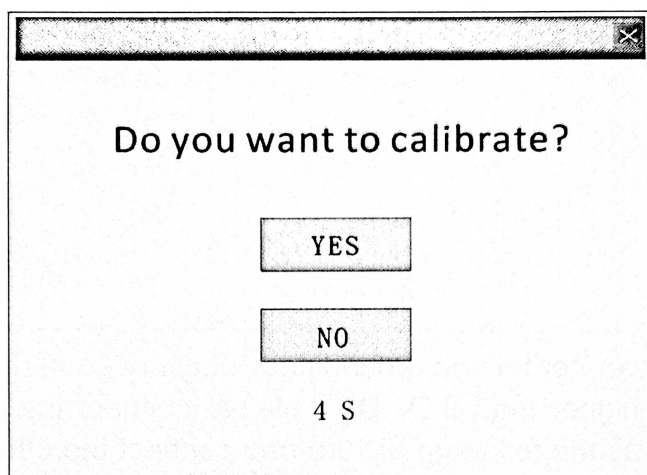
Part II Start the analyzer

1. Press the power switch at the back of the analyzer in the ON position. The analyzer will make a self-checking.

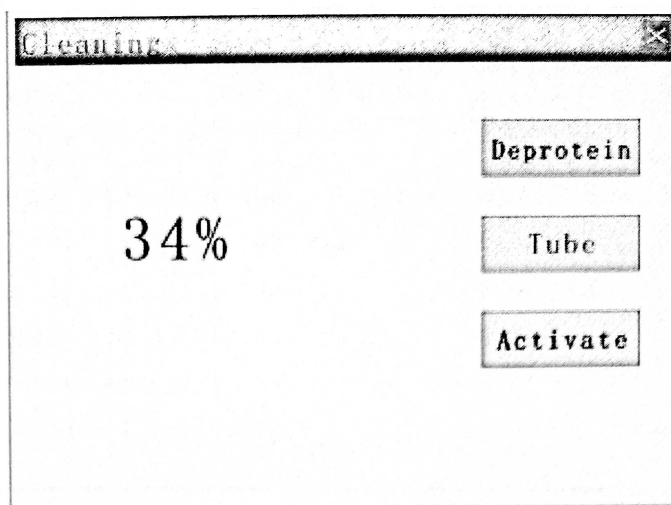


2. After that, a dialog for calibration with a 10s counting down will appear. You can choose either **YES** to do calibration or click **NO** to skip calibration. When you choose **NO**, you will get into main menu, but it is not allowed to run any sample test without calibration.

NOTE: For the first installation, the electrode may not pass the calibration before Activation is done, so you need to check next step.



- Please click **Maintain** → **Cleaning**. After enter the cleaning interface, the sample probe automatically lifts from the aspiration position. Put PVC Activating Solution under sample probe and click **Activate** as following figure, when hearing "di" sound, remove the PVC Activating Solution immediately. The probe will return to the aspiration position and start to do the Activation.



4. When the machine finishes Activation, please go back to Calibration menu. Click **YES** to do calibration. When you choose **YES**, the calibration will start as the following steps: Check liquid sensor – test STD B – test STD A – test STD B – test STD A – test STD B – test STD A – show slope value. Then the analyzer will print the calibration results. If all the electrodes show Pass, please go to test sample or QC. The installation is finished.

	A	B	SLOPE	
K	100.11	100.11	55	Pass
Na	100.11	100.11	55	Pass
Cl	100.11	100.11	55	Pass
Ca	100.11	100.11	55	Pass
PH	100.11	100.11	55	Pass

Part III Troubleshooting

1. Zero minivolt in Calibration.

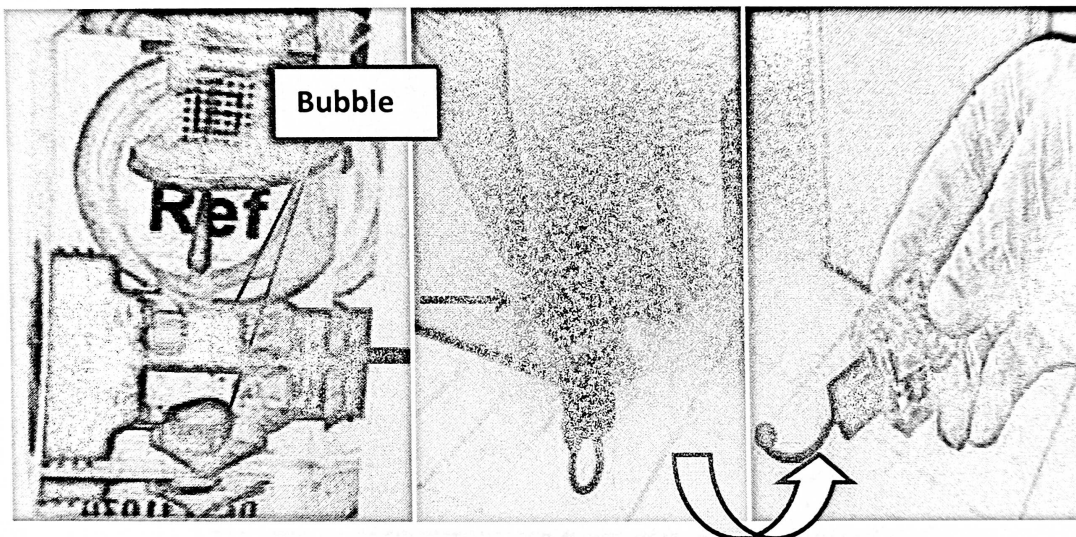
(1) As following figure shows, the potential millivolt values of K^+ ion selective electrode is use to display '0.00'. Try to reconnect K^+ ion selective electrode cable or replace the filling solution and then screw the conductive pole, make sure there is no bubble among the filling solution. Follow step 3 of Part II to activate the electrodes about 2 hours.

Note: If all the values are zero, pay attention to the Ref electrode. Try to replace the Ref filling solution.

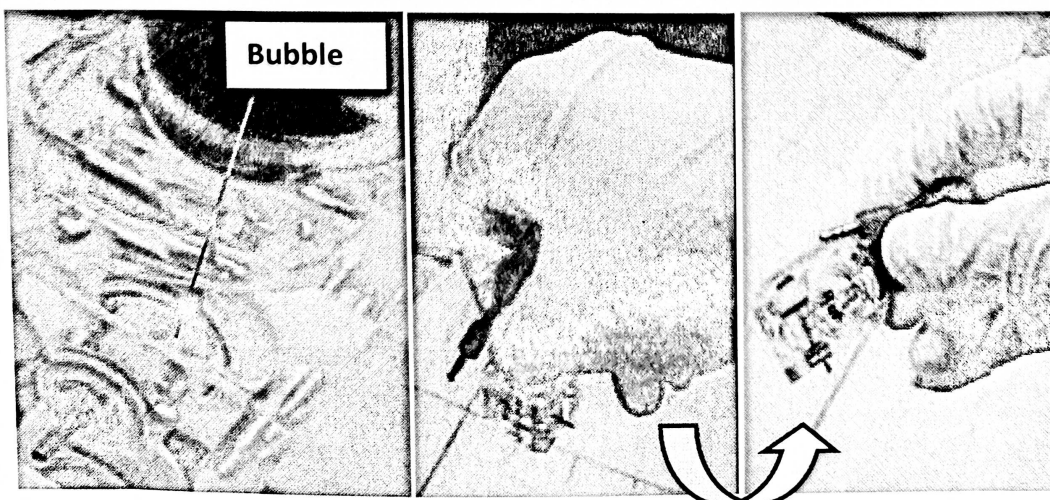
Cal of Ion					
	empty tube ADC	233			
	Calibration A ADC	1400			
	Valve to sense steps	1300			
	K	Na	Cl	Ca	PH
B:	0.00	100.11	100.11	100.11	100.11
A:	0.00	100.11	100.11	100.11	100.11
B:	0.00	100.11	100.11	100.11	100.11
A:	0.00	100.11	100.11	100.11	100.11
B:	0.00	100.11	100.11	100.11	100.11
A:	0.00	100.11	100.11	100.11	100.11

(2) Carefully check whether there is bubble in the Ref electrode as the picture below.

- A. There is bubble at the bottom of the electrode. Please turn the Ref electrode upside down and catch the bottom. Shake it to around 70° in angle back and forth for 5-10 times.



- B. There is bubble on the Ref membrane cover (white plastic cover). Please catch the Ref electrode cap. Shake it to around 70° in angle back and forth for 5-10 times.



- (3) If the potential millivolt values are still display zero, please use cloth with alcohol to wipe the electrode cap and the inner electrode as following figure. There is an extra electrode cap send as accessory. You can exchange a new electrode cap for checking.



2. Drift and Error

- (1) If activation time is not enough, sometimes calibration will display Error or Drift.

Cal Result					
	A	B	SLOPE		
K	100.11	100.11	55	Pass	
Na	100.11	100.11	55	Pass	
Cl	100.11	100.11	55	Pass	
Ca	100.11	100.11	55	Error	
PH	100.11	100.11	55	Drift	
Calibrate Again					

- (2) The system will ask for another calibration until the calibration is successful.

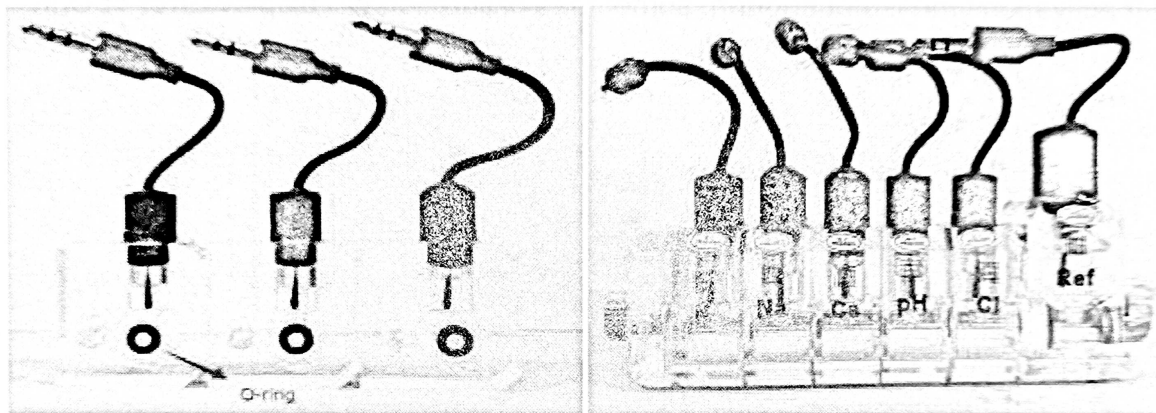
Do you want to calibrate?	
YES	
NO	
4 S	

- (3) You can calibrate the instrument several times to go through calibration, otherwise please shut down the analyzer. Replace the filling solution and then screw the

conductive pole, make sure there is no bubble among the filling solution. Follow step 3 of Part II to activation the electrodes about 2 hours, then check again.

3. Liquid system problem

- (1) During calibration procedure, if Empty tube sensor ADC is not in range (200-500) and Calibration A sensor ADC is not in range (1000-2000), you will get error which means there is something wrong with the liquid flow.
- (2) Please go to Main Menu-->Maintain-->ADC-->Click STD A and STD B. Have a check whether it can aspirate Standard A and B. If no, please go to next step.
- (3) Please make sure all the tubes are connected well, especially tube connection to electrode, peristaltic pump and distribution valve.
- (4) Disconnect the electrode from the machine. Have a check and make sure all O-ring for electrode exist. Screw of the right side of the electrode should be fixed tightly. If the screw is not fixed well, the liquid system can't work well.

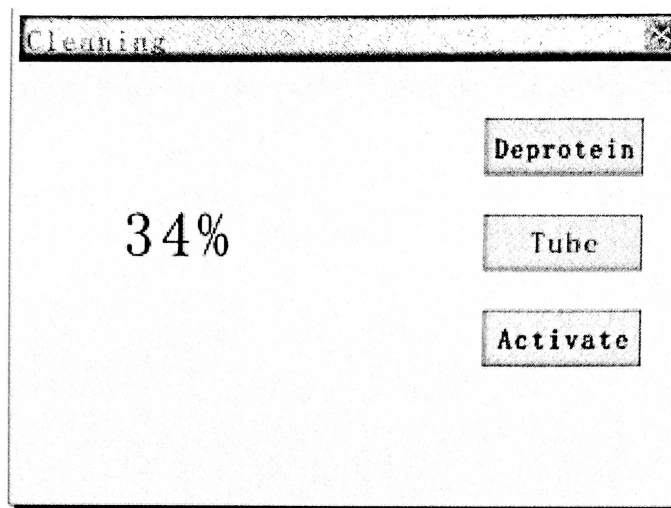


- (5) Make sure pump tube is installed well and pump tube is not pasted together. There are some backup tubes in the package. Kindly replace a new one for checking.

Part IV Shut down and packing

1. Instrument shutdown

- (1) Please click **Maintain** → **Cleaning**. After enter the cleaning interface, the sample probe automatically lifts from the aspiration position. Put Cleaning Solution under sample probe and click **Tube** as following figure to finish instrument washing.

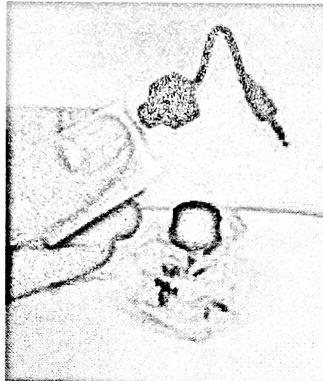


(2) After finishing washing, you can turn off power switch to shutdown instrument.

2. Instrument packing

If the instrument will be kept for a long time such as more than one week, need to follow below steps.

- (1) Put reagent A, B tube in water cup. Go to **Main Menu**→**Maintain**→**ADC**, then click **STD A** and **STD B** more than 20 times to wash the instrument. Please make sure water cup level is enough and water can go through liquid system when you wash the instrument.
- (2) Open electrode cap. Use cloth with alcohol (**cannot use water instead of alcohol**) to wipe the electrode cap and the inner electrode clean as following figure.



- (3) Use distilled water to wash electrode body inside and drain it. Put electrode body in dry place until the electrode inside is totally dry (mostly need 3-4 days to make electrode membrane dry). Fix electrode cap and keep electrode with instrument together.

Electrode Operation and Maintenance Instruction

1. Storage

- 1) New electrode can be stored for a long time at room temperature, but should be placed at a cool and dry place, avoiding direct sunlight and freezing.
- 2) It is best to use the electrode within 3 months. If long time not to use the electrode, drain it and use deionized water to wash away the residual liquid in the electrode inner chamber and membrane tube, and then keep it under seal after drying it in a clean environment.

2. Usage

2.1 Components of the electrode

The ion selective electrode (ISE) consists of ion selective membrane, electrode body, Ag/AgCl inner electrode, electrode filling solution and the seal ring.

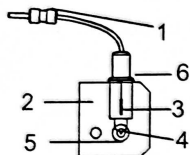
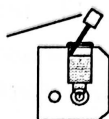


Fig. 2-1 Components of ISE

Use syringe to aspirate appropriate amount of electrode filling solution



Note: Add electrode filling solution into 2/3-3/4 of the electrode chamber.

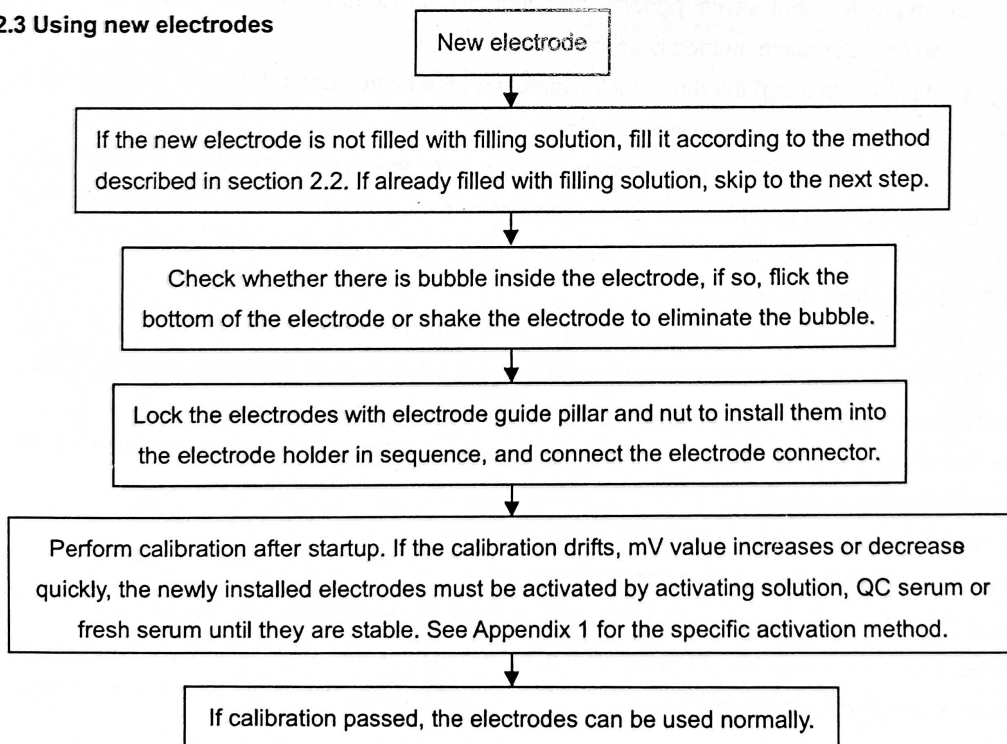
Fig. 2-2 Add in the electrode filling solution

- | | | |
|---------------------------|-------------------|----------------------------|
| 1: Electrode connector | 2: Electrode body | 3: Ag/AgCl inner electrode |
| 4: Ion selective membrane | 5: Seal ring | 6: O-ring |

2.2 Electrode filling

The electrodes must be filled with filling solution before the use and the dedicated syringe needle (with metal part length of 8-10mm, in order to avoid poking the electrode membrane) is needed to add in the filling solution. If there is no syringe, unscrew the cap to fill the solution directly. Add filling solution into 2/3-3/4 of the electrode chamber (see the above figure), then screw the conductive pole, make sure there is no bubble between the filling solution and the membrane. Clean the electrodes and locking them with electrode guide pillar and nut to install them into the electrode holder in sequence.

2.3 Using new electrodes



3. Service and maintenance

- 1) Regularly check the electrode filling solution, the Ag/AgCl inner electrode must always be immersed in the filling solution. If the filling solution is reduced or turbid, screw out the electrode connector, drain the remaining or turbid filling solution and add new filling solution according to **2.2 Electrode filling**. Replace the electrode when it is necessary.
- 2) Regularly check if the silver rod coating is falling off or turned white, if so, replace the rod or electrode.
- 3) Check whether there are contaminants or oxide films on the gold-plated electrode head.
- 4) It is recommended to do deprotein after testing every 20 samples or at least once a week, see Appendix 2 for the specific deprotein method.
- 5) Clean the electrodes after deprotein, see Appendix 3 for the cleaning method. Electrode cleaning is not needed if not do deprotein.
- 6) For new electrode or electrode not used for more than 4 weeks, it is recommended to activate the electrode before the use, see Appendix 1 for the specific activation method.
- 7) Recommended to keep the analyzer powered on for 24 hours to ensure that the electrode film is moist.

Appendix 1 Electrode activation method

Activate new electrodes or electrodes not used for a long time before the use. The activation method is as follows:

1. Use activating solution, fresh serum or QC serum to activate the electrode. It is recommended to use fresh serum or QC serum.
2. Select "Maintain" - "Cleaning" - "Activate", the instrument aspirates activating solution (or fresh serum, or QC serum), then turn off the instrument. Let the electrodes' small pipeline full off activating solution (or fresh serum, or QC serum), then turn on the instrument after 2 hours.
3. The activation time for new electrodes or electrodes not used for a long time is about 2 hours, for daily maintenance, it is about half an hour.

Appendix 2 Electrode deprotein method

It is strongly recommended that users perform the deprotein procedure regularly according to the instrument operation tips. Deprotein method is as follows:

1. Under the "Maintain" - "Cleaning" interface, click "Deprotein", the instrument automatically performs the deprotein procedure after aspirating deprotein solution.
2. If the electrode is heavily polluted or electrode slope is very low, select "Maintain" - "Cleaning" - "Deprotein" to aspirate deprotein solution, then turn off the instrument. Let the electrodes' small pipeline full off the deprotein solution, and then turn on the instrument after 2 hours to do calibration.

Appendix 3 Electrode cleaning method

Clean the electrodes after deprotein every time. Cleaning method is as follows:

1. Under the "Maintain" - "Cleaning" interface, place the cleaning solution under the probe and click "Tube", the instrument automatically aspirates the cleaning solution to clean tubes and electrodes.
2. When the instrument prompts "Remove", remove the cleaning solution, the instrument automatically drains the tubes to finish the cleaning.

Appendix 4 Method for abnormal or reduced electrode slope

1. Perform the deprotein procedure according to Appendix 2.
2. If still does not work when the electrodes' small pipeline is full off the deprotein solution for more than 2 hours, use a wet cotton thread to clean the attachments by pulling back and forth inside the electrode hole (All the electrodes are strictly prohibited poking with a hard object!), then aspirate the deprotein solution to perform the deprotein procedure.
3. If all the above methods are invalid, check if the electrodes are expired and consider replacing them.

Operation and Maintenance Guide for Electrolyte Analyzer



Startup

Switch on the instrument. It first performs self-test automatically, and then goes on to electrode activation which takes 10 minutes by default.



Calibration

After electrode activation, it prompts you for calibration. If no touch on **Yes** or **No** in 8 seconds, the instrument automatically performs calibration. When all electrodes pass calibration, go on to the next step. But if Error is shown, please refer to *Trouble Shooting* and *Checking Procedures*.



Quality Control (QC)

Press **QC** in the Main Menu. Select the sample type and then QC level. Press **Target** to check if the target value(s) is consistent with that specified in the instruction. If not, correct it as specified. Enter lot number if available. Measure QC by following the same procedure of sample measurement as carried out by the instrument, result is shown on the screen.



Measurement

- 1 Press **Measure** in the Main Menu. Select the sample type, **Serum** or **Others**. Sample probe goes up.
- 2 Put a sample under the probe to allow probe needle to be immersed and make sure the needle will be still immersed after aspiration.
- 3 Press **Sampling**. Instrument aspirates the sample. When hearing a "Di" sound, remove the sample quickly.
- 4 Sample probe returns to beginning position. Measurement starts. At the end of measurement, result is shown on the screen.
- 5 Sample probe goes up again. Press **Sampling** to go on to the next sample. When all the samples are measured, exit the menu.



Result and Printout

Instrument prints out results by default. But if **Manual** is selected at the printing setting menu, or more print-outs are needed, do the following. In the Main Menu, press **Result**. Find out the test result(s). Press **Print** to get a printout.



Cleaning

- 1 It is better to do cleaning as follows. In the Main Menu, press **Maintain** and then **Cleaning**. Sample probe rises to the top. Put deprotein solution under the probe. Press **Deprotein**. When hearing a "Di" sound, remove the solution quickly. Deprotein procedure will be completed automatically.
- 2 After finishing deprotein, sample probe rises to the top. Put activation solution under the probe. Press **Activate**. When hearing a "Di" sound, remove the solution quickly. Electrode activation procedure will be completed automatically.
- 3 After finishing electrode activation, sample probe rises to the top. Put cleaning solution under the probe. Press **Tube**. When hearing a "Di" sound, remove the solution quickly. Tube cleaning procedure will be completed automatically.
- 4 After finishing tube cleaning, before sample test, do calibration for one time or more till the calibration result is stable.



Maintenance

Daily Maintenance

- 1 It is better to keep the instrument ON 24 hours a day. Replace the reagent when it is used up or beyond the expiry date.
- 2 If there are visible blood stains on the external surface of the sample probe, wipe off with a soft cloth.
- 3 Check if the waste bottle overflows. If yes, it should be disposed of as medical waste in accordance with local guidelines.



Maintenance

- If the tube within each single electrode is blocked with crystals, wet the tube with tap water and clear out with the provided cleaning needle. Do not use other sharp objects that are not provided, especially those needles, steel wires, and fiber materials that are easy to be distorted.

Weekly Maintenance

- Check the electrode filling solution at least once a week. Make sure the Ag/AgCl is partly immersed in the filling solution. If not, add filling solution.
- Clean the liquid system with deprotein solution at least once a week. After cleaning, the potential of pH electrode rises. Repeat calibrations to resume normal potential. Or in the Main Menu, press **Maintain** and then **ADC**. Press **STD A**. Allow the electrode membrane to be soaked in reagents for about 30 minutes.
- Perform tube maintenance at least once a week. Connect the tubes on two sides of the electrode module directly or by extra tube so that the module is off the liquid path. Disconnect tube from the outlet of distribution valve and put this tube into water (at 50-80°C). Press **Maintain** and then **ADC**. Repeat pressing **STD A** 5 to 10 times. Connect tubes to electrode module again and that to distribution valve. After calibration is passed, measurement can go on.



Trouble Shooting

- Alarm "Please check the tubing or reagent"

If this alarm occurs, follow section *Reagent Check* and section *Liquid System Check*. After both checkings, if this alarm is still on, check if the reagent card of STD solution bottle faces the reader in the end of reagent room, or replace the reagent card with another of the same LOT.

- Abnormal potential in calibration

Potential ranges:

Electrodes	K	Na	Ca	pH	Cl	Li
Potential ranges of STD A (mV)	60-120	60-120	60-120	60-120	60-120	60-120

If the potential of an electrode is below the range, e.g. 30-50 mV, it is probably caused by filling solution. Replace the ISE and Ref filling solutions. If several electrodes show potential lower than the range, replace the Ref. filling solution. In the case of 0 mV potential, there must be air in electrode filling solution. Replace electrode filling solution. Tap the electrode against a table till the bubble is removed.

If the potential is above the range, e.g. reaching several hundred mV or up to the detection limit (>18,000 mV), the reason may be bubble in liquid system, bubble in Ref. filling solution, or bad connection between instrument and electrode. Follow section *Electrode Check* and section *Liquid System Check*. Re-calibrate. In some case, potentials of all electrodes are above the range or up to the detection limit (>18,000 mV). That is probably because of bubble in Ref. filling solution or a gap between the locking screw and membrane of Ref. electrode. Vigorously shake the Ref. electrode or tap it against a table 3 to 5 times till the bubble is removed. If this still does not work, replace the Ref. electrode. Re-calibrate.

- Error shown in calibration

STD A/B potential differences and Slope ranges:

Electrodes	K	Na	Ca	pH	Cl	Li
STD A/B potential differences (mV)	15±3	5.5±2	7.5±2	20±4	6.5±2	8±2
Slope ranges (mV)	25-75	25-75	15-40	25-100	25-75	10-45

Observe the calibration procedure. If big air bubbles appear in the electrode filling solution during aspiration, this indicates electrode membrane is broken. Replace the electrode.

If slopes are below the range, use the provided needle to clear the tube within electrode, replace electrode filling solution and electrode connector. But if these still do not work, and red or black stains are visible on the electrode membrane at the bottom of filling solution, disconnect and take out the electrode module. Transfer 10 mL of water (at 50-80°C) by pipette to tube within each electrode. Repeat 5 times. Rinse the electrode chamber with such water 3 times. Shake it dry. Add filling solution, and calibrate. If error is still shown, the electrode is considered damaged and needs to be replaced.



Trouble Shooting

④ Drift shown in calibration

If potential and slope are normal during calibration, but Drift is shown, the problem may be bubble in electrode filling solution or insufficient activation time. Remove the bubble. Do electrode activation 1 to 2 hours. Re-calibrate.



Checking Procedures

Reagent Check

- ① In the Main Menu, press **Maintain**, then **Reagent**. Make sure the remaining volume of reagent is OK and reagent is within validity.
- ② Make sure that the reagent bottle has sufficient solution left, and the plastic pendant at the start of STD A and STD B tubes are immersed in the reagent.
- ③ Reagents to be measured should be within one month of opening.

Electrode Check

- ① Make sure that electrodes are installed in the right sequence. They are firmly connected to the instrument.
- ② Make sure that Ag/AgCl is partly immersed in the filling solution.
- ③ Make sure that electrodes (including the Ref. electrode) have no visible bubbles in the filling solution. If available, gently tap the electrode against a table till the bubble is removed.

Liquid System Check

- ① Check if tubes and connectors are tightly connected throughout the liquid system. There is no air/liquid leakage or blockage. If any, replace the tube.
- ② Press **Maintain** in the Main Menu. Press **ADC** and then **STD A**. Observe the flow of solution. What is expected is STD A solution fills all electrodes. The potentials shown are in the range of 60-140 mV and stable. Go on to Press **STD B**.
- ③ If reagent cannot fill all electrodes, check if any blockage or leakage section by section. If the result is OK, see if the distribution valve is blocked.
- ④ Press **Maintain** in the Main Menu. Press **Sensor** and then **Ion Sensor**. Press **STD A** and **Empty** respectively to obtain ADC. If the difference between the two ADC values is smaller than 1,000, change the value of R0 as follows.
 1. Press **Empty**. Read the value of ADC. Press + or - to change the value of R0 till ADC is less than 450.
 2. Press **STD A**. Allow STD A solution to fill up the liquid system. Press + or - to change the value of R0 till ADC is greater than 1,200.
 3. Repeat above steps 1 and 2 to get a suitable value of R0. If a suitable R0 value cannot be obtained, check liquid system sensor or replace liquid tube.

Parameter Check

- ① In the Main Menu, Press **Maintain**. Long press the open space at the lower right corner. Enter pass word "860755". This is the service menu. Press **Set STD**. See if the concentrations of STD A and STD B are consistent with those specified on the label of reagent card.
- ② In the service mode, press **Set Slope**. See if each slope is "1". If no need to correct the slope, press **Reset**.
- ③ In the Main Menu, Press **Maintain** and then **Correct**. After selecting the type of sample, press **Manual**. See if k (slope) is 1 and b (intercept) is 0. If no need to correct k or b, press **Reset**.