

Hướng dẫn sử dụng bản gốc

Tài liệu được cung cấp bằng tiếng Anh

Tài liệu được xác nhận bằng chữ ký số

Tp Hà Nội ngày 05 tháng 05 năm 2022



B&E Bio-technology Co.,Ltd.

11 Jieaisi Road, Laishan District, Yantai, 264034, China
Tel: +86-535-6718181 Fax: +86-535-6718080

User manual of Calibration Pack

Calibration Pack

Calibration pack for CBS-300

Intended Use(For In Vitro Diagnostic Use Only)

Calibration Pack is a reagent pack that used on the Electrolyte Analyzer CBS-300. It is for calibration of sodium, potassium, chloride in the CBS-300/30 electrolyte analyzer.

Composition

Standard A 530ml, Standard B 210ml, Rinse Solution 220ml, Reference Solution 310ml

Principles of Procedure: CBS multi-sensor has three ion selective electrodes (ISE) measuring ion concentration of sodium, potassium, chloride, Calcium and pH in sample. Another chloride electrode is integrated in cartridge as a reference electrode. Each ion selective membrane undergoes a specific reaction with the ion contained in the sample. The membrane reacts to the difference of potential of sample and the standard solution A and calculation. Then ion concentration in the sample is determined.

Sample Requirements:

1. The sample of whole blood should be collected in the heparinized syringe and should be analyzed as soon as possible.
2. The sample of plasma should be collected from centrifuge the heparinized blood fast and derive from the RBC, and then seal in the tubes.
3. The sample of serum should be collected in the blood collecting tubes and centrifuge 30 minutes later, and then get rid of the clot and then seal in the tubes.
4. Urine samples should be collected at random according to the regulations or 24 hours urine.

Testing Method: Under the room temperature, installing the reagent pack and then run the auto calibration procedure of the analyzer.

When calibrating is OK, the sample testing could be start.

Refer Value: It was made according to the refer value which is set by CBS-300 and clinical data.

Na⁺ 141—155 mmol/L K⁺ 3.6 – 5.5 mmol/L Cl⁻ 97 – 111 mmol/L

Limitation: User should consider the possible factors which influence the result combined with the clinical reaction. Because the drug using or the inner uncertain inflicts of the material, the doctor or the lab staff should calculate the testing result of the patient.

Assay value:

| | PH | K ⁺ mmol/l | Na ⁺ mmol/l | Cl ⁻ mmol/l |
|--------------------|---------|--------------------------------|------------------------|--------------------------------|
| Standard A | 7.4±0.3 | 4.0±0.4 | 140.0±10.0 | 125.0±10.0 |
| Standard B | 6.8±0.3 | 16.0±1.5 | 35.0±10.0 | 41.0±10.0 |
| Reference Solution | 5.5±1.5 | (1.2±0.05) ×10 ³ | / | (1.2±0.05) ×10 ³ |

Precautions: Avoid contact with skin and eyes. In case of skin contact, flush the area with water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, induce vomiting and seek medical advice.

Storage and Stability

Unopened **pack** stored at 2--35 °C has a product life of 24 months after the date of manufacture. The expiration date is indicated on the container label. Once opened, product stability is 5 months at 2--35 °C.

Disposal Procedure

Disposal procedures should meet requirements of applicable local regulations.

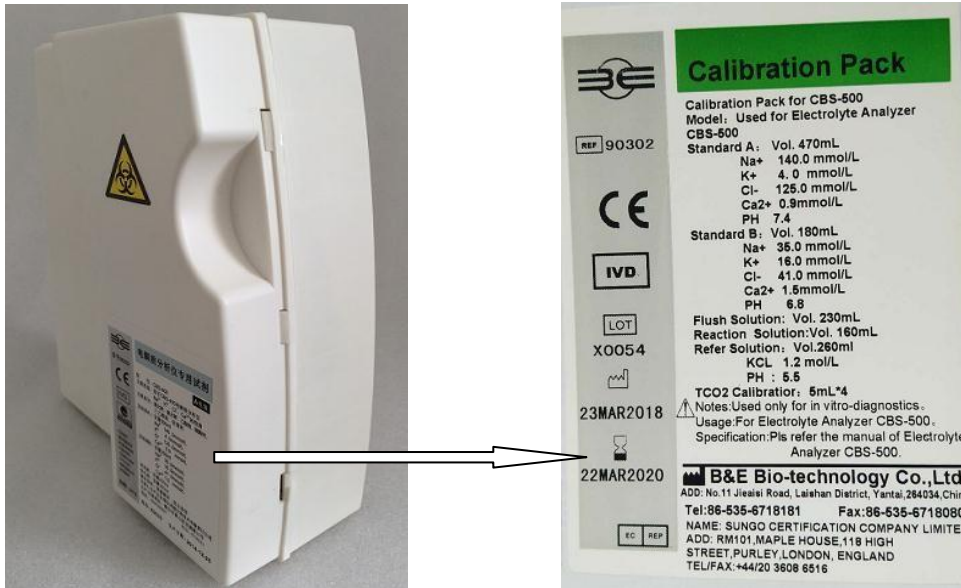
Manufacture:

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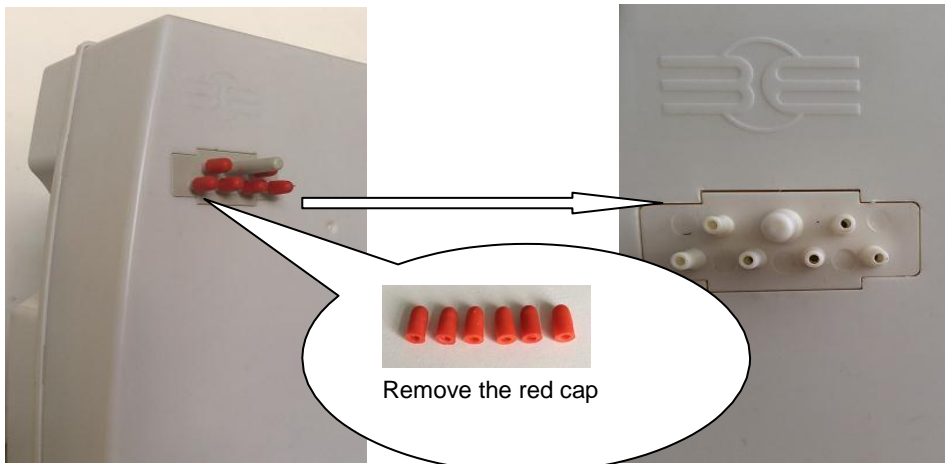
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Reagent pack installation

1. Take out the reagents pack from the package ,and ensure the reagent pack labeled model is same as the analyzer model.



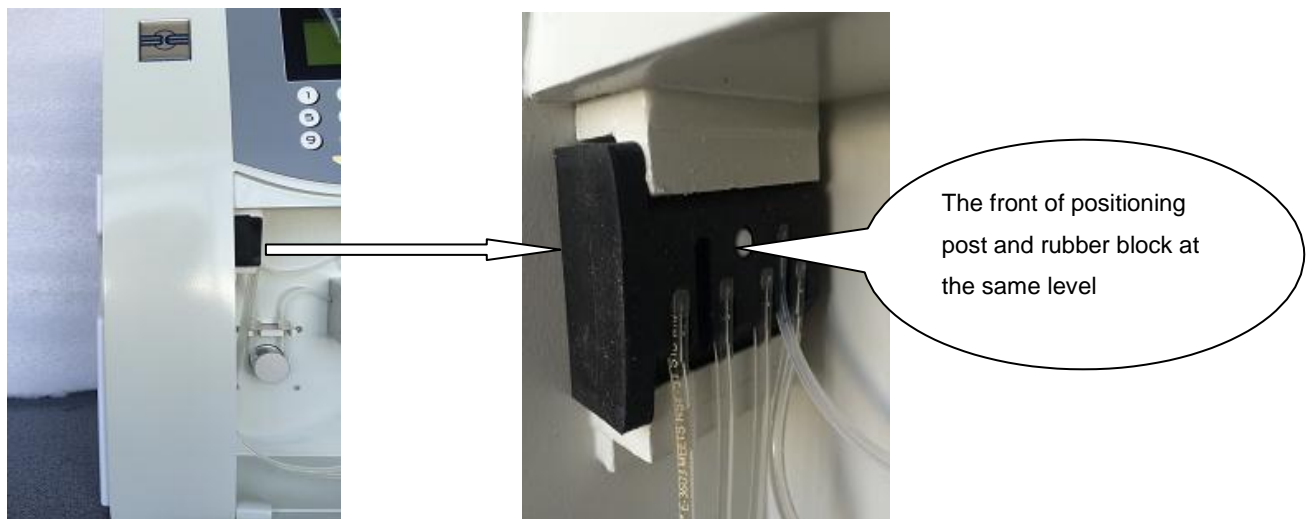
2. Remove the red protective cap and keep it .



3. The positioning post at the connectors of pack aim at the location hole of the rubber block of analyzer .



4. Push the reagent pack slowly and forcibly into the analyzer . When the front of positioning post and rubber block at the same level ,then the reagent pack installation finished .



Note: Once the red protective caps of the pack are removed ,please keep it into the unit until it is expired to avoid the pollution.

1. The new reagent pack detachable red protective caps onto replaced the old reagent packet interface, prevent pollution.
2. Put a new reagent kit, enter "3. OPERATION " screen, press ">" Select "5. Change Pack" menu

Screen prompts

Solution Remain :
5%

Press "YES", it will display:

**Replace Fluid
Pack And Reset?**

Press "YES", it will display:

**Solution Remain :
100%**

Press "NO" repeatedly until you return preparation state, the remaining amount to 100% the upper right corner to complete the operation.

**READY 100%
V25.1.8
21-April-2015
13 : 15 : 55**

3. Enter "3. Operation" menu, press "3. Priming" twice to pipeline filled with liquid.

Note: Performing this action is to ensure that the instrument calculates the remaining solution is consistent with the actual use of the remaining amount of the solution