Specific Protein Analyzer

Model: PPC 800G

Specific Protein Analyzer

User’s Manual

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1. Detection Principle

After the sample mixture and reagents has been respectively added onto the cartridge and all reactions are completed. The analyzer will quantitatively analyze the color intensity of the cartridge, and the concentration of the sample is hence determined.

2. Intended Use

Use for quantitative or qualitative detection of one or more proteins of the human body fluid biological sample.

3. Product Performance

3.1 Repeatability

Coefficient of Variance (CV) ≤1.0%

3.2 Detection deviation

Detection deviation ≤10.0%

3.3 Linearity

In no less than an order of magnitude, and within five concentrations of detection range, the correlation coefficient is not less than 0.9900.

3.4 Stability

After turning on the device, use it to do tests in 0.5 hour, 1 hour, 2 hours, and 3 hours, the coefficient of variance (CV) of each point of time should be ≤1.0%, detection deviation

should be ≤10.0%.

3.5 Detection time

The whole process of the test, from placing the cartridge on the calibration plate until the result is displayed should be not over one minute.

3.6 Normal operation conditions

After the analyzer is powered, it should be able to turn on and turn off normally. After turning on the device, the screen will turn bright and automatically enter the test interface.

4. Main components

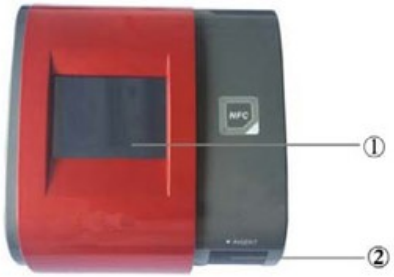
4.1 Pictures

4.1.1 Front

4.1.2 Back

4.1.3 Side

4.2 Appearance pictures



Number	Name	Function
①	Touch screen	Operate the device by toughing the screen
②	Tray	It is a part which is used to install the testing device, and it is driven by a motor drive
③	Adapter connector	Use for connecting the power adapter
④	RS232 connector	Use for connecting the barcode scanner
⑤	RJ11 connector	Use for upgrading the software
⑥	Communications equipment connector	Use for connect the external communication equipment
⑦	Printer connector	Use for connecting the printer

4.3 Standard configurations

1	Device
2	Power adapter
3	Calibration plate (on the tray)
4	Printing paper (1 roll)
5	User's Guide
6	RS232line
7	Pipette

4.4 Main components

The analyzer consists of the device, power adapter, calibration plate and software. The device mainly consists of stepper motor, a light source, a circuit board, MFRC card components and the touch screen.

5. Device parameters

5.1 Size and weight

Size (width*length*high): 178*195*77mm

5.2 Power and voltage

Input power: 12W;Adapter input voltage： AC 100-250V, 50/60Hz

Analyzer voltage: DC 12V, 2A

5.3 Interface

LED touch screen, built-in mini printer, or link external

normal printer

5.4 Port

R111, and have MFRC communication function

5.5 Working environment

Temperature: 5℃～40℃; Relative humidity: 15%～75%; Altitude: 3000 m

6. Installation

6.1 Analyzer Installation

- In order to achieve the optimum performance of the analyzer, and obtain a satisfactory clinical result, the initial installation of the Abeille Specific Protein Analyzer must be installed and adjusted by the engineers who are authorized by PKL. If you moving the device or plan to move the device to another place, please install and use the device based on this installation procedure.
- Any unauthorized installation or any installation by personnel who without professional training may result in damage to the device. Damages in this case are not included in the free warranty from PKL. Any unauthorized person is not permitted to install or dismantle the device.

6.2 Open box and check

Be careful when you take out the device and accessories from the packing box. Retain the original package for the purpose of future transportation or storage.

- Check the accessories according to the packing list

- Check whether it has liquid inlet or water immersion
- Check whether these is any mechanical damage
- If there are any problems, please contact our company or agents immediately.

6.3 Space requirement

- Device must be allocated on a flat and stable workbench, avoids of direct sunlight, away from too cold or too hot air vents, and away from the high-power vibrating devices. In order to maintain great ventilation, please retain a certain space for the analyzer.

  For ventilation, the device and the surrounding (including the wall) should be kept a distance at least 30cm. It requires a 1㎡ workbench for placing the device and reagents.

  There should be enough space around the device for device maintenance and repair. Furthermore, please do not place the device in a position, where it is difficult to operate or difficult to connect the device.

6.4 Printer installation (if there is)

If there is a printer, connect the printer to the printer

connection port, which is located on the back of the analyzer, and then turn on the printer.

6.5 Personal safety and inspection control

- User must comply with the laboratory or clinical tests operational requirements when testing samples, implementing daily maintenance, or implementing product care. User should wear surgical gloves and safety glasses to avoid the direct contact of the skin with the sample.
- Since all clinical samples, quality controls samples, calibration object are likely to contained substances of human origin, and may he potentially infectious. Therefore, in handing of these items, you must comply with the laboratory or clinical test procedures; wear work clothes, gloves and safety glasses. Please do not smoke or consume food in the working area, and avoid the using of month to blowing or sucking the line for work.
- Since the samples and the waste liquid that are produced by the device may be containing potential pollutants, and it may have biological or chemical hazards. Therefore,

must be careful when you are handing these items. When cleaning, processing or discharging these items, please strictly comply with the relevant local laws and regulations.

6.6 Electromagnetic Compatibility Information

The specific protein analyzer has met the GB/T 18268.1 and GB/T 18268.26 standard EMC requirements.

- This device is designed and tested based on the Class A device design requirement of GB482. If using this device at home, it may cause radio interference, therefore need to take protective measures.
- Prohibit using the device near strong radiation sources; otherwise it may disturb the normal operation of the device.

7. Operation Interface Introduction

7.1 LOGO Page

After turning on the device, the screen will display the company's LOGO, and then it will automatically enter the test item selection page

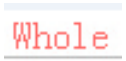
7.2 Selection Page

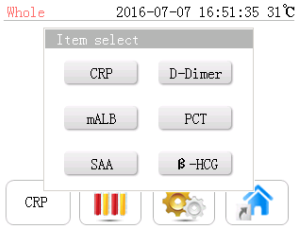
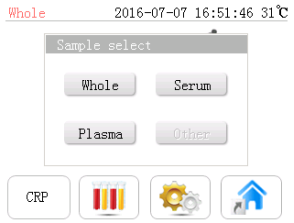
Select the item which you need to detect, and it will enter to the corresponding initial page.

- If testing HbA1c, then select the "HbA1c" button
- If testing other items then select the "others" button

7.3 Initial Page

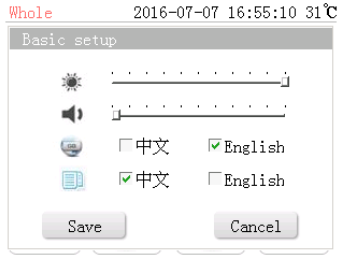
There are following options in the initial page:

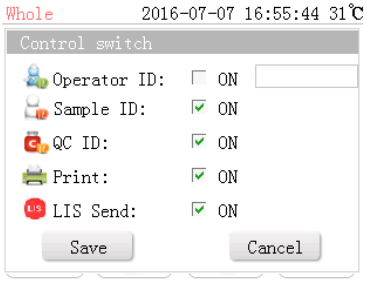
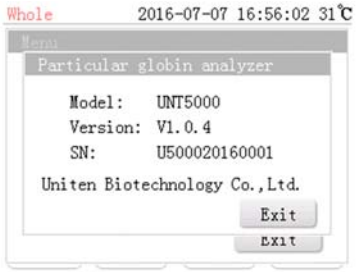
Sign	Second-level icons	Explanations
		Selected sample type
		Back to the last page

		Test item/ Change test item
		Choose sample type
		Analyzer setup

7.4 Analyzer setup

The functions of the second-level icons within the "analyzer setup" are as following:

	- Change the brightness of the screen - Change the sound volume - Change the operation language - Change the voice prompt language

	➢ Place the calibration card on the scanning area of the analyzer ➢ The analyzer will display the test kit information that are saved in the calibration card
	➢ Date and time setting
	➢ Choose whether required to enter the operator ID, patient IC and QC ID ➢ Choose whether to automatically print result ➢ Choose whether to automatically upload the data to the LIS system
	➢ Basic information of the analyzer

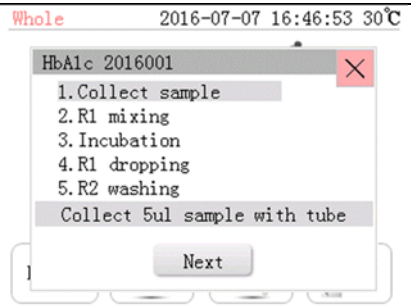
8. Analyzer test function

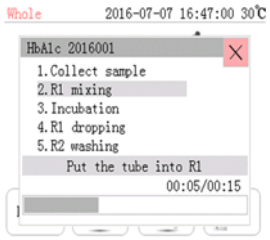
8.1 Standard Test Procedure

The analyzer has auto calibration function. Each time, after turning on the device it will start auto calibration. Please start to do tests after the analyzer has successfully calibrated. In addition, please operate corresponding quality control tests based on the laboratory requirements. In order to evaluate whether the analyzer is in control, implementing quality control test is recommended before starting the daily tests. For those test items which requires scanning the calibration card to input the calibration curve, it is necessary to input the calibration curve before the first time to using of the test kit and when replacing test kit batches.

✧ This analyzer is only suitable for the test kits that produced by Paramedical S.r.l..

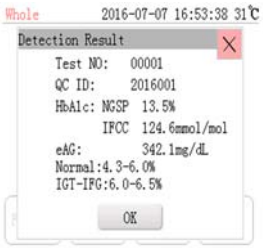
Please do not use other test kit that is produced by other manufacturers.

	Collecting blood. Please critically follow the specific sample requirement that is illustrated in the test kit instructions.



➢ Put the collected blood sample into the R1 reagent according to the required sample volume that is stated on the test kit instructions.

➢ After the blood sample and the R1 reagent are completely reacted, pipetting a certain amount of the mixture and add onto the cartridge. And then according to the notice of the test kit instructions, add R2, R3(if there is) reagents to the cartridge in a proper order.



➢ After completed adding sample and reagents to the cartridge, the tray of the device will pop out, please place the cartridge on the tray.

➢ After placing the cartridge on the tray, click the "√" button, then the analyzer will start automatically detecting.

➢ After analyzing the result, the tray will pop out and the screen will illustrates the test result simultaneously. If further test is required, please click the "OK" button and then enter the sampling stage.

➢ If select auto printing in the setup page, the test result will be automatically printed out when the test result is illustrated on the screen

✧ Please avoid the tip of the pipette to touch the cartridge, and avoid the reagents or samples spilling out when adding samples or reagents to the cartridge. Furthermore, avoid bubbles occurring when adding reagents or samples, because bubbles may impact the test results.

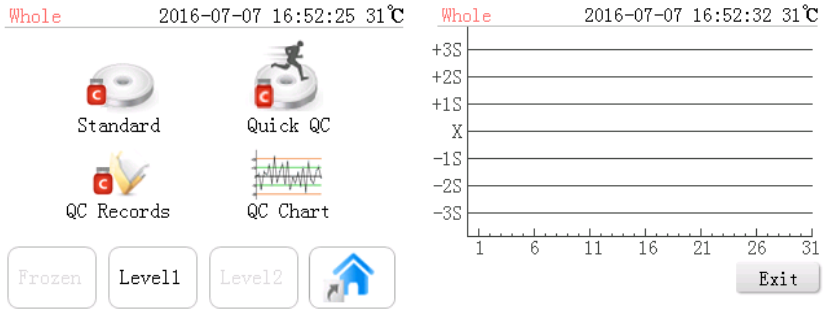
8.2 Fast mode

After selecting fast mode in the setup page, select "test" on the detection page and the tray of the analyzer will pop out. If there are multiple samples needed to be tested, after sample and reagents have been completely added onto the cartridge, place the cartridge on the tray and click the "Yes" button. There will be voice prompt, and then place other completed react cartridges onto the analyzer to continually testing.

8.3 Quality control mode

Select the "quality control" mode, and select the concentration level of the quality control material. The following operation is the same as the operation of the "standard mode" and the "fast mode" that stated above. The data of the "quality control" will be saved separately. Click the quality control graph, you can observe the historical test results of detecting the same concentration level, and it will automatically calculate the mean and standard deviation of the last 30 test results, and it will automatically generate a quality

control graph. The laboratory can be interpreted according to the quality control standard of the laboratory.



8.4 Data saving

Test results will be automatically saved into the database. The maximum storage of the test results is 2000, after the saved results are exceeding 2000, the systems will delete the earliest saved data. Therefore, please upload the test results to the hospital's system in time.

8.5 Search for test result and other relevant operations

Click the "test result" button to search detailed information of all test results that are saved onto the database. Select the test result which you want to print out, and then click the "print" button, thus the selected test result which is saved onto the database will be printed out. Select the test result which you want to delete, then click the "delete" button, thus the selected test result will be deleted.

8.6 Others

- Using the standard mode, the whole procedure of the detection will cost 3-4 min/sample (from preparing reagents until obtaining the result). If using the fast mode, the test time will be not over 1 min/sample.
- If the automatic calibration is unsuccessful, it is necessary to clean the calibration plate. After using the analyzer, daily cleaning of the appearance and the calibration plate of the analyzer are recommended; it can help avoid cross-infection.
- After turning on the analyzer, if the operator does not have any operation during 10minutes, the analyzer will enter standby state, and the screen will turn black. Click the screen then it will resume.

9. Product Care and Maintenance

9.1 Appearance cleaning

User can based on the actual need, use 75% alcohol to wipe clean the appearance of the device, the device can be reused after the alcohol is evaporated. Use of water or other liquid to clean are strictly prohibited.

9.2 Maintenance

- If the device notices that the temperature is too high, turn off the device and place the device under the room temperature for 10 minutes then it can be reused.
- After daily use of the calibration plate or when the automatic calibration is in failure, please take out the calibration plate, and use 75% alcohol to clean it. It can be reused after the alcohol is evaporated.

9.3 Replace printing paper

During printing, if the printing paper is not enough, the screen will show the corresponding notification. Please replace printing paper and click the “yes” button, then it will start printing. Replace process is showing as below:

9.4 Built-in battery replacement

In order to save the user’s data, there is a battery inside the device. Once the battery has ran out of power, it may result in the data initialization. Please contact our sales or the manufacturer directly when you have this type of problems.

- Please do not disassemble the device if you want to replace the built-in battery.

10. Product Transportation and Storage

10.1 Product transportation: During transportation, please do not allocate our product in open areas, should avoid of exposure to the sun, rain, ice, and prepare damping measure to avoid damage.

10.2 Storage: Our product should be stored in clean, protected from light, dry, ventilated, cool space. And please do not storage together with hazardous, harmful, corrosive, smelly, volatile and contaminated goods.

11. Signs and Symbols Explanation

	**Production Date**
	**Expiring Date**
	**Batch Number**
	**In vitro diagnostic medical devices**
	**Attention，refer to attached file**
	**Refer to instructions**
	**Temperature range**

12. Warning, Prompts and Troubleshooting

12.1 Warning: this product should only be used by inspectors who have relevant professional knowledge or trained nurses and doctors.

12.2 Prompt and Solution

Prompt symbol	Reasons of error	Solutions
Calibration Failure	Device calibration failure	Clean the calibration plate inside the analyzer
Test Device Error	Cartridge placed incorrectly	Check whether the cartridge has been put in, or re-placing the cartridge
Printer Paper Empty	Not enough printing paper	Replace printing paper
Temperature is too high	Temperature exceeds the upper limit	Place the analyzer for 10 minutes and then can reuse

13. Product information

[Product name] Specific Protein Analyzer

[Model] PPC 800G