CE

GeTein BioMedical Inc.

FIA8000 Quantitative Immunoassay Analyzer

User Manual

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Catalogue

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GeTein BioMedical Inc.

1. Introduction

1.1 Identification

analyzer: FIA8000 Quantitative Immunoassay Analyzer

Abbr. used in the manual: FIA8000

1.2 Product classification

When classified by protection against electric shock, FIA8000 is in transient over-voltage class II.

When classified by pollution grade, FIA8000 is in rated pollution degree 2.

When classified by working system, FIA8000 is a continuous running analyzer.

1.3 Environment conditions

Working environment:

Temperature	+15℃ ~ 35℃
Relative humidity	10% ~ 85%
Air pressure	70.0kPa ~ 106.0kPa

Environment limitation in transport and storage process:

Temperature	-15℃ ~ +40℃
Relative humidity	≤ 93%
Air pressure	50.0kPa ~ 106.0kPa

1.4 Intended purpose

The FIA8000 is an analyzer that used to measure biomarkers in human whole blood, serum, plasma or urine samples. The test result can be used as an aid in clinical diagnosis. The FIA8000 can be applied to laboratory and point of care testing.

Together with different test items, the FIA8000 can be used to determine 10 different biomarkers in human blood quantitatively: 1) cTnI, 2) NT-proBNP, 3) hs-CRP, 4) CK-MB, 5) Myo, 6) D-Dimer, 7) PCT, 8) CysC, 9) mAlb, 10) β_2-MG

1.5 Matching test kits

The test items listed below are used to determine the concentration of corresponding biomarker by FIA8000.

a. One Step Test for Cardiac Troponin I (Colloidal Gold)
b. One Step Test for NT-proBNP (Colloidal Gold)
c. One Step Test for hs-CRP (Colloidal Gold)
d. One Step Test for NT-proBNP/cTnI (Colloidal Gold)
e. One Step Test for CK-MB/cTnI/Myo (Colloidal Gold)
f. One Step Test for D-Dimer (Colloidal Gold)
g. One Step Test for PCT (Colloidal Gold)
h. One Step Test for CysC (Colloidal Gold)
i. One Step Test for mAlb (Colloidal Gold)
j. One Step Test for β_2-MG (Colloidal Gold)

If you need them anytime, please contact with your service engineers.

2. Principle of measurement

2.1 Overview: running a test

After sample (for example, serum) is added to the test kit, insert the test kit into the FIA8000 and press “ENT” button. Then the concentration of the selected item is be measured and displayed on the screen in a certain time. The test result is stored in the FIA8000 and is available when required. The result can also be transmitted to the lab or hospital information system through the LIS or HIS system when connected to FIA8000.

2.2 Working principle

The combination of the antigens in the sample, the gold-label antibody in the colloidal gold pad or nitrocellulose membrane, and the antibody pre-coated on the test line can form a purplish red streak on the test line. The color intensity of the test line is proportionate to the quantity of antigens detected in the sample. The analyzer system can obtain the photo-electric signal intensity of the complex by scanning the test line with a photo-electric component. Then the voltage difference between the voltage of the test line and the background is obtained. The voltage difference has a linear relationship with the antigen concentration which can be used to calculate the antigen concentration. The relationship has been established and varying from the measured parameter. In conclusion, the antigen concentration in whole blood, plasma, serum, urine can be calculated quantitatively in one-step according to the color intensity of the test line.

3. Package, appearance and technical specification

3.1 Package

The FIA8000 and related items are provided in a single box. The test kits are packed separately including instruction for use. If you find any part missing or if you have any questions, contact our agents in your area, or contact us directly.

Packing List

No.	Description	Unit	Quantity
1	Mainframe	set	1
2	Power Wire	pc	1
3	Printing Paper	pc	1
4	CD	pc	1
5	Data Cable	pc	1
6	User's Manual	pc	1
7	Product Qualification Certificate	pc	1
8	QC kit	pc	1
9	Barcode Scanner	pc	Optional

3.2 Appearance

Dimensions (L×W×H) 250mm x 250mm x 120mm
Weight 3.97 pounds (1.80 kg)
Appearance shown as Fig.1

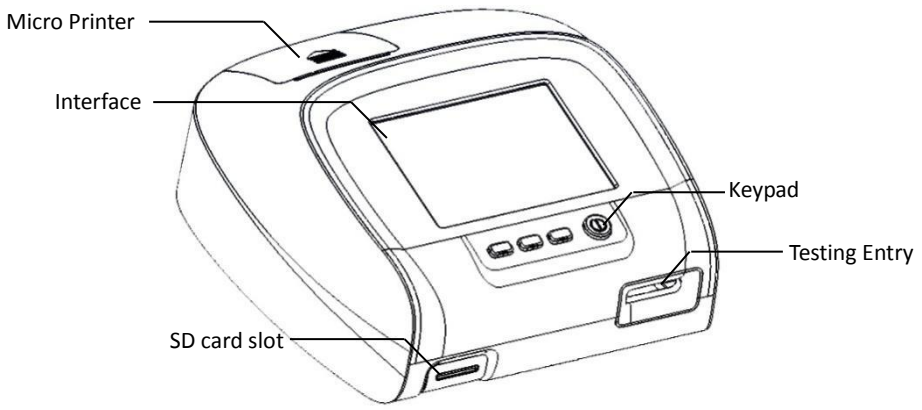

Fig.1 Appearance of FIA8000

3.3 Keypad functions

[ENT]: Used for start of measurement and the choose of various operation interface
[RET]: Used for return to the previous interface from the current interface status
[PRT]: Used for test the "print" function condition and manual printing measurement results
[QC]: Shortcut key for "QC(SD)" Operation

3.4 Technical specification

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Power voltage	AC 100~240V, 50~60 Hz; DC 12V 5A, supplied via AC/DC adapter in package
Power	60 VA
AC/DC adapter	Model: SKUN90W-03, approved according to IEC/EN 60950
Operating wavelengths	540 ± 5nm
Measurement range	0mV ~4000mV
Voltage resolution	1mV
Keypad display	4 buttons
Screen size	5.6 inch touch screen, 640*480
Printer	Thermal printer
Data storage	10000 data can be stored
Data output	The concentration results and voltage results are obtained, one of them can be selected to display on the screen.

4. Performance characteristics

4.1 Quality control of FIA8000

a. The voltage of background QC test kit should be ≥ 3500mV
b. The linear correlation coefficients (r) should be ≥ 0.990 within 0mV~4000mV
c. The relative standard deviation (CV) of repeated measure should be ≤ 1%
d. The voltage difference of QC test kits of the same concentration within one hour should be falls in the range of -2%~+2%

4.2 Performance characteristics of matching test items

Performance Characteristics				
Biomarkers	Abbr.	Measurement range	Intra-assay precision	Inter-assay precision
Cardiac Troponin I	cTnI	0.50~50.00 ng/ml	⩽ 10%	⩽ 15%
N-terminal B-type natriuretic peptide precursor	NT-proBNP	100~35000 pg/ml	⩽ 10%	⩽ 15%
High sensitivity C-reactive protein	hs-CRP	0.5~200.0 mg/L	⩽ 10%	⩽ 15%
Creatine Kinase - MB	CK-MB	2.50~80.00 ng/ml	⩽ 10%	⩽ 15%
Myohemoglobin	Myo	30.0~600.0 ng/ml	⩽ 10%	⩽ 15%
D-Dimer	D-Dimer	0.10~10.00 mg/L	⩽ 10%	⩽ 15%
Procalcitonin	PCT	0.10-50.00 ng/ml	⩽ 10%	⩽ 15%
Cystatin C	CysC	0.50-10.00 mg/L	⩽ 10%	⩽ 15%
microalbuminuria	mAlb	10.0-200.0 mg/L	⩽ 10%	⩽ 15%
β_2-Microglobulin	β_2-MG	0.50-20.00 mg/L	⩽ 10%	⩽ 15%

5. Warnings and precautions ⚠

a. Only used for *In Vitro* diagnostic analysis of human whole blood, plasma, serum and Urine.
b. Only the test kits mentioned in this instruction manual can be adopted, otherwise the obtained results might be unreliable.
c. Read this instruction manual carefully before operating and keep it properly for future use.
d. If the analyzer gives off an unusual smell or smoke, cut off the power and contact with service engineers immediately, otherwise it would result in a fire, electric shock or personal injury.
e. If any liquid enters in the interior of the analyzer, cut off the power and contact with service engineers immediately, otherwise it would result in a fire, electric shock or personal injury.
f. Take proper safeguard measures according to health and safety standards in local country.
g. Wear protective goggles, surgery gloves and laboratory coat, don't touch the patients' blood samples directly, and obey lab safety regulations, to avoid the potential biological pollution risks of samples and reagents.
h. The test kits and transfer pipettes should be discarded after single use as patients' samples, used test kits and transfer pipettes may be infectious. Proper handling and disposal method should be established by the laboratory director in accordance with local, status and federal regulations.

6. Installation

6.1 Unpack

a. Take the FIA8000 from the packing box and put it on the table or other flat surface.
b. Avoid dusts, vibrations, noises and power interferences. Avoid direct sunshine, hot sources and wind.
c. Open the packing box, and check the packing list. If you find any part missing or broken, contact our agents in your area, or contact us directly.

6.2 Power on

Using the adapter packed together with the FIA8000. Supply voltage must be within AC100V~AC240V, Frequency: 50~60Hz.

a. Remove the AC/DC adapter from the box.
b. Connect power and FIA8000 through the AC/DC adapter.

6.3 Install printing paper

a. Open the printer door.
b. Put the printing paper into the printer, facing down to the hot sensor of the printer. Leave the rest part of the paper outside of the door and close the printer door.

7. Operating the FIA8000

7.1 Preparations before power on

Before power the system on, make sure the system is ready to use. Check the system as the following steps：

Check if the power supply is ready and connected safely.

Check if the printer is ready, including the paper and paper installation.

7.1.1 Power on

1. Turn on the power switch of the analyzer.
2. The system will check its hardware automatically. The self-check procedure shows in Fig.2.
3. After self-check is finished, the system will enter the main interface, as shown in Fig.3.

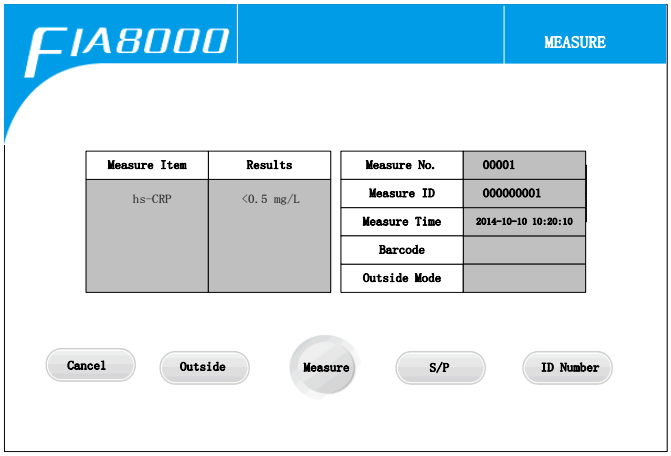


Fig.2 Boot screen

7.1.2 The main interface

The main interface (as shown in Fig.3) consists of five main modules: Debug (the debug interface), QC Check (quality control calibration), Measure, Search and Settings.

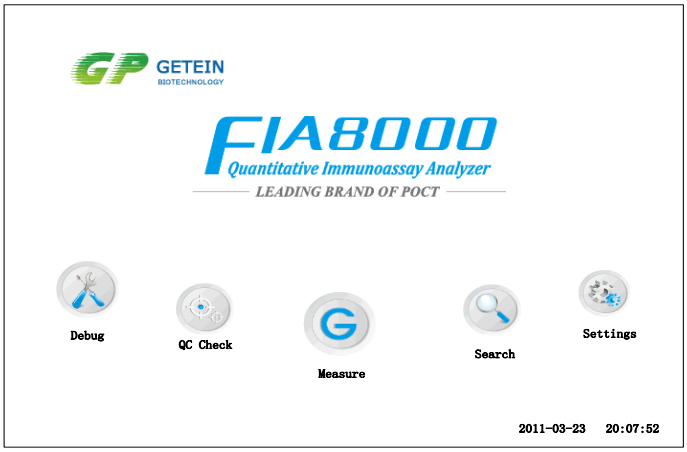


Fig.3 The main interface

1. Debug: It is used to adjust equipment parameters and common functions of testing;
2. QC Check: Set parameters of the analyzer, ensure the accuracy of the measurement system;
3. Measure: Measurement of different items. Operator can set the ID number, types of

exhibition board and sample;

4. Search: No. and ID Results can be searched from the saved measurement results and be printed manually;
5. Settings: Set the commonly used functions of the analyzer.

7.2 Sample collection

WARNING

DON'T TOUCH THE PATIENT'S BLOOD OR URINE sample

Operators should treat patient's blood or urine samples carefully to avoid infectious diseases. In order to avoid or reduce the related infection risks, please use disposable gloves.

7.3 Sample measurement

Press the "ENT" button or touch the "Measure" icon on the main interface and then enter the measure interface as shown in Fig.4. This interface includes: sample mode, exhibition mode, ID Number, the measurement icons. Meanwhile, Measure No., Measure ID, Barcode are also shown on the screen.

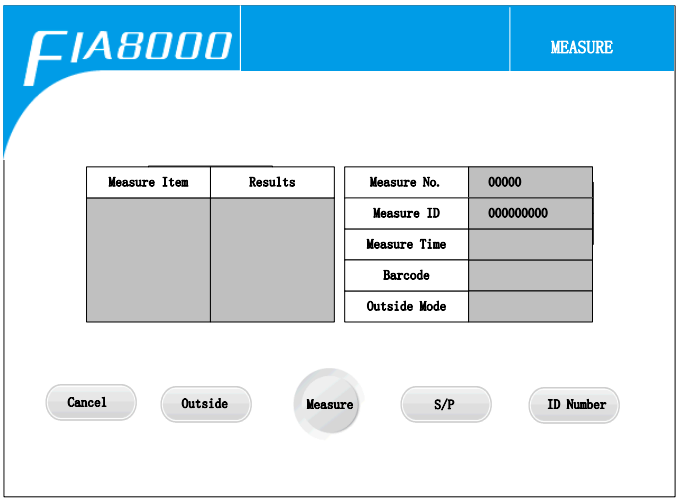


Fig.4 Ready to measure interface

1. Sample mode: clicking on "S/P" icon to choose sample type (including whole blood, serum/plasma and urine).
2. Exhibition mode: clicking on "Outside" or "Inside" icon, switch exhibition mode (including inside-mode and outside-mode);

   Inside-mode: After sample is added to the detection tab, the kit will be detected immediately after it is inserted into the analyzer, click on the "measure" icon, panel of the analyzer will countdown the measure time, when time arrived, the analyzer will detect the inserted kit automatically.

   Outside-mode: After the sample is added to the detection tab, keep it at room temperature for a period of time until the time arrives, then insert the kit into the analyzer, click on the "Measure" icon to determine the test kit.

3. Measure: Click on this icon, start to measure corresponding item.

4. ID Number: Click this icon manually to set the desired ID Count, as shown in Fig.5, Click on the "Count" icon to switch to Count Input Mode. Set Count when ID is not 0 and Count will minus one automatically after each measurement, and ID number will increase automatically until the Count value is zero.

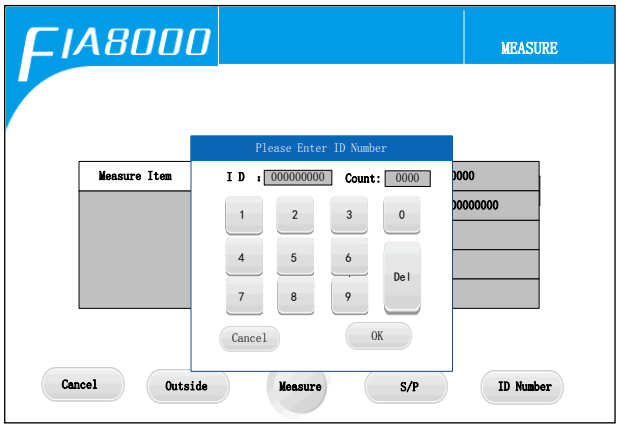


Fig.5 ID set interface

In Fig.6 interface, add sample to kit vertically and keep the sample at room temperature for a period of time, then insert it into the analyzer, when hear "click" sound, it indicates the test kit have been placed in the correct location, at this time, click "Measure" icon or press "ENT" button, the analyzer will automatically scan the kit and determine the item (see Fig.6). When the test finished, the analyzer will display measurement results, and save the current measuring time, number, and other information, as shown in Fig.7.

Note: refer to the sample volume and the test time of different items according to test kit instruction.

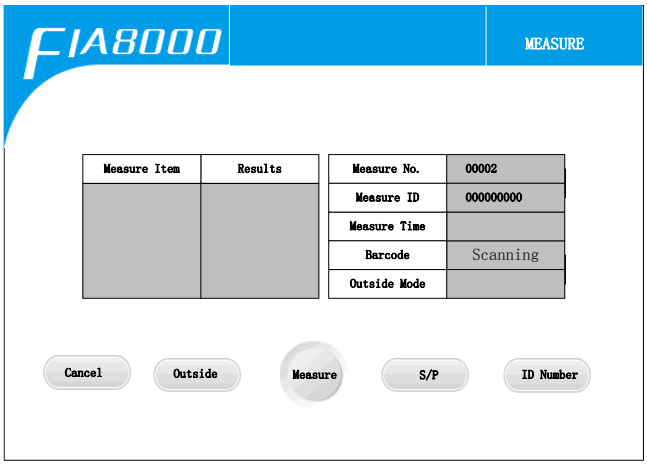


Fig.6 Measurement interface

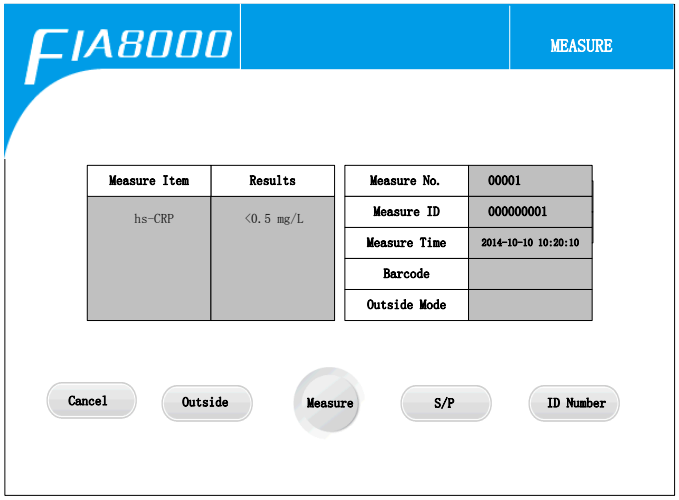


Fig.7 Measurement results interface

7.4 Sample queries

In the main interface, click the "Search" icon and enter the search interface (see Fig.8). Searching has two ways: No. and ID number. Number query is system default. But you can click on "Inquire ID" and switch to the "Inquire ID" interface.

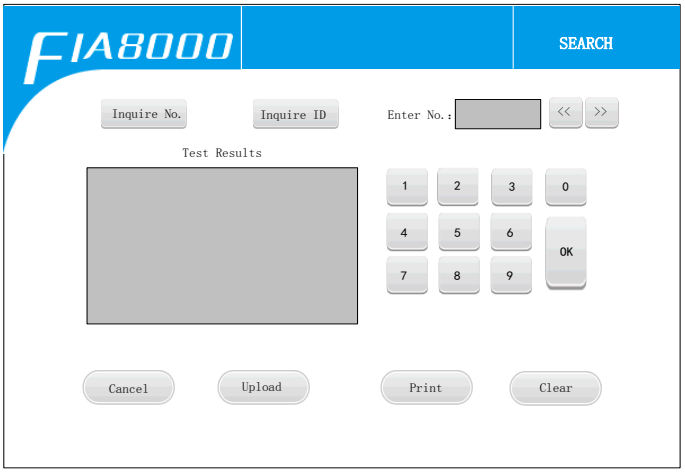


Fig.8 Search display interface

Operation:

1. Touch "Search" icon to enter search interface (see Fig.8);
2. Click on the number " 0~9 " icons, enter the No. or ID number you want to search;
3. Click on the "OK" icon to begin search. Search result shown as Fig.9;
4. Click on the "Print" icon to print the current search result.

Note:

1. The analyzer has a capacity of 10000 samples results, therefore, you cannot enter more than 10000 items when queried.

2. If no search results shown, "No Results" dialog box will show.
3. Click on the “《 ” or “ 》” icon to see previous or next search results.
4. Click on the "Clear" icon, you can clear the search information, re-input the number you want to search.

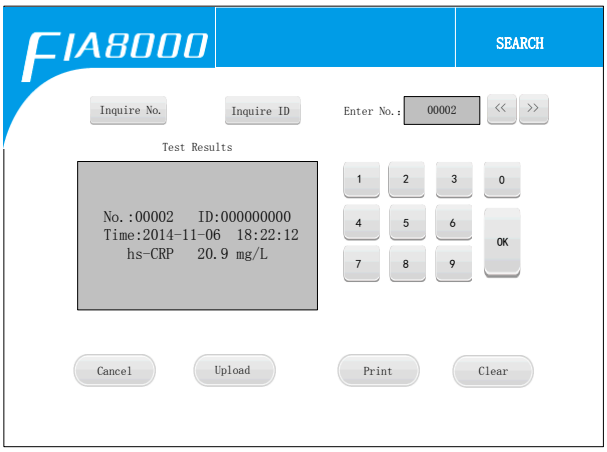


Fig.9 Number search interface

7.5 Shutdown action

The power switch can be used to shut off the machine directly at any interface.

8. Settings

Operation system will be set up by manufacturer. Considering customers’ convenience, many parameters can be reset to meet different requirements of different laboratories.

8.1 System settings

Click on the "Settings" icon in the main interface and enter "Settings" interface(see Fig.10). Settings interface includes: "Auto Upload/Auto Lis", "Auto Screen", "Auto Print", "Auto Scan", "Auto Beep", "Date & Time", "Reset", “Screen Cal", “About", “Brightness" and "Sleep".

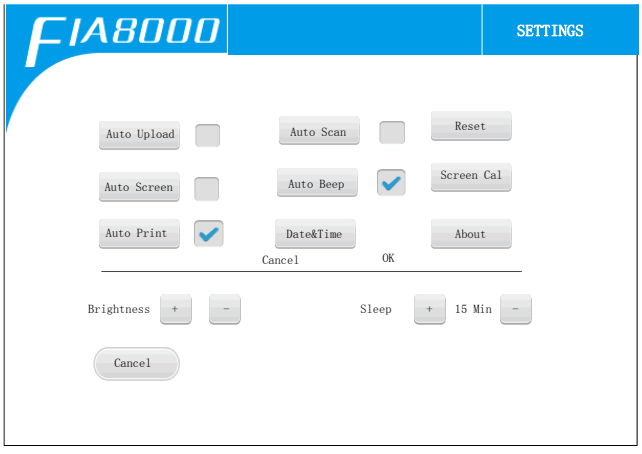


Fig.10 System settings interface

8.1.1 Auto Upload/Auto Lis

“Auto Upload/Auto Lis” presents the current status of Auto upload/Auto Lis, “√” means the status of Auto upload/Auto Lis is on, otherwise, it means off. You can click “Auto Upload/Auto Lis” to convert the status.

The default status of "Auto Upload/Auto Lis" is "off". "Auto Upload/Auto Lis" function can process measurement data collected by inferior machine and upload these data to PC software system. PC software will store, search and print these data.

8.1.2 Auto Screen

“Auto Screen” presents the current status of Auto screen, “√” means the Auto screen is on, otherwise, it means off. You can click “Auto Screen” to convert the status.

When the status of “Auto Screen” is on and no operation is taken within a defined time, system will close the screen backlight and enter screen-saver mode. Click any area of the screen or any keys to recover.

8.1.3 Auto Print

“Auto Print” presents the current status of Auto print, “√” means the Auto print is on, otherwise, it means off. You can click “Auto Print” to convert the status.

System default of “Auto Print” is “on”. Machine will print the testing data automatically when it is on, otherwise, it won’t. You can also print the data manually.

8.1.4 Auto Scan

“Auto Scan” presents the current status of Auto scan, “√” means the Auto scan is on, otherwise, it means off. You can click “Auto Scan” to convert the status.

When the status of “Auto Scan” is “on”, click "Measure" icon on the measuring interface, “Scanning” will appear which represents that it is waiting to be scanned (as shown in Fig.11). At this time, you can scan the barcode to start the test or click “Measure” icon again to skip this step. After barcode scanned, barcode value will display in the right box of “Barcode”, barcode value will be uploaded to the PC software system and display in the test results.

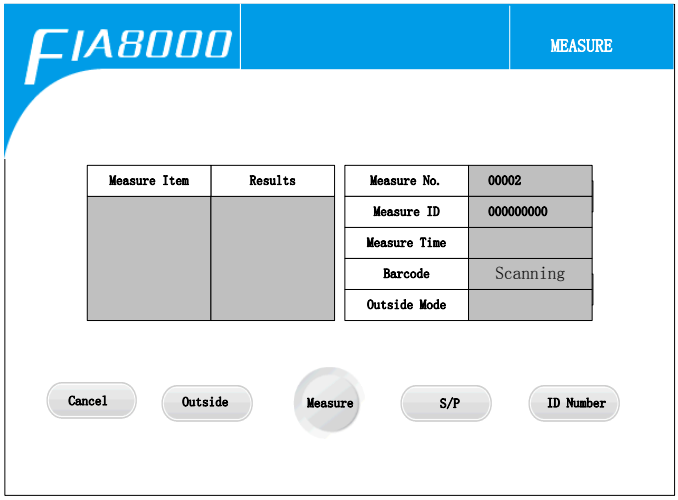


Fig.11 External barcode scanning interface

8.1.5 Auto Beep

“Auto Beep” presents the current status of Auto beep, “√” means the Auto beep is on, otherwise, it means off. You can click “Auto Beep” to convert the status.

When the "Auto Beep" is on, you will hear the sound of the keys when you click them.

8.1.6 Date & Time

"Date & Time" is mainly used to adjust the time.

In the interface showed as Fig.12, Click "+" to add time, click "-" to reduce time. Click "OK" to save these changes and back to the previous interface, click "Cancel" icon to cancel the time setting and back to the previous.

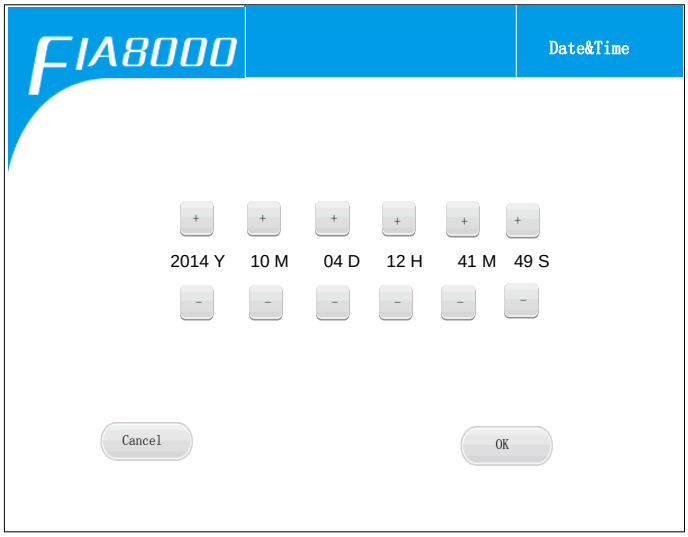


Fig.12 Date & Time interface

8.1.7 Reset

If setup parameters have a difference or when you need to debug, you can choose to restore the "Reset". It is not suggested to use “Reset” unless operated by professional and technical personnel.

Click the "Reset" icon as shown in Fig.13 interface, then a dialog box pop out and shows "Factory Reset?", Click "OK" to restore the factory settings, then "Factory Reset Success" will pop out (see Fig.14). Click on "Cancel" icon and exit this interface.

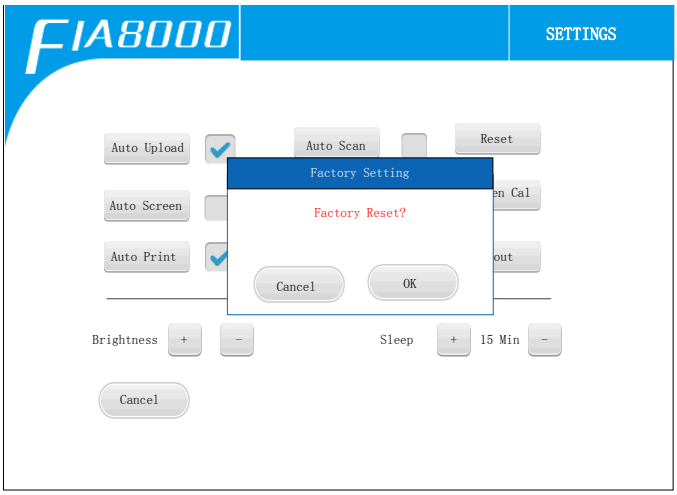


Fig.13 “Factory Reset” interface

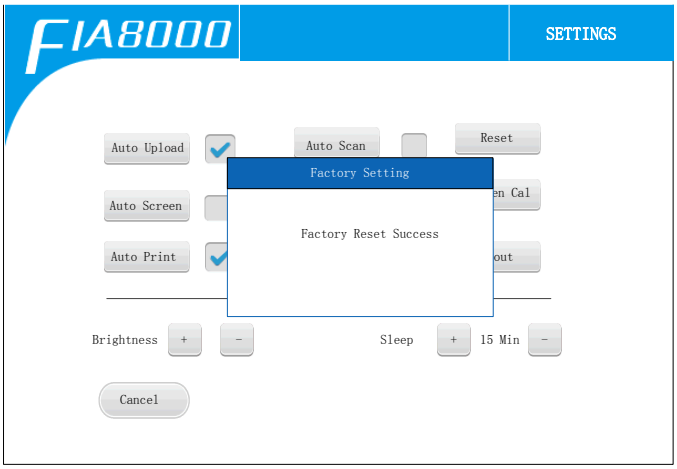


Fig.14 “Factory Reset Success” interface

8.1.8 Screen Cal

The subtitles position may shift when the analyzer is used for a long time, at this time you can re-calibrate the screen.

Click on the "Screen Cal" icon and enter the interface of Fig.15, click on the cross center on the screen according to the instructions. Five points located in the four corners and the center of the screen, when five points have been calibrated, the system will automatically

determine the deviation. If the deviation is too big, the system will calibrate again until meet the requirements (Fig.16). Touch the screen at any place to exit the calibration interface.

Fig.15 Screen calibration interface

Fig.16 Calibration complete interface

8.1.9 About

Click on the "About" icon to check the program version, as is shown in Fig.17.

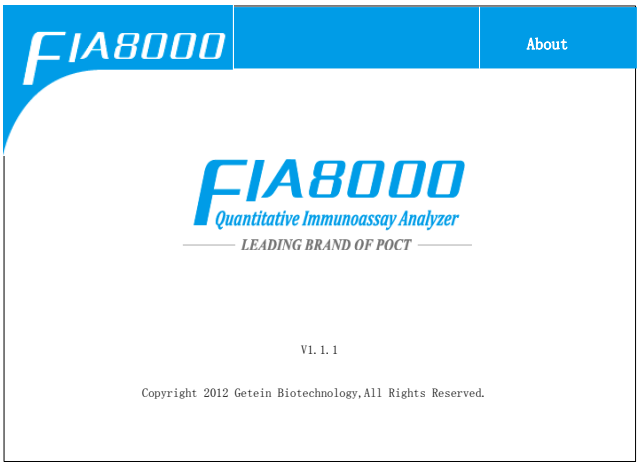


Fig.17 Software version interface

8.1.10 Brightness

"Brightness" is mainly used for adjusting the brightness degree of screen, click "+" to increase brightness of screen; click "-" to reduce the brightness of the screen, which can be set according to user's preference.

8.1.11 Sleep

The analyzer will automatically turn off the screen backlight if no operation was done for a period of time and switch into power-saving mode. Click on the "+" to increase the auto screen time, click on the "-" to reduce the auto screen time, and time range can be set between 1~60 minutes.

8.2 QC CHECK

"QC Check" include: "QC(SD), "QC kit" and "Reaction Time", "(No.)Zero", Manual calibration" and so on, as shown in Fig.18:

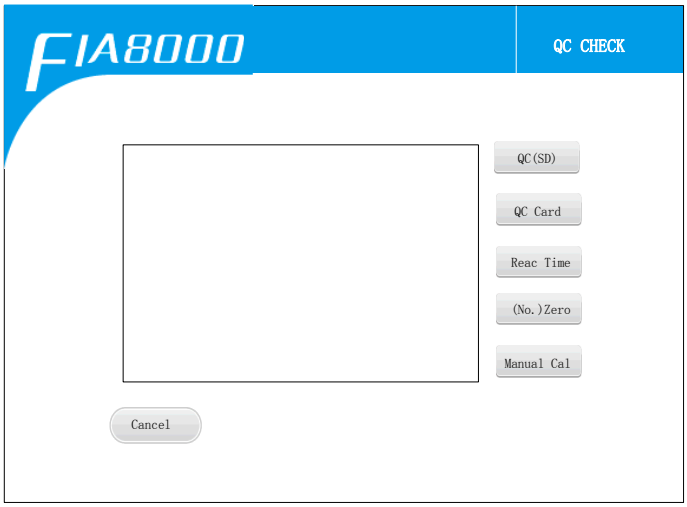


Fig.18 Quality control interface

8.2.1 QC (SD）

In order to ensure the accuracy of measurement and the comparability of measured data, use the corresponding SD cards of different batches to calibrate the analyzer before test different batches of kits.

Do as the following introduction:

Click on “QC Check” icon on the main interface and enter QC CHECK interface, then touch "QC(SD)" icon, as shown in Fig.19, then "Please Insert SD" dialog will pop out; When SD card is properly inserted into the slot, press the “OK” icon to do the quality control (as shown in Fig.20)：

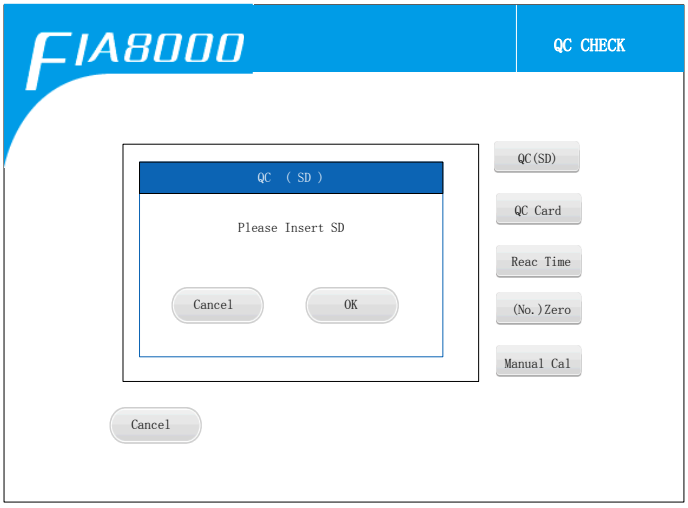


Fig.19 Plug in SD interface

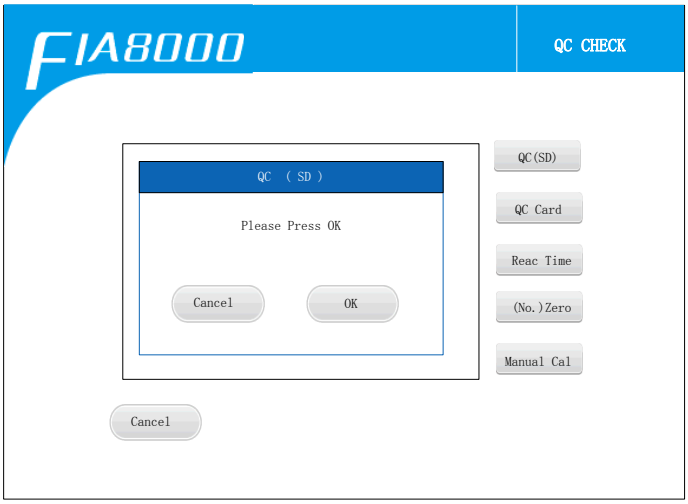


Fig.20 Proper insert SD interface

Click on "OK" icon, the screen will show "Loading" status (as shown in Fig.21). This procedure must not power off as to avoid losing data and failure of quality control;

"QC (SD) Success" or "QC (SD) Failed" dialog box will pop up after SD card is read (as shown in Fig.22 (a) and Fig.22 (b)). After the success of quality control, the parameter will automatically store in the analyzer system; if quality control is failed, please check whether the SD card is inserted properly or something is wrong with SD card and so on.

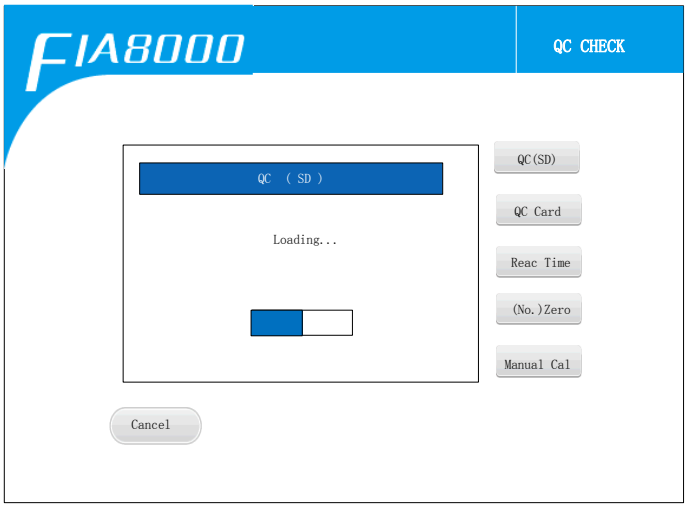


Fig.21 Quality control (SD) read interface

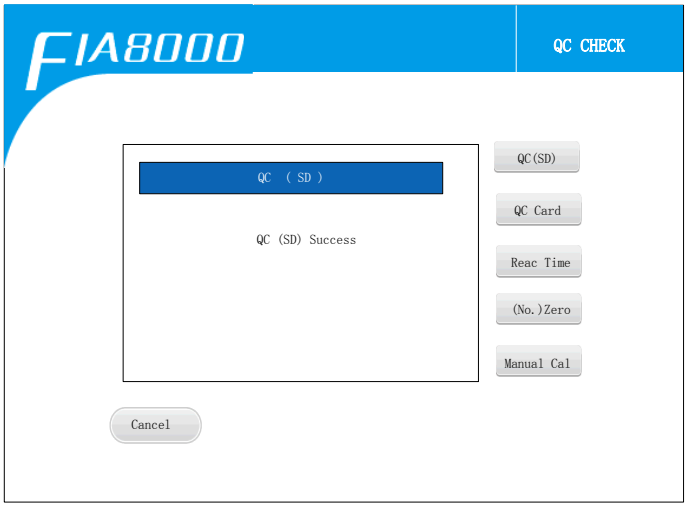


Fig.22 (a) Quality control (SD) success interface

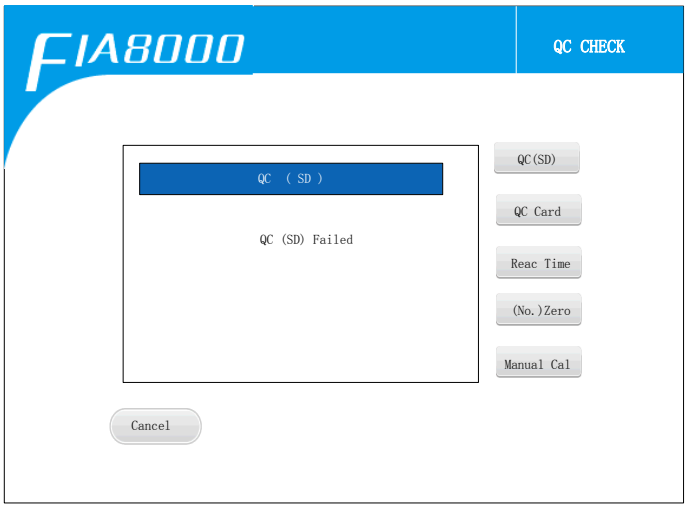


Fig.22 (b) Quality control (SD) failed interface

8.2.2 QC card

In order to ensure the accuracy of measurement and the comparability of measured data, the optical part of the analyzer also need to calibrate on a regular basis. Click on the "QC card" icon as shown in Fig.23 interface, the dialog box of "Please Insert QC card" will pop up. After you insert QC card, click on "OK" icon, internal parameter of the system will calibrate the analyzer (see Fig.24). If the light intensity falls in the normal range, the calibration is successful (see Fig.25), otherwise indicates failure as shown in Fig.26.

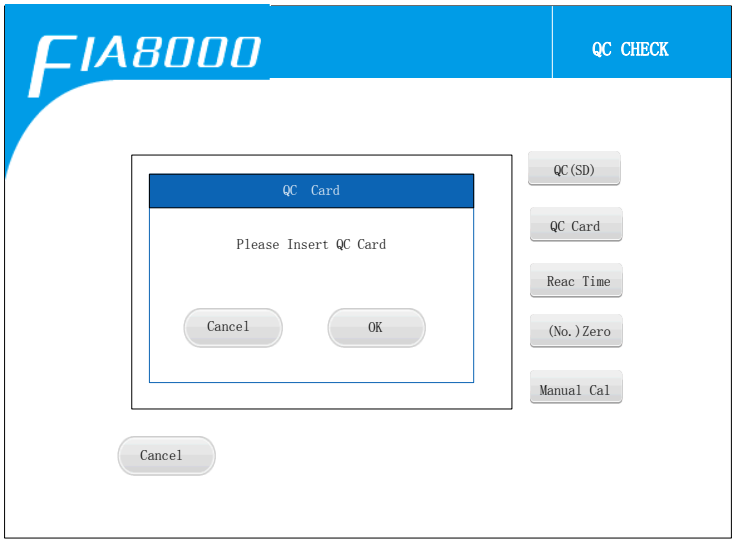


Fig.23 Please Insert QC card interface

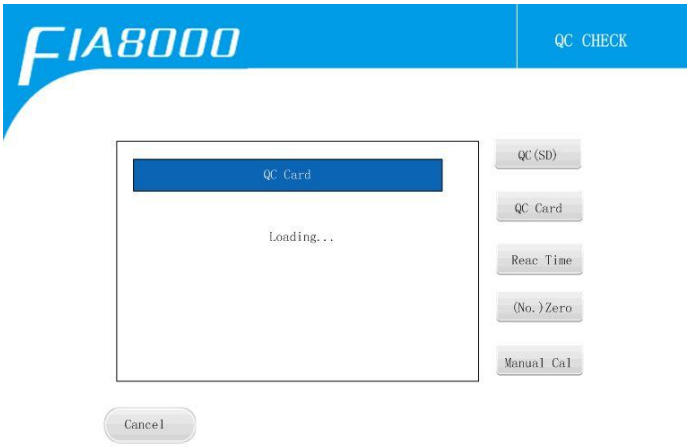


Fig.24 Quality control card reading interface

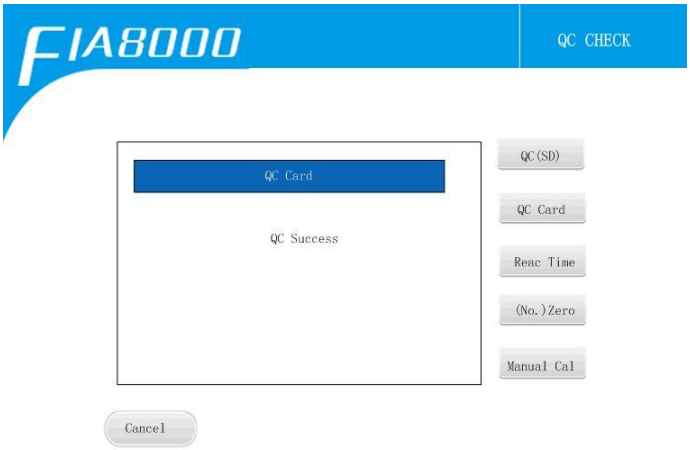


Fig.25 QC success interface

Fig.26 QC failed interface

8.2.3 Reaction Time

Desired reaction time can be manually adjusted in the interface of "Reaction Time" through time display panel. "Reaction time" settings as shown in Fig.27, the system

default time of all test items shows the normal reaction time. "+" and "-" icon on the left and right side of test item respectively, click "+" to increase the reaction time; click"-" to reduce the reaction time.

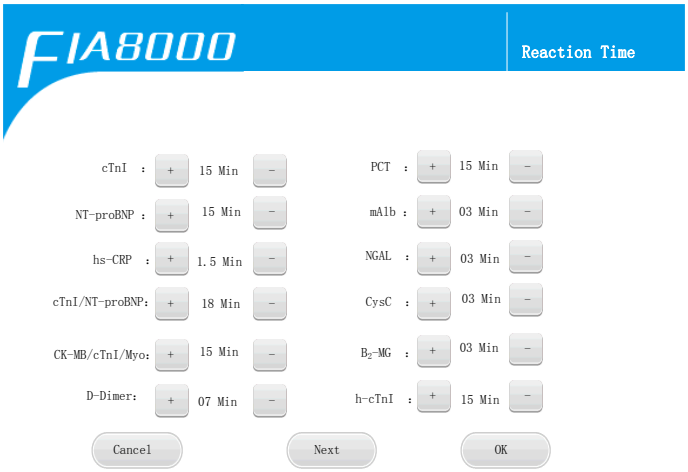


Fig.27 Display board interface

8.2.4 (No.) Zero

The "(No.) Zero" function allows you to record No. of tests and count from zero. Click the "(No.) Zero" as shown in Fig.28 interface and continue to click "OK" to achieve (No).zero, as shown in Fig.29.

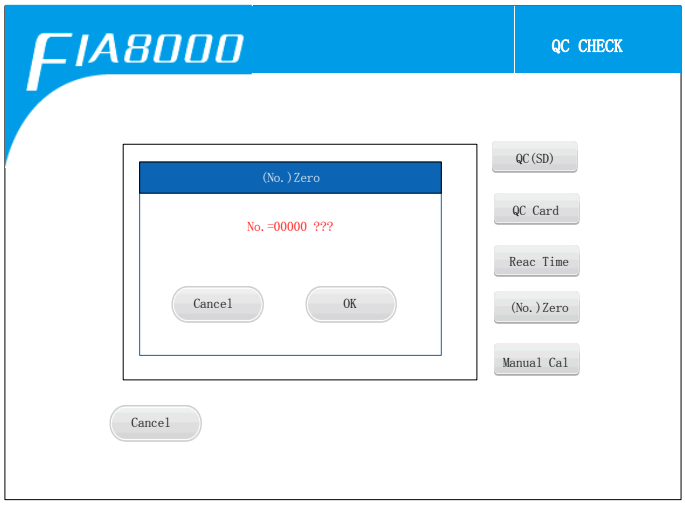


Fig.28 Zero (No.) interface

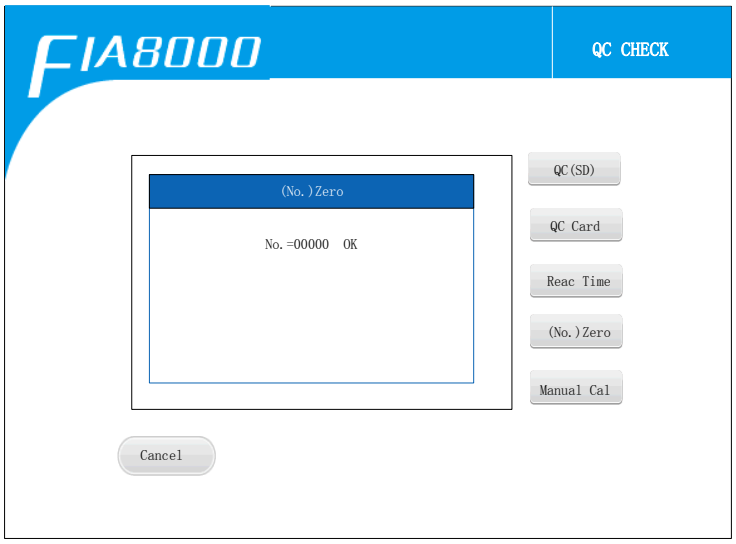


Fig.29 Number zero success interface

8.3 Debug interface

Debug interface is only used for factory debug.

9. Communication

9.1 Overview

Upper Computer Software of FIA8000 Series Quantitative Immunoassay Analyzer (hereinafter referred to as the PC software) can communicate with and transfer data and the set parameters to FIA8000 Series Quantitative Immunoassay Analyzer, it also can display real-time circumstance of the Analyzer. PC software also can be used to build, modify and save user database, search and browse, data statistics and backup. When use PC software during test some items with FIA8000 Series analyzer, the user can real-time observe experimental status and receive experimental data. When the test finished, user can input patients' information and browse, print the patient's test report.

9.2 Software version

Software name: Upper Computer Software of FIA8000 Series Quantitative Immunoassay Analyzer

Model: FIA8000

Version: V1.1.0

9.3 Environmental requirements

Hardware environment:

CPU ≥ Pentium II; RAM ≥ 1000MB; Hard disk ≥ 10GB

Display: resolution is no less than 1024×768

Printer: resolution is no less than 600×600dpi

Software environment:

Windows XP / Win7

9.4 Analyzer maintenance and troubleshooting

9.4.1 Analyzer maintenance

a. Please operate the analyzer following the requirements of the instruction manual, to ensure the reliable long-term work.

b. Calibrate the analyzer periodically by QC card to ensure the results accurate.

c. Preheat the analyzer for 20 minutes before testing samples to ensure the results accurate and reliable.

d. Analyzer should be placed in stable temperature, dry place.

e. Wipe the surface of analyzer gently with a clean dry cloth regularly.

f. Do not try to disassemble the analyzer. Operation done by laypeople may damage the analyzer.

9.4.2 Troubleshooting

If there is an abnormal circumstance occur when operating the analyzer, the analyzer will perform the alarm process, and enter the alarm interface. The name, explanation, and treatment measures of alarms are showed in the following.

Err01: Display board is invalid and C Line on the strip is too shallow or no C Line; the solution: Change a new card.

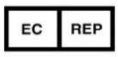
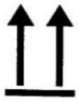
Err02: Inconsistent measurement items and samples; the solution: switch sample mode, re-measure.

Err03: The barcode on the card surface failed to be identified; the solution: Change a new card with a clear barcode.

Err05: Internal parameters error; the solution: Re-QC (SD) or Reset.

If you have any questions regarding the use of this analyzer, please contact with local agents or contact with Getein's service engineer directly.

10. Labeling Symbols

Labeling Symbols			
	Manufacturer		*In vitro* diagnostic medical device
	Consult instructions for use		Authorised representative in the European Community
	Caution, consult accompanying documents		Biological risks
	Serial number		CE Marking
	Symbol for “Environment protection– Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice”		Keep away from sunlight
	This way up		Keep away from rain
	Fragile		Maximum number of identical packages which may be stacked on one another is “4”

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Version: WYQ8600-SM-XX-02