Fluoescence Immunoassay Analyzer

User Manual

AFR-300/300S

Contents

Chapter 1 Introduction

1.1 Intended Use

Fluorescence Immunoassay Analyzer is an analyzer that based on detection of fluorescence emitted during an immunoassay with antigen-antibody interaction. The analyzer is designed to provide quantitative or qualitative test results by the examination of human samples with specific *in vitro* diagnostic test units including Inflammation Markers, Tumor Markers, Nephrology, Diabetes, Cardiac Markers, Coagulation, Endocrinology, Autoimmunity, Infectious Diseases and etc. Fluorescence Immunoassay Analyzer offers the advantages of high accuracy, strong stability and fast results. Fluorescence Immunoassay Analyzer should only be used with *in vitro diagnostic* tests manufactured by Hangzhou AllTest Biotech CO., Ltd. as per package insert provided with specific test kits.
For professional and Point of Care Use.
Please read this User Manual carefully before operation.

1.2 Scope of Application

Analyzer works with certain fluorescent reagents. It's for *in vitro diagnosis* use by laboratory professionals only. It may be used in central laboratories of medical institutions, outpatient or emergency departments, clinical departments or medical services (such as community health centers), or medical center, etc. It can also be used in research laboratories.

1.3 Product Name

- **Product Name: Fluorescence Immunoassay Analyzer**

1.4 Software Description

1.4.1 Name and Version

Name：FIA
Version: V8.3

1.4.2 Software Installation and Operation Environment

Analyzer can be connected to a standalone computer or Laboratory Management System. Minimum Hardware and Software requirements are as follows.
- Minimum hardware requirements: Intel Pentium Ⅳ 1.0 GB processor, 1.0 GB memory, 10 GB space on hard drive
- Minimum software requirements:
  Microsoft Windows XP or Windows 7 or newer versions
  Microsoft Excel 2007 or newer versions.

Chapter 2 Components and Structure

2.1 Standard Equipment List

Packing List

No.	Description	Model	Quantity
1	Fluorescence Immunoassay Analyzer	AFR-300/300S	1
2	USB cable and adapter	BS-12W0502000G7	1
3	QC ID Card	/	1
4	QC Standard Cassette	/	1
5	User Manual	/	1
6	Lithium Battery	1546-CT-1P1S18650-AB	2
7	Scanner	/	Optional
8	Printer	/	Optional

On receiving the box, please check the contents with this list and ensure that nothing is missing. Barcode Scanner and printer are optional accessories, which are available only for specific requirement and not as standard accessory.

Note: If some parts are missing or damaged, please contact with local distributor.

2.2 Fluorescence Immunoassay Analyzer

The external appearance of the analyzer and accessories should be based on the actual product.

2.2.1 External View (Ref Fig 1, Fig 2)

LCD Touch Screen

Home Button

COM Port

Test Cassette Slot

Fig 1

Built-in Battery

ID Card
Port
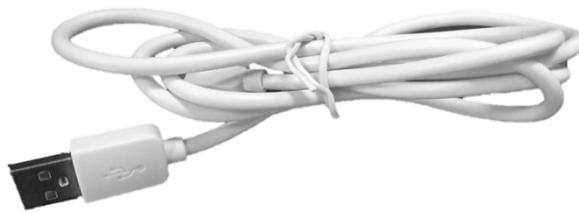
USB
Port

Fig 2

2.2.2 USB Cable（Ref Fig 3）

Fig 3

2.2.3 QC Card

QC ID card and QC Standard Cassette provided with the analyzer are used for the quality control of the analyzer. (Ref Fig 4, Fig 5)
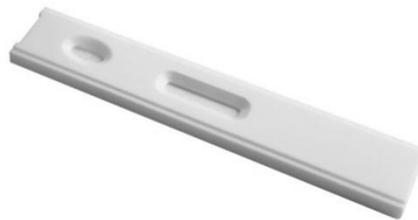

Fig 4

Fig 5

2.2.4 Bluetooth scanner

Scanner provided with the analyzer is shown as Fig 6.

Fig 6

Chapter 3 Parameters and Conditions

3.1 Checklist upon Opening the Box

3.1.1 Check before opening the box:

Before opening the box, check the packaging is in good condition and box was not damaged during transportation.

3.1.2 Check after opening the box:

① Open the box carefully, check the contents according to *2.1 Standard Equipment List* to ensure it is complete.

② Examine the analyzer power adapter to see whether it is in good condition. If any defects are found, please contact the manufacturer or local distributor.

Note-1: Please keep the analyzer's original box and packing materials for any future shipping/reference purpose.

Note-2: AllTest strives to provide the right kind of power plug suitable for each country. However, in some cases, it may not be possible. Using right kind of adapter to connect to power is recommended in such cases.

3.2 Technical Specification

•	Principle	Fluorescence Immunoassay
•	Test formats	Cassette
•	Measurement	Quantitative, Qualitative
•	Read Time	< 20 seconds
•	Test Time	Ref: Analytes
•	Specimen	Ref: Package Insert
•	Power Source	2*3400 mAh
•	Dimensions	220 mm (Length) × 100 mm (Width) × 75 mm (Height)
•	Weight	< 1.5kg
•	OS	Windows-Compatible proprietary program
•	Excitation light source	LED
•	Memory	4000 records
•	Spectrum	Excitation spectrum: Mean wavelength λ0=365nm Reception spectrum: Mean wavelength λ1=610nm
•	Connecting Ports	RS232, USB
•	Storage Conditions	-10-40℃, relative humidity: 20% to 90%, atmospheric pressure: 86 to 106 kPa; and in a ventilated environment free of corrosive gases. Measures should be taken to avoid moisture, and prevent impact and severe vibration during transport.
•	Operating Conditions	4-30℃
•	Repeatability	CV≤10%
•	Stability	CV≤10%
•	Scanner (Optional)	Bluetooth Scanner

3.3 Placement

① The analyzer should be placed on a stable and level countertop, and in an indoor environment free of dust, direct sunlight or corrosive gases. The countertop must be able to sustain a weight of 1.5kg.
② No strong vibration source and strong electromagnetic fields around.
③ The analyzer should be placed in a well-ventilated place. There should be at least 10cm space around the analyzer to ensure the necessary space for operation and maintenance.

3.4 Environmental Requirement

- Surrounding temperature: 4~30℃;
- Relative Humidity：20% to 90% RH;

  Avoid strong magnetic field, vibration, shock, corrosive gases, direct sunlight, high humidity, and high temperature in working area, where the analyzer is placed for operation.

3.5 Power Supply Voltage Requirements

The power supply of the analyzer is 2*3400 mAh DC supply. Avoid short circuit and electric shock during the use.

Chapter 4 Analyzer Installation

Please use the analyzer under the proper conditions mentioned in *3.4 Environmental Requirement.*

● Analyzer Charging

The **Analyzer** should be connected to computer with USB cable for charging, and the power will be displayed in upper right of the screen.

Note: Before turn on the analyzer, the batteries should be fully charged, and the charging time should be 3-8 hours. Be sure to keep the remaining power and charge it in time. Be careful not to overcharge or over discharge, otherwise batteries will be damaged and the analyzer will not work properly.

● Turn on the analyzer

Click the Home Button to turn on the analyzer, and enter to the initialization interface. (Ref Fig 7)

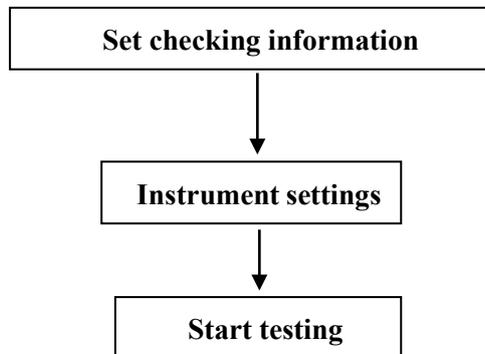**Note:** Please remove the insulating sheet in the battery slot before starting up.

Fig 7

● Turn off the analyzer

Press the Home button until turn off the analyzer.

Chapter 5 Directions for Use

The Fluorescence Immunoassay Analyzer can be operated by commands on touch screen or by keys below the screen.

Generally, the operations for analyzer with default factory settings are as follows.

```
┌─────────────────────────────────┐
│   Set checking information      │
└─────────────────────────────────┘
              │
              ▼
┌─────────────────────────────────┐
│      Instrument settings        │
└─────────────────────────────────┘
              │
              ▼
┌─────────────────────────────────┐
│         Start testing           │
└─────────────────────────────────┘
```

5.1 Operating Instructions for Touch Screen

Press the Home button to turn on the Analyzer, the analyzer will initialize and have self-testing as Fig 8.
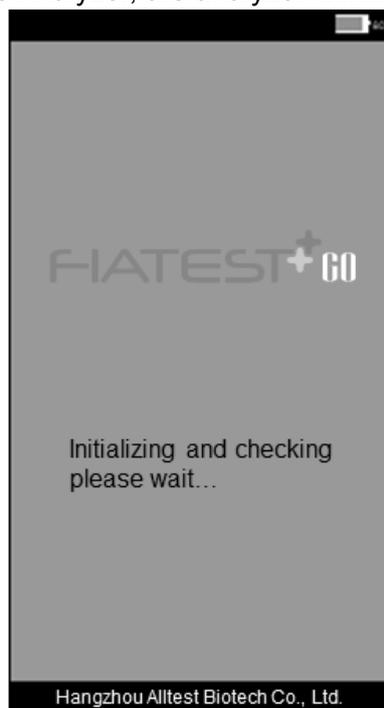

Fig 8

After initializing, Ready Screen would show as in Fig 9. The analyzer self-test result will be displayed. If passed, click the blank area to enter the main interface as Fig 10.

Note: if the self-test failed, it also can enter the main interface by clicking the blank area. But it is recommended to contact the manufacturer or the local distributor.
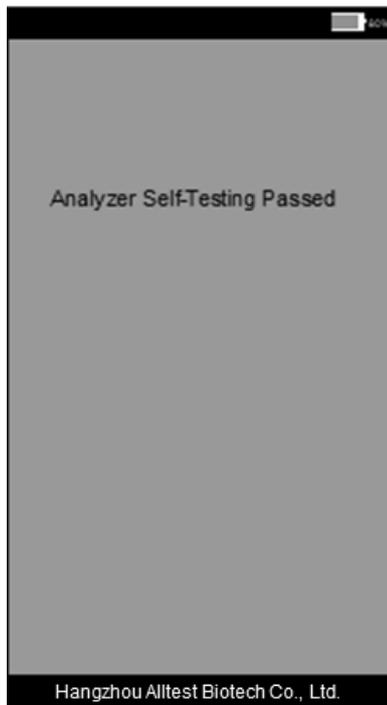
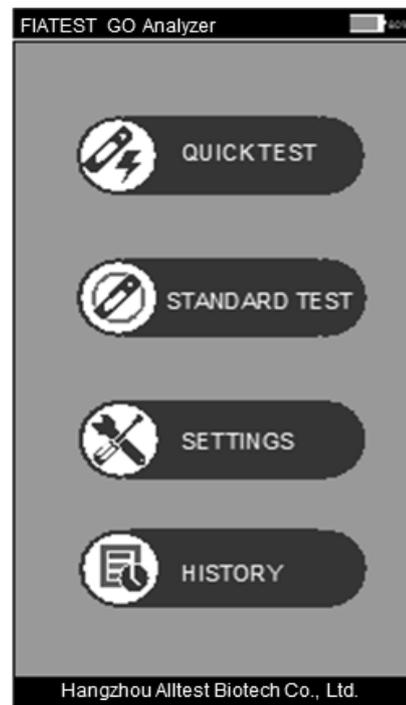|	
Fig 9	Fig 10

Main operation interface of the analyzer. Here you can choose the **quick test** (Incubation outside), **standard test** (Incubation inside the analyzer), **settings** and **history**.

5.1.1 Different Operations

Once you start operating the analyzer, there would be two kinds of operations

A. Auxiliary operations: These are the operations, which check the Quality Control and/ or other information about the system and the analyzer, such as history.

B. Core Operations: These are the operations, which are used to run the tests.

Section *5.1.2* gives information on auxiliary operations, while sections *5.1.3 and 5.1.4* give information on core operation

5.1.2 Setting

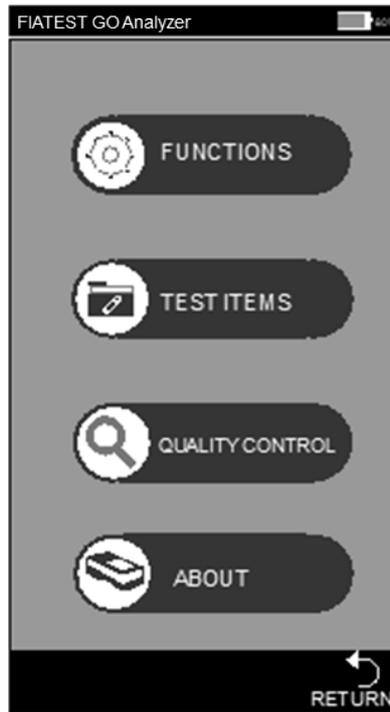Click "**SETTINGS**" to enter the interface as Fig 11

Fig 11

● **Functions**

Press "**FUNCTIONS**" and enter into the interface. (Ref Fig 12)

The functions of Built-in barcode and Auto print can be chosen if needed. The clock and date also can be changed in the interface. The information of operator can be added in this interface. If the analyzer is connecting to outside printer or a Bluetooth scanner, Auto-Print and Bluetooth are recommended to be turned to "On" position by tapping off/on area.
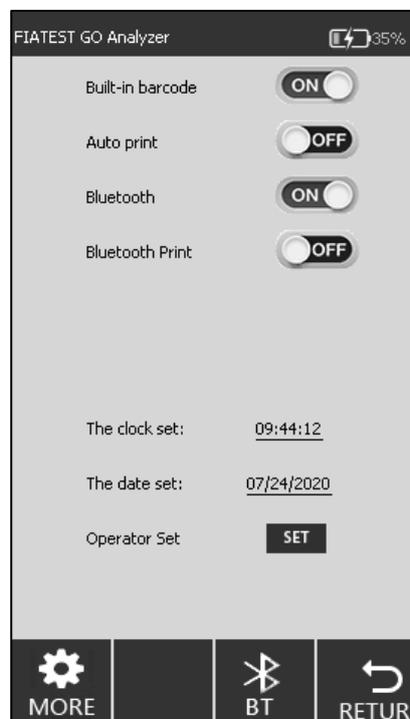

Fig 12

Bluetooth scanner connection settings:

1) Bluetooth setting:

Click"**SETTINGS**" → "**FUNCTIONS**", and turn the "**Bluetooth**" function **ON**, the **BT** icon ⬛ will be displayed on the bottom of the interface, shown as Fig 12. Click the **BT** icon will enter the Bluetooth connection interface, shown as Fig 13.
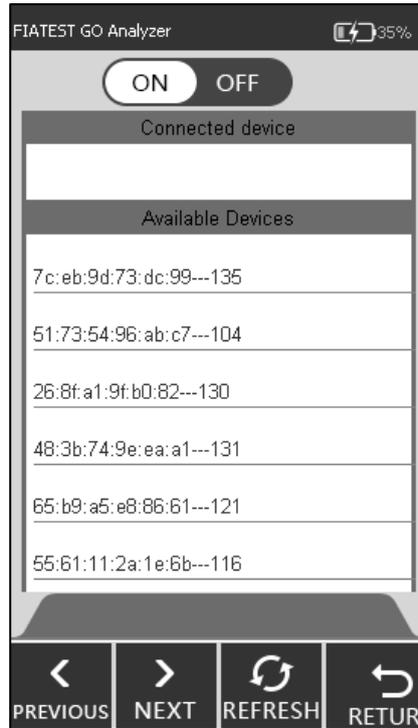

Fig 13

2) Scanner setting:
Remove the scanner and the user manual from the box, before using the scanner, please read the user manual first.
Note: The user manual has English and Chinese versions, choose the corresponding format to read according to your requirement.
Step 1: Bluetooth pairing step(refer to the user manual)
Choose **Mode 2**, press the the scanner blue button, scan the three barcodes in Mode 2 *in turn*, the indicator light will flash blue and green alternately.
Step 2: Communication mode switching(refer to the user manual)
Scan the (A)Entry setting mode barcode, choose and scan the (B) **Bluetooth BLE mode barcode**, and then scan the Exit setting mode barcode, the indicator will flash blue light.
3) Connection
Make sure the analyzer Bluetooth is turned on, shown as Fig 13, click **REFRESH**, the scanner bluetooth will be found and then the analyzer and the scanner will automatically be paired and connected, shown as Fig 14, a "beep" will be heard and the indicator light will keep blue.
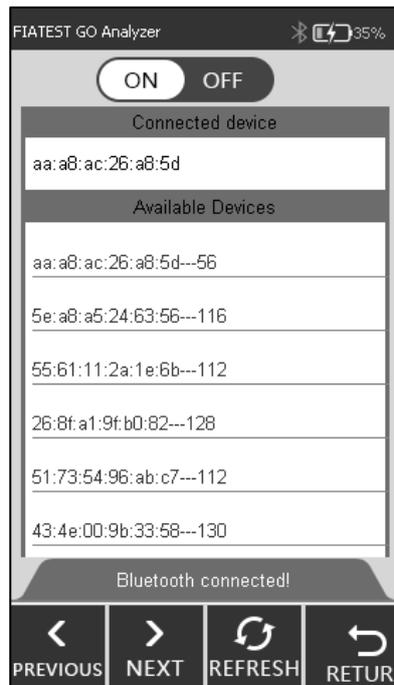After the successful connection, the scanner can be used.

Fig 14

Note:

1) If the scanner is not used within about five minutes, it will automatically shut down, and   two "beeps" will be heared . User can press the blue button and it will be connected again.
2) Please use the provided cable to charge the scanner.

Time and Date settings:

Click "**The clock set**"/ "**The date set**", fill the information of clock/date in the interface of Fig 15， Fig 16.

Fig 15

Fig 16

The procedure of adding operator:

Click "**SET**" to enter the interface as Fig 17, the operator can be deleted, added and modified.

Fig 17

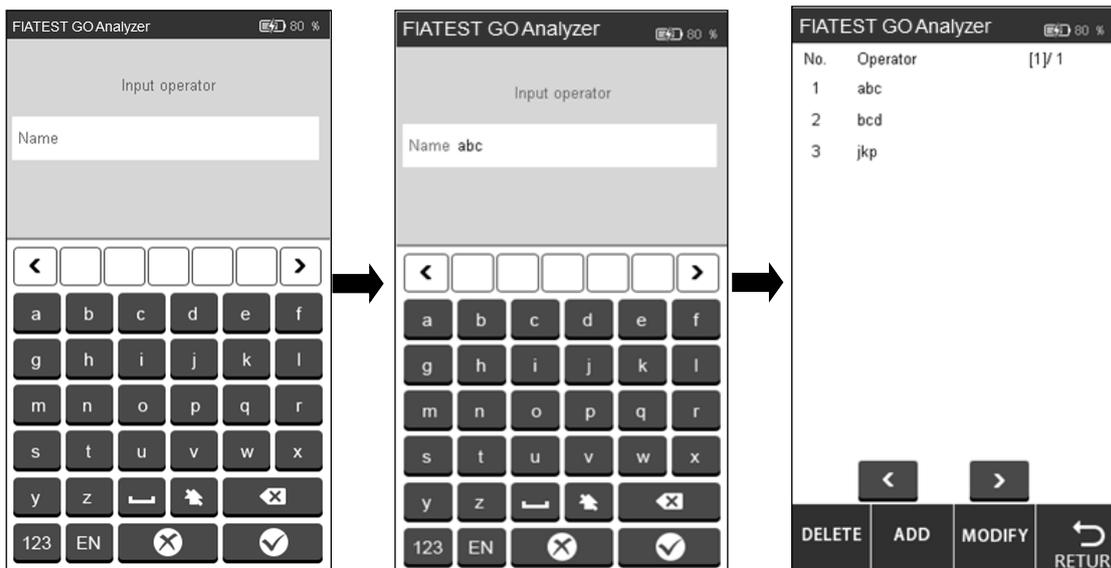Click "**ADD**", key in the operator name, click to complete the adding. (Ref Fig 18)

Fig 18

Click the operator which needs to be deleted or modified, and the color will be changed to blue. Click "**DELETE**", the selected operator will be deleted, click "**MODIFY**" to enter the interface as Fig 18.

Click "**RETURN**" to return to the previous screen.

● **Test Items**

Press "**TEST ITEMS**" to switch the interface as Fig 19

Insert the ID cards to the ID card slot one by one and the test items will be fed automatically, the selected item will show in gray color.
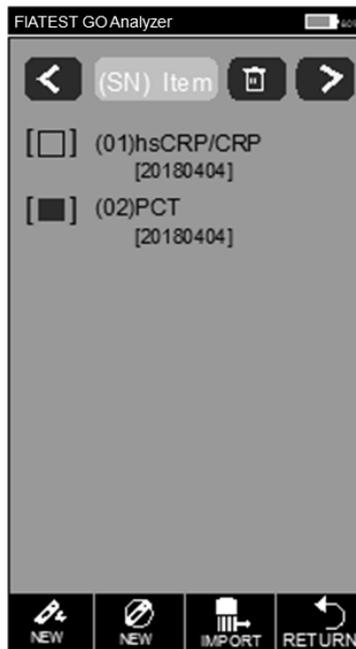
Fig 19

Click or to have a quick test or standard test directly, if the standard curve in the ID card is

not uploaded to the analyzer, click to upload.

- **Quality Control**

The analyzer guarantees quality and reliability of the analysis results only under the right conditions. The analyzer needs periodic quality calibration. Please perform the following procedures periodically to ensure the right performance of the analyzer. Press "**QUALITY CONTROL**". (Ref Fig 20)
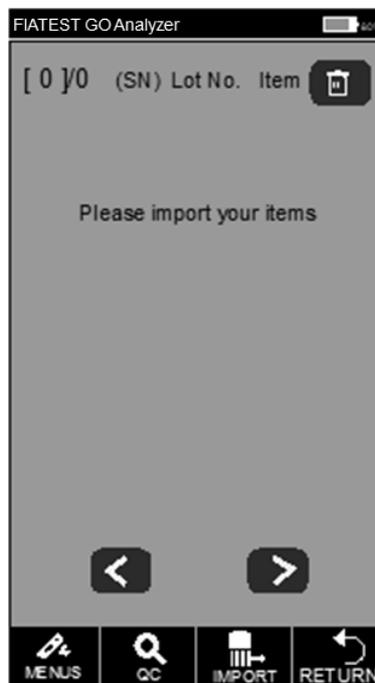

Fig 20

Insert the QC ID card into the ID card slot, then insert the QC standard cassette into the test slot.

Press "**QC**" Tab. The quality control testing interface will display as Fig 21 and Fig 22.
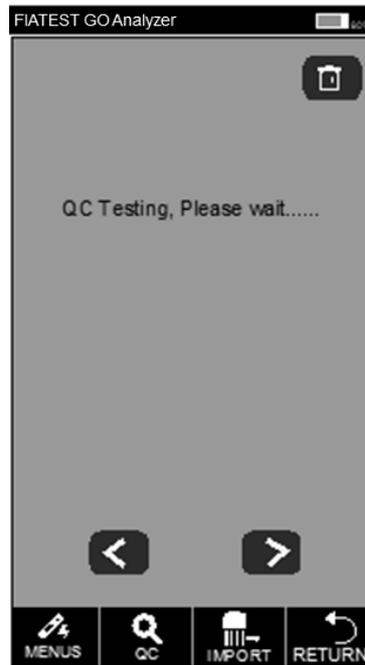
Fig 21   Fig 22

If the analyzer works properly after the quality control testing is completed, the interface prompts "**Passed**". (Ref Fig 23) Otherwise, it will display "**Failed**". (Ref Fig 24)
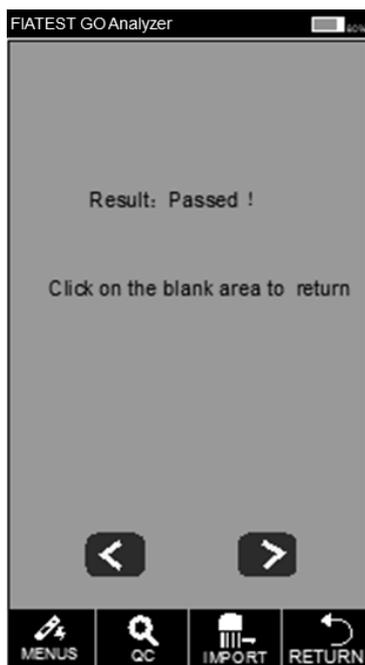

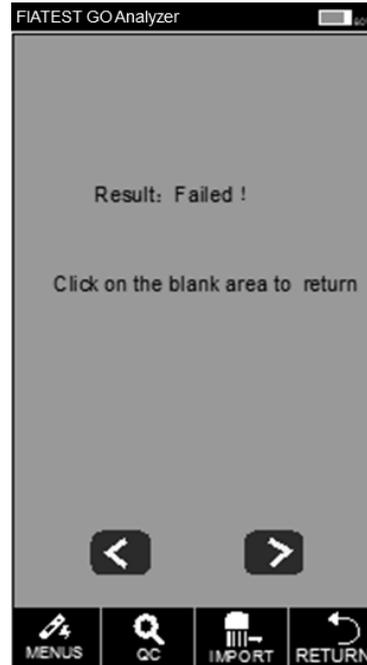Fig 23   Fig 24

If it shows "Passed", you can have the test continued, if "Failed" or "QC Testing, Please wait…"shows up, please do not test and contact the manufacturer or your local agent.

Note: It is recommended that the QC test should be done every 3 month at the normal circumstances.

● **About**

On tapping "**ABOUT**", you can get the following screen (Ref Fig 25). This screen gives the information about the Model, Software, Serial Code, GPRS Version and SIM number. This will also give you option to perform "**FACTORY RESET**".

WARNING: Do not tap Factory Reset, unless you have some problems with the analyzer. Tapping Factory Reset would lead to losing all the stored information such as the performed tests and values.

15

Factory Reset procedure is explained here for use in extremely rare situations, where Factory Reset is genuinely required. Remember to save all your data before tapping Factory Reset.
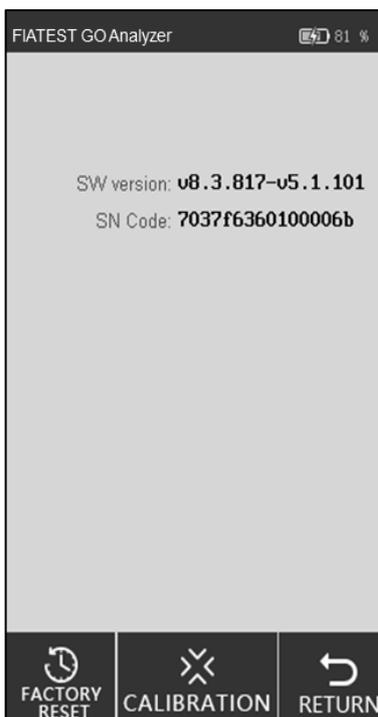

Fig 25

i.   Reset to factory settings

You can clear all data and restore to the factory settings by tapping "**FACTORY RESET**", as Fig 26. The analyzer will restart automatically after resetting.
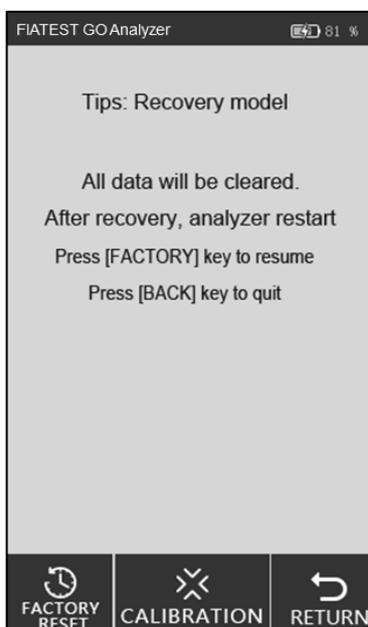

Fig 26

ii.   Calibration

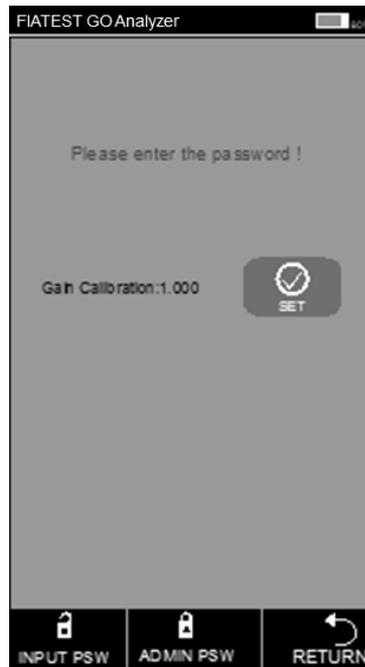Tap "**CALIBRATION**". You will see following interface. (Ref Fig 27)

Fig 27

This function is for professional technicians to debug the analyzer in cases of any malfunction

WARNING: Do not tap Calibration and go for Calibration without consulting with service team. This function is only for servicing or repairing after any malfunctioning of the analyzer.

5.1.3 Quick Test

In this mode, the incubation of the test cassette is done outside the analyzer. This mode can also be called Batch Mode as multiple tests can be done in one batch, without waiting for finishing incubation of one test after another. This Mode is suitable, when more than one test is to be performed as incubation time can be utilized for another test too.

Step 1: Turn on the power switch to start the analyzer.

Step 2: Insert the ID card of the analyte (Must be from Test Kit from which test cassettes are to be used. Use of ID card from another test kit may lead to erroneous results)

Step 3: Tap "**QUICK TEST**" or press the home button to switch to the testing interface. (Ref Fig 28)
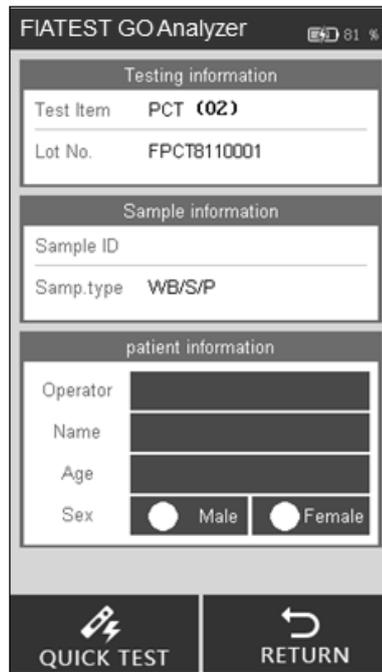
Fig 28

Step 4: Input Sample ID and patient information on the screen.

Scan the Sample ID by a scanner or tap the space beside Sample ID, key in the number and then press "√" to save. (Ref Fig 29, Fig 30)
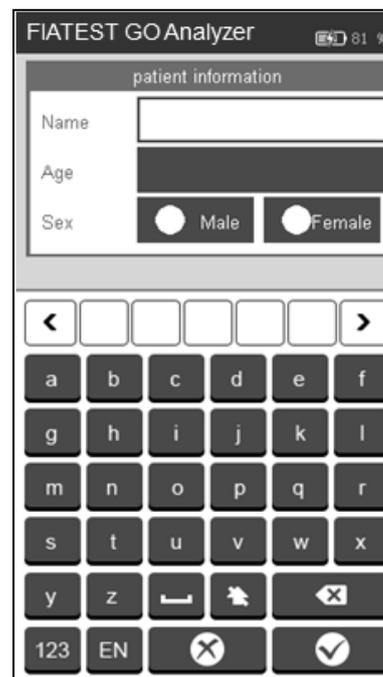

Fig 29

Fig 30

Step 5: Fill the information of patient, such as operator, patient name, age and gender. Tap the area besides operator, the interface will appear as Fig 31. Select the Operator. Feeding in Operator's Information is explained with Fig 18 in section *5.1.1*.
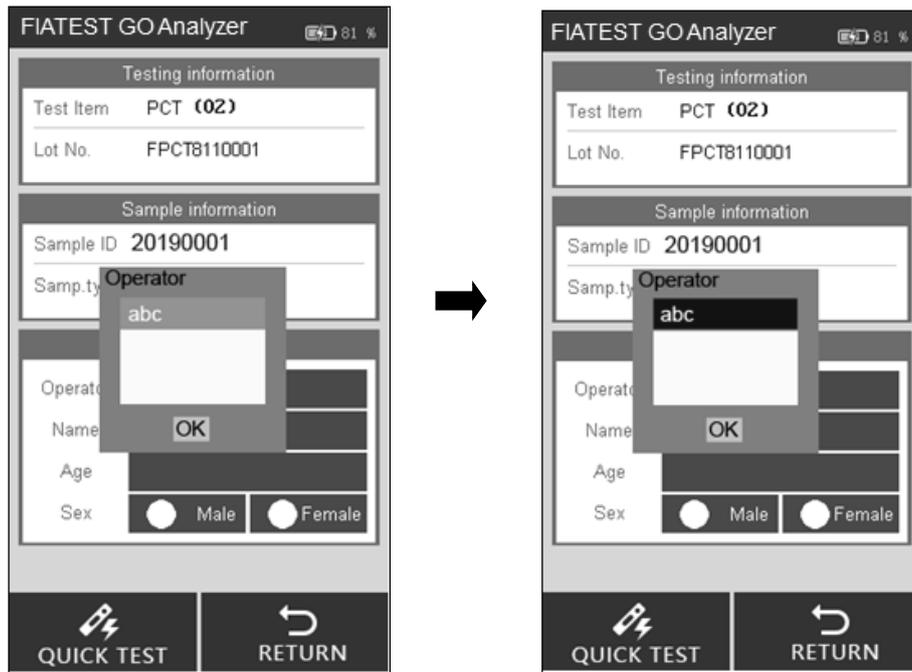
Fig 31

Key in or scan in the patient name and age, select the gender. (Ref Fig 32)
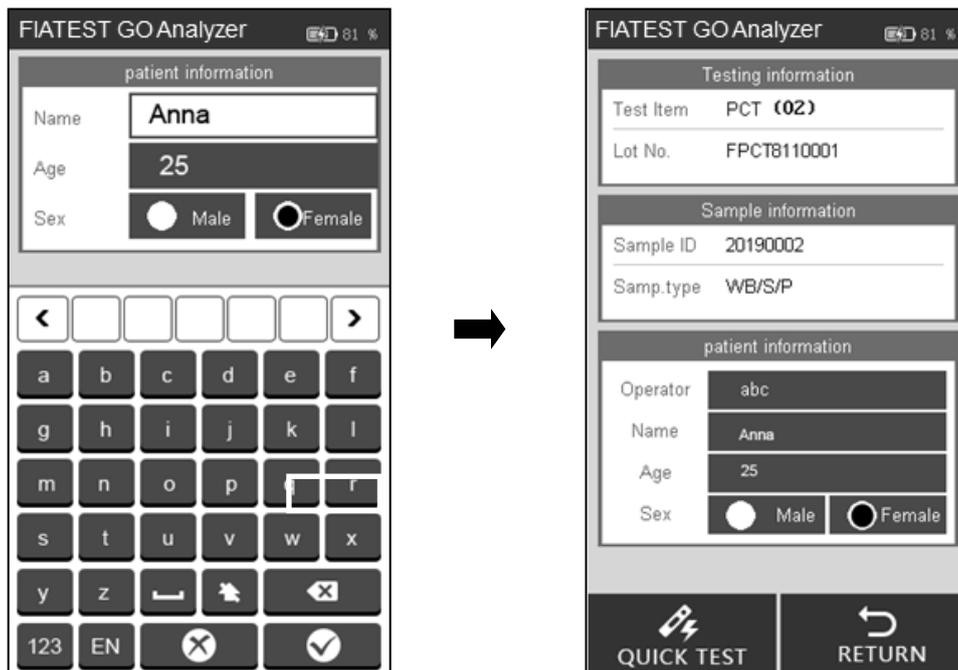

Fig 32

Note: The test can be performed without sample ID too. So in cases of emergency, if there is no time to assign the sample ID, this step can be omitted. Nevertheless, as part of good laboratory practice, assigning sample ID is highly recommended.

Step 6: Take out the test cassette and add the sample (and buffer, if required) to the test cassette as per the package insert and place the test cassette on a clean and flat surface by the side of the analyzer for the incubation time mentioned in the package insert.

Step 7: Insert test cassette (after incubation) into the slot and click "**Quick TEST**" or press the Home Button. (Ref Fig 33)

The process: Testing barcode -> testing ->receiving data ->calculating the result.
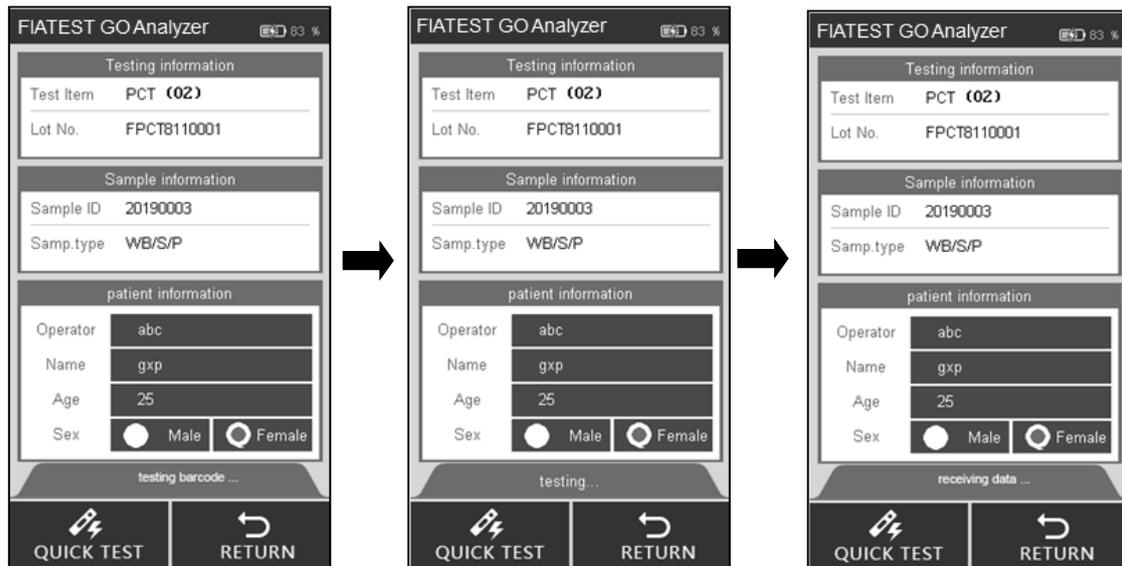
Fig 33

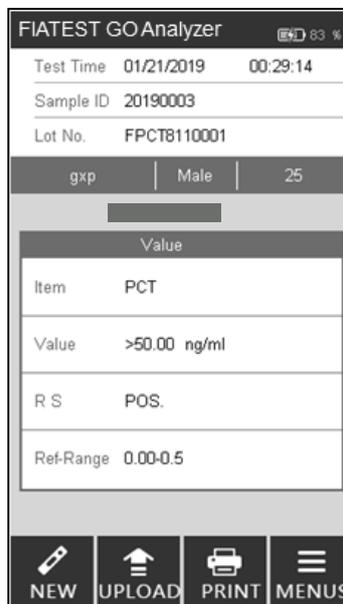**Step 8:** The results will display after testing. (Ref Fig 34)

Fig 34

Note: The test result will be uploaded to the PC if the analyzer is connecting to the PC with the USB cable.

5.1.4 Standard Test

In this mode, incubation of the test cassette is done inside the analyzer. This mode can also be called Single Test Mode (similar to Walkaway Mode). Once the new test is selected to be performed here and test cassette is loaded after sample addition (and if required buffer addition) in the test cassette slot, nothing more needs to be done. The user can walk away from the analyzer and perform other tasks. The results would be automatically available at the end of the incubation period, when the analyzer reads the results.

Step 1: Turn on the power switch to start the analyzer.

Step 2: Insert the ID card of the analyte (Must be from Test Kit from which test cassettes are to be used. Use of ID card from another test kit may lead to erroneous results)

Step 3: Tap "**STANDARD TEST**" to enter the testing interface.

Step 4: Select the Operator with the same method as Quick Test Mode.

Step 5: Input Sample ID and patient information on the screen with the same method as Quick Test Mode.

Note: The test can be performed without sample ID too. So in cases of emergency, if there is no time to assign the sample ID, this step can be omitted. Nevertheless, as part of good laboratory practice, assigning sample ID is highly recommended.

Step 6: Perform the test according to product's Package Insert.

Step 7: Insert test Cassette into the slot immediately after sample addition (and buffer addition, if required) and click "**STANDARD TEST**". The Analyzer will start to count down for incubation. Please wait for the pre-determined incubation time for each test. (Ref Fig 35)
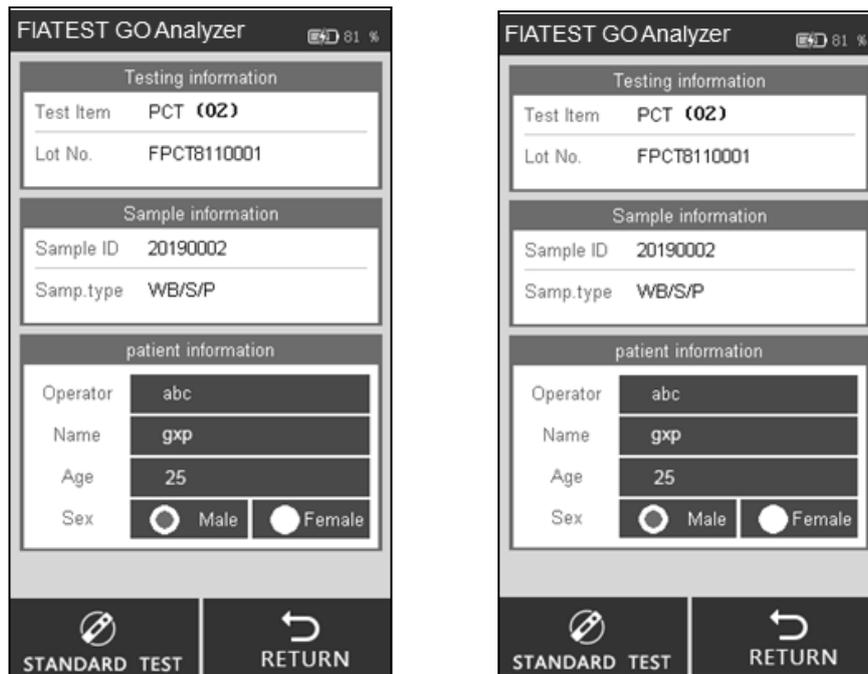

Fig 35

Step 8: The results will be displayed when test is completed. (Ref Fig 34)

5.1.5 History

Tap "**HISTORY**" to switch to the following interface. (Ref Fig 36)

Fig 36

● **History review**

Press "**HISTORY REVIEW**" to switch to the following interface. You can review all the historical data. (Ref Fig 37)
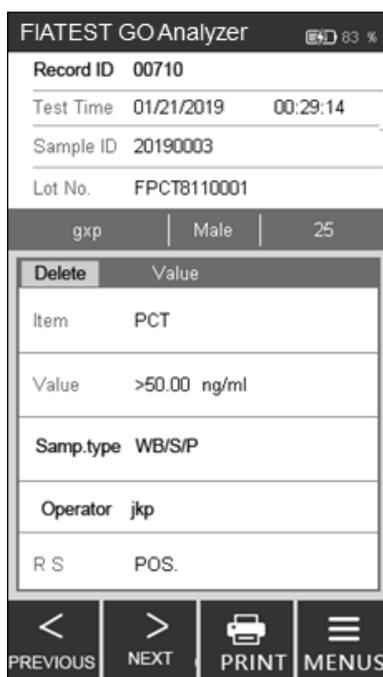
Fig 37

The main information and results of each test will be displayed on the screen.

i.   Record ID: The serial number will be automatically assigned after each test.
ii.   Sample ID: A sample's unique identifier (patient's information/ barcode number.)
iii. Lot No.： The batch information of the test cassette.
iv.   Item: Test (Analyte)
v.   Test Time: Time stamp recorded in the system for the test.
vi.   Value: Values obtained as the result of testing.

vii.   Sample Type: The specimen type
viii.   Operator: Information of the operator.
 ix.   RS: Result.
    Tap "**PREVIOUS**" or "**NEXT**" to review the history.
    Tap "**PRINT**" to print the test results by outside printer.
    Tap "**MENUS**" to return the main menu interface.
    ● **History management**
    Tap "**MANAGEMENT**" to switch to the interface. (Ref Fig 38) You can upload or clear the history. The interface shows statistics for all test records
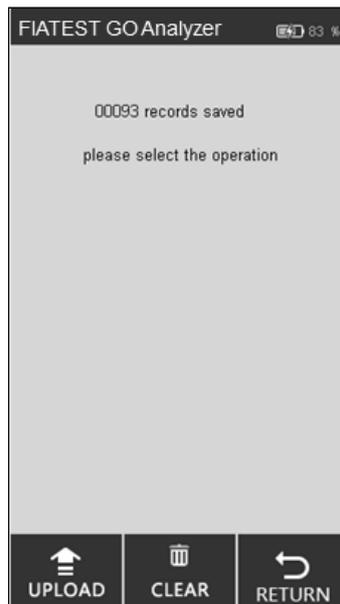

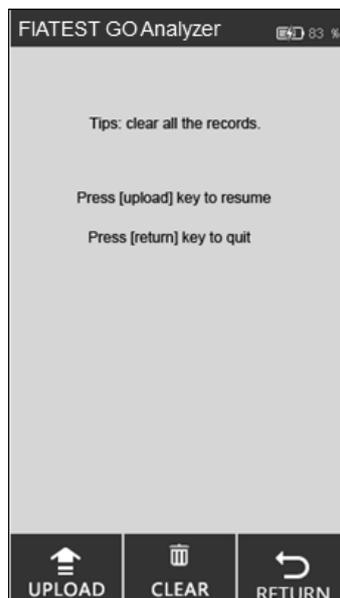
Fig 38

Tap "**CLEAR**" to delete a record. (Ref Fig 39)

Fig 39

5.2 Operations of PC Software

5.2.1 The Main Functions of the PC Software are as follows:

i. Operate the analyzer from the computer, without help of touchscreen. The data will be automatically uploaded to the PC after each test, and the results will be displayed in the Local Record Section.
ii. Keep record of all results and back up the records.
iii. Input relevant information regarding a test such as patient's name, technician's name, institute's name etc. and print a report with an external printer with all the required details.

5.2.2 Operating Analyzer through a computer

Special Note: The analyzer has been programmed to work with Windows-based systems. If an institute uses any other system, such as Linux or Mac Os, the software may not operate.

1. Before the first time use, it is important to install the program to run. Install the program through the software provided by email. The program runs best, when installed in "C:\." Always remember to get the shortcut icon [FIA] on the desktop and operate through the desktop shortcut icon for optimal performance.
2. Connect the analyzer and the computer through provided cable and connecting through USB port (COM port is for connecting with laboratory system or a printer), and turn on the power switch.
3. Double-click the icon [FIA] on the desktop screen to open the homepage of the software (Ref Fig 40)
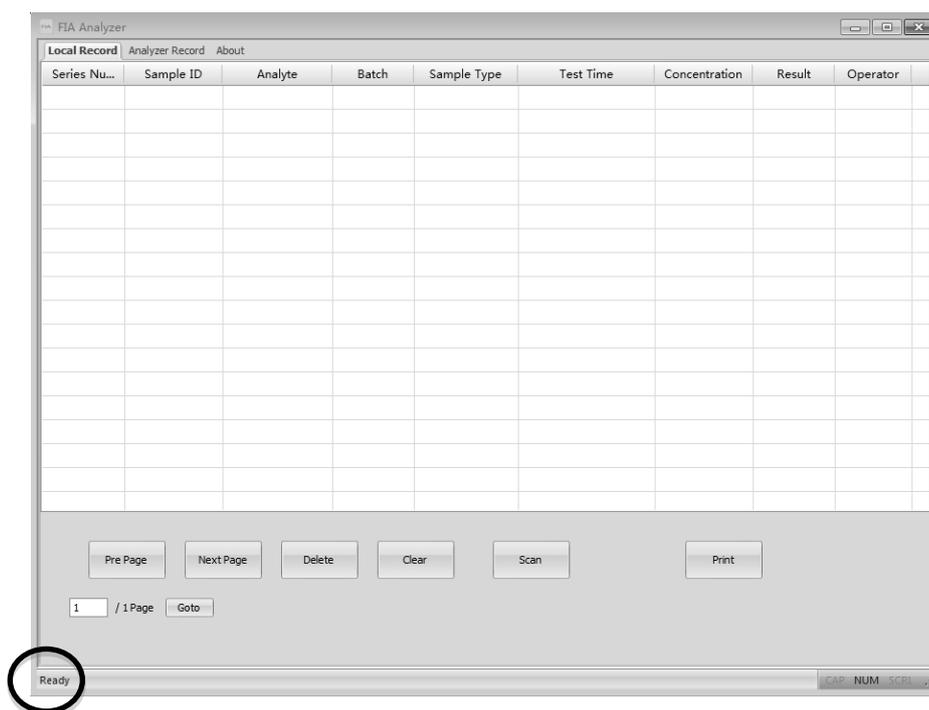
Fig 40

Note: If the analyzer is not connected to PC, it prompts "Make sure the USB is connected" on the left bottom. If the analyzer is connected to PC, it shows "**Ready**" on the left bottom.

Functions of Local Record Tab

● Local Record means the records saved on the computer. On the side tab, you can see Analyzer Record, it means the records saved on the analyzer. The "about" tab gives the information on the software.

● "**Pre Page/Next Page**": Click the bottoms to show the information in the previous or next pages.

● "**Delete**": Select the items to be deleted and click "**Delete**" Tab, you can get a prompt as in Fig 41 to confirm. Click "**OK**" to delete.

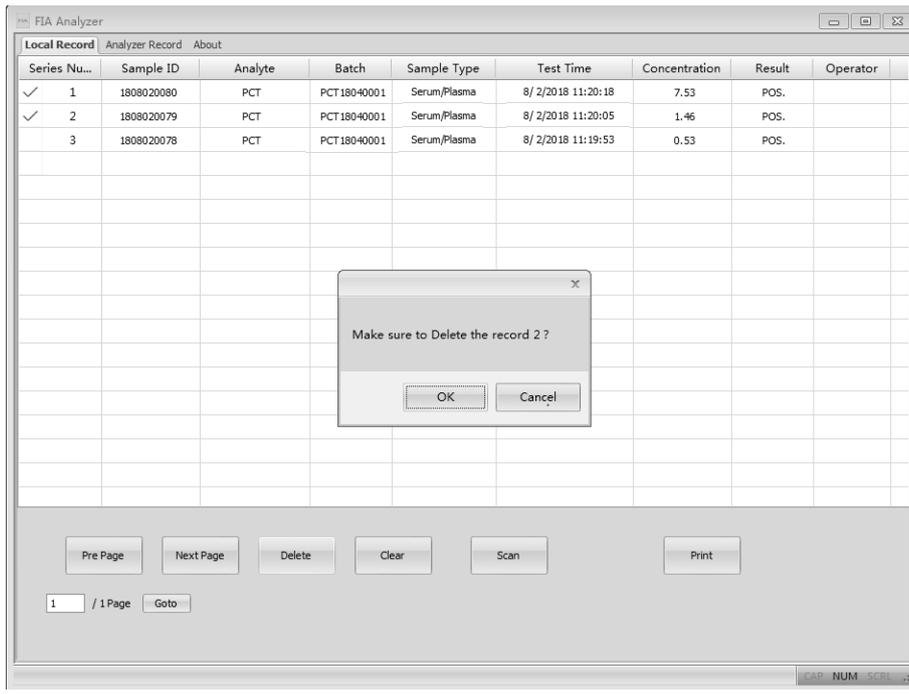Fig 41

● "**Clear**": Click "**Clear**" to clear all the records from the system. (Ref Fig 42). You will get a prompt to confirm the operation. Once you click "**OK**", all the data will be cleared.

Warning: Click "Clear" only, if you want to delete all the records. Once cleared, the data cannot be stored back.

Fig 42

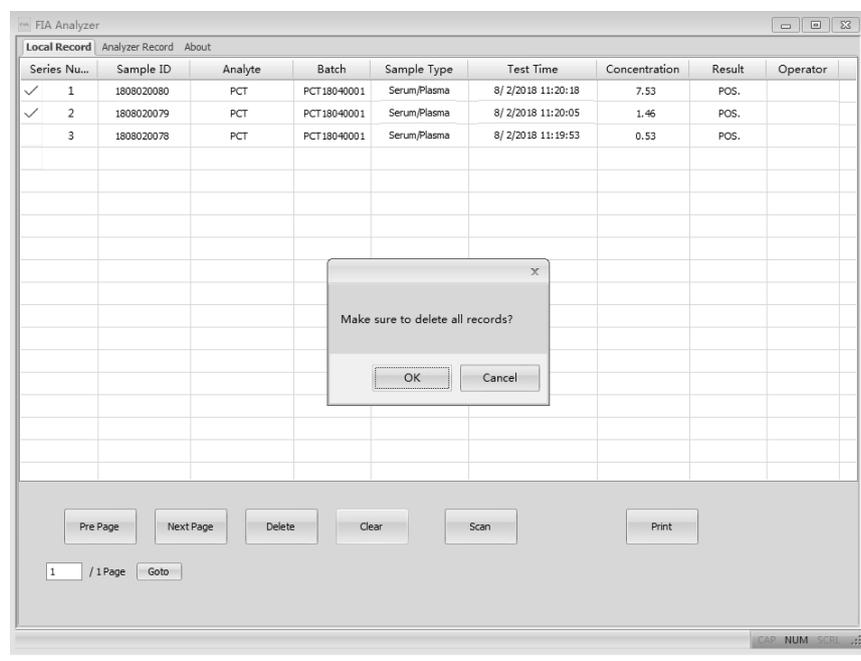● "**Scan**": Scan command would perform the same functions as pressing Test key or tapping new test on the analyzer. Place the test cassette, after sample addition (and buffer addition, if the method requires so) into the test card slot, and <u>double click</u> "**Scan**" command. (Same function as **Quick Test** mode in the analyzer), the test result will appear on the Local Record tab.(Ref Fig 43)
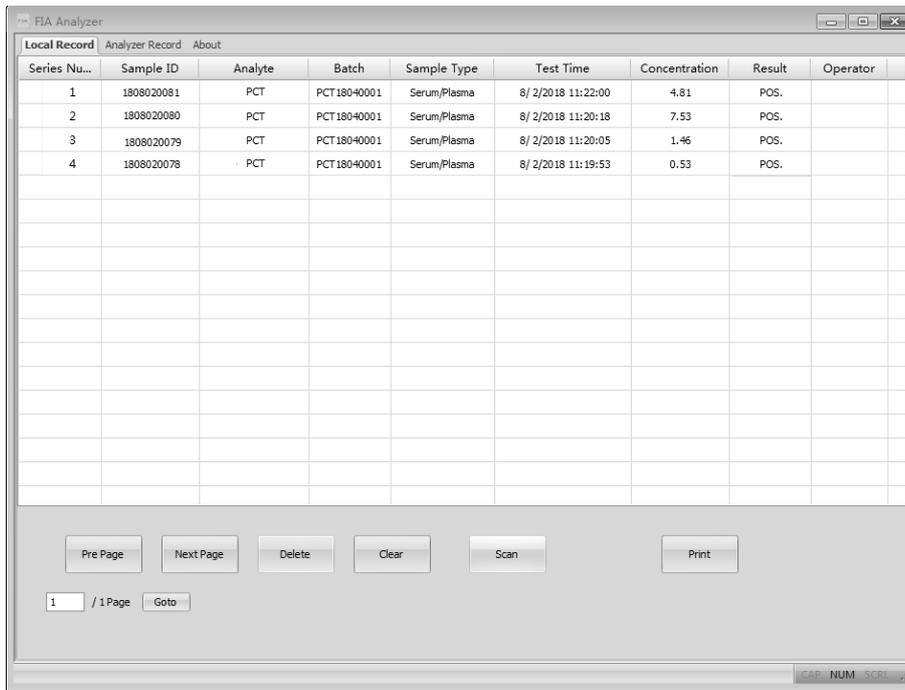
Fig 43

- "**Print**": Select the items to be printed and click **"Print"** command, the screen would appear as shown as Fig 44. The information about the institute and the patient need to be filled.
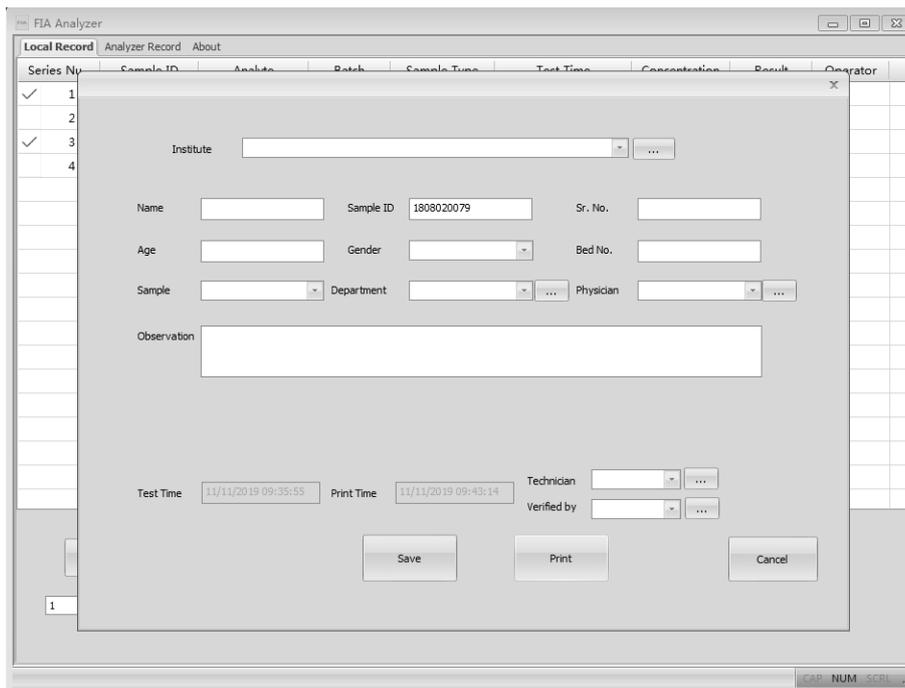
Fig 44

There are several commands that look like [···] on the print command screen. They are used for filling in the required information. Upon clicking the command [···], you can see a new pop-up, wherein you need to feed in the required information, such as institute's name, technician's name, referring doctor etc. Click "**New Item**" to add this information. If you have already fed in this information and need to change it, you need to select the item to be changed and click "**Change Item**" to change the item to be changed. Close the information filling window and click the Drop down Menu. You can see the

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filled information here. Select the right information to be printed. Please check all the information that you need to print on the window. If all the information is correct, click "**Print**". A preview of the report will be shown as in Fig 45. The preview window can be zoomed by clicking the "**Zoom In**" or "**Zoom Out**".
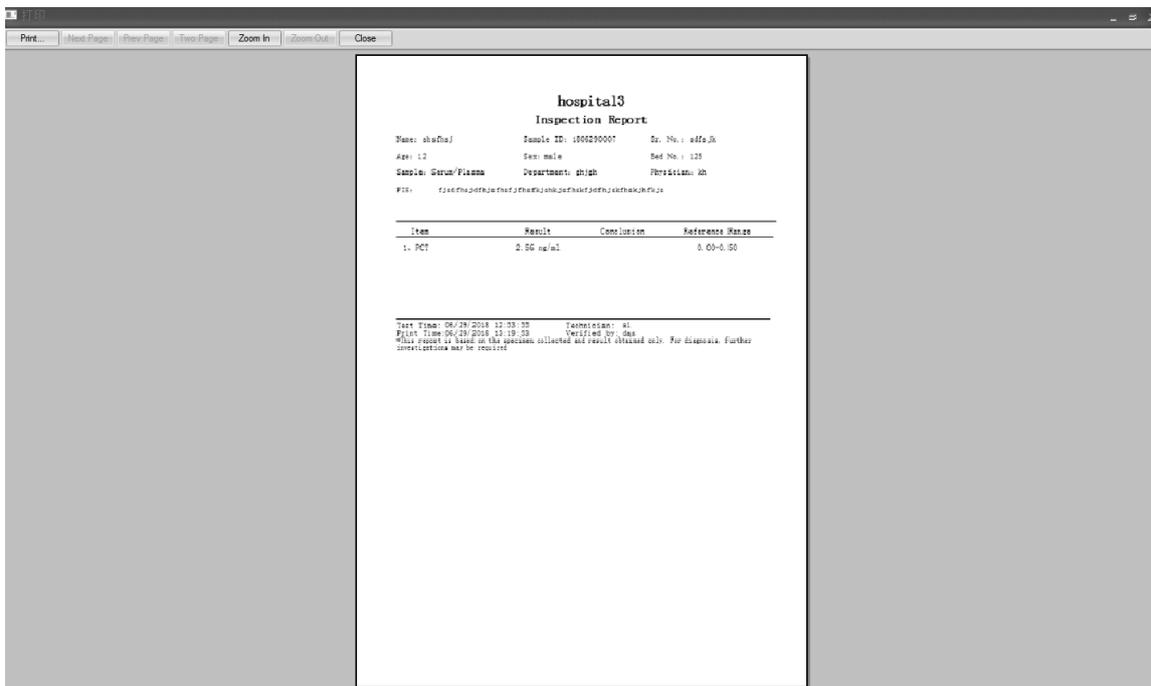
Fig 45

Functions of Analyzer Record Interface

● "**Conditional Search**": According to the specific options, the corresponding items can be shown by the search function.

● "**Get record**": Click this command to get the test records from the Fluorescence Immunoassay Analyzer.

● "**Export**": Click "**Export**" to save all test records on computer as an excel file.

● **"Time Sync**" : Click this command to change the time of analyzer according to the local time zone.

5.2.3 Shut down the Software

Click on the icon on the right corner of the Window to turn off the software.

Chapter 6 Daily Maintenance and Cleaning

6.1 Maintenance

Basic maintenance is to keep the outside of the Fluorescence Immunoassay Analyzer clean.
External cleaning and maintenance method: Clean the outer surface of the analyzer with a damp cloth with no more than 70% alcohol. Do not use strong bleach (≥ 0.5% bleach solution), because oxidizing substances and solvents may damage the analyzer's parts and touch screen. **Do not clean any internal parts and inner surface.**

⚠ Turn off the power switch before cleaning! Ensure the power cord is disconnected to avoid the risk of short circuit and electric shock!

6.2 Maintenance Plan

Maintenance item	Every week	Every three month	When needed
Dust cleaning	X		
QC calibration		X	
Replace print paper			When the paper runs out

6.3 Precautions

i.   Do not place the analyzer in a position that is difficult to operate or inconvenient to disconnect.
ii.   Do not insert anything into the test cassette slot except for the test cassette provided by the manufacturer.
iii.   Treat tested samples as potentially contagious and use protective gloves and other protective measures, and avoid skin contact with sample loading port of the test cassette.
iv.   Please dispose the used cassettes according to "Medical Waste Management Regulations" complying to local regulations in force to avoid biohazards.
v.   Use test kits manufactured by Hangzhou Alltest Biotech Co., Ltd. and supplied by authorized distributors of Hangzhou AllTest Biotech Co., Ltd. only. Do not use the assay test from other manufacturer, it may lead to inaccurate test result.
vi.   **Description of the procedures of data storage and recovery:** The analyzer can save the calibration curves related to projects and batches provided by the manufacturer, and records of tests by users. The analyzer will automatically save the calibration curves imported from ID cards. The analyzer can save up to 50 projects, and each project has 3 batches of calibration data. The test results will be saved to the analyzer automatically in the form of records during the normal use. The analyzer can save up to 4000 records. The stored data can be automatically restored after power failure. The data will be cleared when users select "RESET" to return to factory settings.
vii.   Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.

Chapter 7 Service, Repair and Disposal

Fluorescence Immunoassay Analyzer does not require special maintenance except for keeping it clean and replacing printing paper when needed. If service is required, please contact with the local distributor. Fluorescence Immunoassay Analyzer's internal parts, including the circuit boards, optical detection modules, display, printer, and one-dimensional barcode scanning module, can only be provided by manufacturer. Such items should not be sourced from any third-party, even if they claim to provide the same function. When issues related to the analyzer or PC software occur, contact the local distributor. We provide technical support for users to perform troubleshooting. If the analyzer needs to be sent back to manufacturer, please contact local distributor and/ or Hangzhou AllTest Biotech Co., Ltd. It normally takes about a week to fix problems. If it turns out not repairable within warranty period, we will replace it with a new one. If for any reason the analyzer needs to be disposed of, please follow the procedures and rules of disposing off for Class B electric analyzers.

We provide technical support and software maintenance, including functional maintenance, corrective maintenance, software fixes or upgrade. We are only responsible and provide services when the analyzer is properly used in compliance with the manufacturer's instructions, otherwise any damages incurred will not be covered.

This product is required to comply with the European Unions' Waste Electrical & Electronic Equipment (WEEE) Directive. If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.

Chapter 8 Manufacturer Information
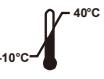
Name：Hangzhou Alltest Biotech Co., Ltd.

Address: # 550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China

Tel: +86-571-56267891

Web: www.alltests.com.cn

Email: info@alltests.com.cn

Index of Symbols

	Consult Instructions For Use	Σ	Tests per kit	IVD	*In vitro* diagnostic medical device
40°C -10°C	Temperature limit -10-40°C	REF	Catalog #	EC REP	Authorized Representative in the EU
	Manufacturer	CE	CE Mark		Keep dry
	Fragile, handle with care		Keep away from sunlight		Protect from heat and radioactive sources
⚠	Caution		Biological risks	UDI	Unique device identifier

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn   Email: info@alltests.com.cn

CE
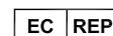
EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster
Germany

Imported in UE from:
PM2 Services srl
C.so Mazzini 38 - Largo Marchi
Arzignano 36071, (VI) Italy
info@pm2services.it
www.diagnosti.care

Number: F145003802
Revision date: 2022-08-18

Appendix

A. Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within one year of purchase.

For your records, write the purchase date of your starter kit here:

_____

Note: This warranty applies only to the analyzer in the original purchase. It does not apply to the other materials included with the analyzer.

AllTest Biotech Co., Ltd. warrants to the original purchaser that this analyzer will be free from defects in materials and workmanship for a period of one year (12 months).

The one year starts from the later of the date of original purchase or installation (except as noted below). During the stated one year period, ***AllTest*** shall replace the unit under warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. ***AllTest*** shall not be responsible for shipping charges incurred in the repair of such an analyzer.

This Warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. ***AllTest*** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the analyzer in accordance with the operations manual, or maintenance by anyone other than ***AllTest***.

Furthermore, ***AllTest*** assumes no liability from malfunction or damage to analyzers caused by the use of products other than products manufactured by ***AllTest***. ***AllTest*** reserves the right to make changes in the design of this analyzer without obligation to incorporate such changes into previously manufactured analyzers.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by ***AllTest***.

Limitations of Liability

In no event shall ***AllTest*** be liable for indirect, special or consequential damages, even if ***AllTest*** has been advised of the possibility of such damages.

For warranty service, please contact your local distributor.

B. Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within one year of purchase.

Purchaser	
Model	
Serial Number	
Date of Purchase	
Address	
Telephone Number	
E-Mail Address	

FIATEST+ GO