



FinecareTM FIA Meter II Plus SE

Model No.: FS-114

Operation Manual





Guangzhou Wondfo Biotech Co., Ltd.

No.8 Lizhishan Road, Science City, Luogang District, 510663,

Guangzhou, P.R.China

Tel: +86-20-32296083 400-888-5268(Toll Free)

Fax: +86-20-32296063

E-mail: Finecare@wondfo.com.cn Website: www.wondfo.com.cn



Contents

Section I Introduction	2
Section II Package Contents	3
Section III Technical Specifications	7
Section IV Warnings, Precautions and Limitations	9
Section V Installation	12
Section VI Operation	14
Section VII LIS Connecting	47
Section VIII WIFI and Bluetooth	53
Section IX Maintenance and Care	54
Section X Trouble Shooting	56
Section XI Contact Information	57

Index of Symbols

Read all contents of this Manual carefully prior to use.

If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

The following symbols are used on the **Finecare™ FIA Meter II Plus SE**, related components and accessories, labels or in the text of this Operation Manual:

	Biohazard
<u> </u>	Cautionary information
[]i	Consult Operation Manual
EC REP	European Authorized Representative
	Manufacturing Date
SN	Serial Number
学 ※	Keep Dry
*	Keep away from Sunlight
IVD	For in vitro Diagnostic Use only
•••	Manufacturer
===	Direct Current
	Power ON
0	Power OFF
X	WEEE (Waste Electrical and Electronic Equipment)
T	Fragile, handle with care
<u> </u>	This side up
6	6 identical packages can be stacked at maximum
10°C	Operate at 10°C to 30°C Temperature Limitation
-10°C	Store at -10°C to 50°C
CE	CE Marking
ll/ondfo®	Trade mark

Section I Introduction

Thank you for choosing Finecare™ FIA Meter II Plus SE which is developed, designed, manufactured and sold by Guangzhou Wondfo Biotech Co., Ltd. Finecare™ FIA Meter II Plus SE (Model No. FS-114) is a compact, portable and easy-to-use fluorescent instrument for quantitative determination of concentration of various analytes in human blood or urine or QC solution.

The Operation Manual describes the construction and performance characteristics of this instrument, as well as the instruction for operation and maintenance of it.

1. Test Principle

Finecare™ FIA Meter II Plus SE uses a LED as the excitation light source. The light from the LED hits a test device that has been inserted in the instrument. This causes the fluorescence dye in the test device to give off energy. The more energy the fluorescent dye gives off, the stronger the signal.

After a buffer-mixed sample is added to the test device, the test device is inserted into the Fineca™ FIA Meter II Plus SE. The instrument measures the concentration of the analyte based on a pre-programmed calibration process. Finecare™ FIA Meter II Plus SE can only accept test devices that are designed specifically for use with this instrument.

The instrument can simultaneously carry out the quantitative detection of single or multiple analytical materials, the detection sensitivity can reach **Pg/ml** level.

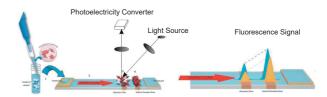


Fig. 1.1 The light path principle

2. Intended Use

Finecare™ FIA Meter II Plus SE is designed for *IN VITRO* DIAGNOSTIC USE ONLY, for quantitative determination of concentrations of various analytes in human blood or urine or QC solution.

The instrument should be used along with immunofluorescence quantitative test reagents manufactured by Guangzhou Wondfo Biotech Co., Ltd. The instrument and test reagents (mentioned as "Test Cartridges" hereinafter) are applicable to **PROFESSIONAL USE ONLY**.

Finecare™ FIA Meter II Plus SE can be used in central laboratories, ICU/emergency rooms, GP offices, clinics and medical examination centers etc.

Section II Package Contents

1. Unpacking

The Finecare™ FIA Meter II Plus SE and the items that come with it are provided in a single box. The Test Cartridges are packaged separately and include instructions for running specific tests.

After open the box, please check to ensure that the contents listed below are included. If any item is missing, please contact your sales distributor or **Guangzhou Wondfo Biotech Co., Ltd**.

Detailed contact information is mentioned in **Section XI**.

2. Contents of the Packaging

No.	Item	Quantity
1	Finecare™ FIA Meter II Plus SE	1
2	Power adapter (including the power cord)	1
3	Quality Control Card	1
4	Ethernet cable	1
5	Printer paper (roll)	1
6	Operation Manual	1
7	Quick Operation Instruction for Use	1
8	Warranty Card	2
9	Packaging List	1
10	Product Certification	1
11	Acceptance Form	1
12	Quality Guarantee	1

3. Optional Accessory

Rechargeable lithium battery

riangle Note: The user should use the rechargeable lithium battery supplied by Wondfo Company.

4. Materials Needed but Not Provided

Material Name	Requisite/optional
Finecare™ series test cartridges	Requisite
Finecare™ series buffer solution	Optional, for designated tests needed
Finecare™ Fincubator	Optional, for designated tests need constant temperature incubating environment for the immunofluorescence test cartridges and buffer solution

5. Diagrams of Instrument Configuration



Fig. 2.1 Finecare™ FIA Meter II Plus SE - Front View



Fig. 2.2 Finecare™ FIA Meter II Plus SE - Rear View

Fig. 2.3 Finecare™ FIA Meter II Plus SE - Left View



Fig. 2.4 Power Adapter



Fig. 2.5 Quality Control Card

Test Cartridge and ID Chip

The test cartridge and ID chip are test reagent's consumables. They are packaged separately from the instrument and include instructions for running specific tests.

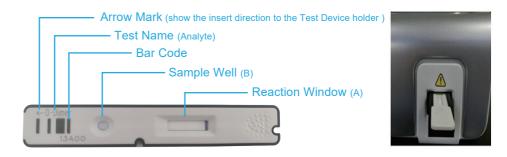


Fig. 2.6 Test Cartridge



Fig. 2.7 ID Chip

Section III Technical Specifications

1. Basic Specification

	Adapter: Input: 100-240Vac, 50/60Hz, 1.3-0.6A		
Power	Output: 15V=== 6.0A, 90W MAX		
	Power input: 15V===, 90W		
Excitation light source	LED		
Excitation spectrum	Center wavelength $\lambda_0 = 470$ nm		
Absorption spectrum	Center wavelength λ ₁ = 525nm		
o . T	Whole blood, serum, plasma or urine (refer to instruction		
Specimen Type	for use of designated test reagent when actual use)		
0 "	Linux, English and Chinese input method,		
Operation system	customized intelligent management module		
Detector	Photodiode		
Storage Capacity	Up to 50,000 test results		
Size	278*239*148mm		
Weight	About 3.3 kg		
Interface port	RS 232 / USB / Ethernet network		
	Thermal printer,		
Miscellaneous	LCD touch screen		
	English / Chinese operation interface available		

2. Battery Specification

Туре	Rechargeable Lithium Battery	
Working Hours	Under full charged situation, Quick Test mode ≥200 tests; Standard Test mode ≥10 tests (15 minutes per test)	
Charge Time	No longer than 10 hours	
Minimal Capacity	7800 mAh	
Nominal Voltage	11.1 V	
Charge Mode	Constant current/constant voltage	
Charge Current (Standard)	Maximum charging current as 1A	
Maximum Continuous Discharge Current	6A	
Cycle Life	Capacity over 70%, no less than 300 cycles	

3. Operating Environment

Temperature	10 ~ 30°C (50~86°F)		
Humidity	10% ~ 80% (No condensation)		
Atmospheric pressure	860~1060hPa		
Location	Dry, clean, flat, horizontal surface away from direct		
	sunlight, dust, acidic volatile gases, mechanical vibration,		
	and strong electromagnetic interferences.		

4. Storage and Transportation Environment

Temperature	-10 ~ +50°C (14~122°F)
Humidity	≤85%
Storage place	No corrosive gas, well ventilated room.

Section IV Warnings, Precautions and Limitations

1. Application Notice of Test Cartridge

(Caution:

- Test sample should be added onto the sample well in Test Cartridge (as shown in Fig. 2.6).
- Ensure the sample fluids are fully absorbed before the Test Cartridge is inserted in the instrument, in order to prevent internal contamination of the instrument.
- When the Test Cartridge was inserted into the Test Device Tray (as shown in Fig. 2.1), its sample well/reaction window should be faced upward, and the arrow mark should point to the instrument.
- · Insert the Test Cartridge into the Test Device Tray until resistance is felt, with the thumb or forefinger to push, do not force too large, for preventing any mechanical fault or personal injury.
- The used Test Cartridge should be treated as potentially bio-hazard and should be disposed of according to the standard procedures and relevant regulations.
- Gloves, goggles or other protective measures should be used when handling potential infectious materials.

2. Application Notice of Finecare™ FIA Meter II Plus SE



Warning:

- Finecare™ FIA Meter II Plus SE is for in vitro diagnostic use only.
- Finecare™ FIA Meter II Plus SE is applicable to **professional use only**. It should be used by a trained qualified healthcare professional
- Finecare™ FIA Meter II Plus SE must be used within the operating environment as specified in Section III.
- Finecare™ FIA Meter II Plus SE is only applicable with Test Cartridge or Quality Control Card provided by Guangzhou Wondfo Biotech Co., Ltd. In case of use other test cartridges, it may cause malfunction of the instrument or incorrect test results.
- Use only the Power Adapter and the power cord provided with Finecare™ FIA Meter II Plus SE. If replacement needed, please contact Guangzhou Wondfo Biotech Co., Ltd. or its sales representative.
- The instrument does not contain components that can be maintained/repaired by the user, and regular maintenance must be performed by authorized technical service personnel to avoid electric shock.
- Do not dismantle Finecare™ FIA Meter II Plus SE without written authorization from Guangzhou Wondfo Biotech Co., Ltd. or its sales representative.
- The mains outlet for Finecare™ FIA Meter II Plus SE shall be located in a user accessible position for easy unplugging in emergency.

 Prohibit using a power socket without ground protection in case of shock hazard or system damage.

Caution:

- The Test Device Tray shall be kept inside the main body of the instrument all the time unless the user intends to put a Test Cartridge or Quality Control Card in it.
- Do not drop or crash Finecare[™] FIA Meter II Plus SE.
- Do not move the instrument while a test is in process.
- · Do not spill any liquid onto the instrument. Do not immerse the instrument into water or other liquids.
- · Do not place objects on the instrument. This may damage the optical alignment and result in compromised performance or mechanical damage.
- Discontinued use due to maintenance, handling or damage in transit, please call customer service representative of Guangzhou Wondfo Biotech Co., Ltd. via 400-888-5268(Toll Free).
- The test results are used as a reference for auxiliary diagnosis, and the test results should be explained by professional medical personnel.

3. Application Notice of Quality Control Card



Caution:

- The Quality Control Card must be stored away sunlight and moisture when not in use.
- · Do not write or place a label anywhere on the Quality Control Card, as it may interfere the instrument functionally.

4. Application Notice of Battery



Warning:

- The user should use the rechargeable lithium battery supplied by Wondfo Company. And the battery must be used within the operating environment as specified in Section III.
- · Waste battery containing heavy metal can pollute the environment. It should be treated as special garbage and disposed of according to local regulations.



Caution:

· When the battery reaches the end of its service life, or if the battery is with odor, discolored, deformed, or twisted, stop using the battery and dispose of the waste battery in accordance with local regulations.

- To prevent the battery from being unusable because of over discharge, charge the battery at least once every six months if the battery is not used for a long time.
- Keep away from the place with static electricity when the battery is charged, used and stored.

Note:

- When an invalid adapter is inserted or an adapter is not inserted in the instrument, the indicator light will not be on, and the battery will not be full charge for a long time.
- Whether the instrument is turned on or off, you can connect an alternating current to charge the battery.

5. Information of EMC

⚠ Warning:

 Do not use this instrument in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper instrument operation.

A Caution:

• Suggest the user evaluating the electromagnetic environment prior to operation of the instrument.

⚠ Note:

- It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
- It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
- The instrument complies with the immunity requirements and emission requirements described in EN 61326-1 and EN 61326-2-6.



In the use of Finecare™ FIA Meter II Plus SE, please follow the instructions and notice reminders in this Operation Manual. Otherwise, the instrument built-in safety characteristics may cause electrical, mechanical or biological hazards to the user.

Section V Installation

1. Preparation Before Starting-up

The operator should check out following steps every time before starting the instrument up.

1) Please use this instrument at ambient temperature of 10~30°C and relative humidity under 10%~80% conditions (see detailed requirement in "Operating Environment" of Section III).

Note:

Please note that the operating temperature of the immunofluorescence quantitative test reagent should be based on its instruction for use.

2) Before powering on, connect a power cord and power adapter provided by Guangzhou Wondfo Biotech Co., Ltd. to the external power interface on the left side of the instrument.

2. Install/Change Paper

The printing paper is a consumable and should be replaced immediately if it is insufficient.

1) There is a built-in thermal printer in this instrument, and it need to be used with corresponding thermal paper whose width is 57 mm.



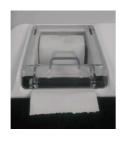
2) Remove the printer cover by pulling up the cover.



3) Install the thermal paper into the printer slot and then close the cover. About 2cm paper should be left outside.









Right

Wrong

Expose about 2cm outside

Loose of the paper

4) After installing or replacing the thermal paper, turn on the instrument and choose one of the test records in the "History" interface, and then click "Print" to test the installing of the thermal paper.



If the paper is not correctly placed or loose, the printing may be blurred, jammed or unable to print. In this case, you need to take out the paper, arrange it and then reinstall.

3. Install the Instrument

- 1) Place Finecare™ FIA Meter II Plus SE on a dry, clean, flat, horizontal surface, with the front surface at least 10 cm inside of the table edge.
- 2) Plug one end of the adapter into power outlet, plug the opposite end into the external power interface.
- 3) Press the "Power ON/OFF" for 3 seconds to switch.



Fig. 5.1 Powering on the instrument

Note:

For instruments with battery, the power adapter can be disconnected when the battery has power.

Section VI Operation

1. Start-up

- 1) Press the "Power ON/OFF" for 3 seconds to turn on the instrument, refer to Fig 5.1.
- 2) Log in interface

After the instrument is turned on, wait about 10 seconds to enter the log in interface of the instrument. The log in interface is shown in the following figure:



Fig. 6.1 Log in interface

Log in steps:

- Select the user to log in from the user selection drop-down box on the log in interface. Among
 them, "Adm" is the administrator user, "Fac" is the factory user, and the other options are the
 already-submitted doctor or inspector or reviewer user.
- After selecting the user, enter the password of the corresponding user, and click the "Log in" button to log in.

3) Main interface

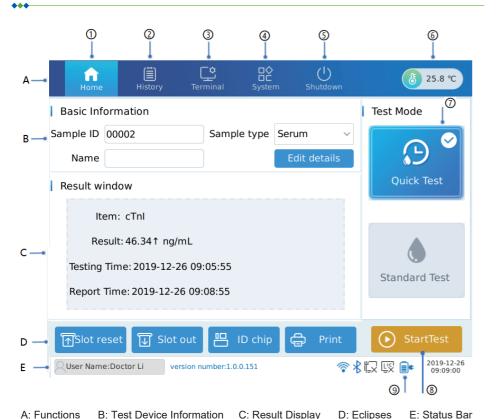
The user can operate the Finecare™ FIA Meter II Plus SE by touching the LCD touchscreen by fingertip, or by mouse and keyboard.

After switching on, wait the instrument to boot and show the main interface.

The Test Device Tray will protrude automatically. The main interface is shown as below:



If the instrument cannot log in the initial interface successfully in one minute, switch off the instrument and restart. If it still doesn't work, please contact your sales distributor or Guangzhou Wondfo Biotech Co., Ltd.



o information O. Rosalt Bioplay B. Lonpsco E. Gta

Fig. 6.2 Main interface

1)	[Home]	Choose the specific test to be run		
2	【History】	Inquire history data		
3	【Terminal】	User setting, print setting, statistical design,		
		communication setting, quality control setting		
4	[System]	Quality inspection, setting, function, consumables, advanced setting		
(5)	【Shutdown】	Turn off the device		
6	【Temperature】	Display internal temperature of the instrument		
7	【Test Mode】	Choose test modes, Quick Test or Standard Test		
8	【Start Test】	Start to measure the test result		
9	【Battery icon】	Display the battery level, five levels in total.		
		The main interface has this icon,		
		which means the instrument with battery.		

Description of other buttons on the main interface:

1 [Slot reset] Click this button to retract the card slot.

2 [Slot out] Click this button to extend the card slot from the instrument.

3 【ID chip】 Click this button, the instrument will read and keep the ID chip information.

4 [Print] Click this button to print the test result.

5 【Edit details】 Click this button, you can edit the patient information in the pup-up dialog

box. Such as the sample ID, the patient name, the age and so on.

2. Run a Test

Run a test to analysis a test reagent.

To start running a test:

1) Choose test mode by click on "Quick Test" or "Standard Test".

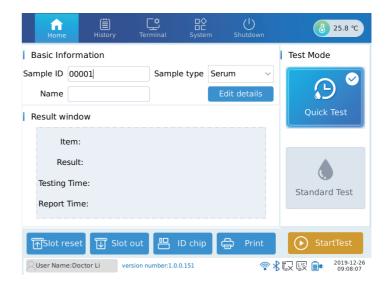


Fig. 6.3

Finecare™ FIA Meter Plus provides two test modes, the Standard Test mode and Quick Test mode. Standard Test:

Push the test cartridge into the test device tray right after the specimen is fully absorbed.

The instrument acts as an incubation place for reaction for a preset time duration.

Wait until the instrument counts down to zero, the test result will be shown on the screen.

Push the test cartridge into the test device tray after the reaction completes, the test result will be shown on the screen.

2) Insert ID chip into the ID chip port until resistance is felt.

⚠ Note:

- It is recommended to insert the ID chip after successful booting.
- This step is necessary when a new batch of test cartridge of specific test is applied on the
 instrument for the first time. Once the instrument recognizes the batch information of the chip,
 there is no need to read ID chip again before running test, unless a new batch of test cartridge is
 applied.
- The ID chip can either be pulled out once the batch information is recognized or remain inserted.
- 3) Navigate to the main interface.
- 4) Click "ID chip", Finecare™ FIA Meter II Plus SE will read and keep the ID chip information.

⚠ Note:

- For initial interface of first boot, the default test mode is a "Quick Test", then the subsequent power-on defaults to the test mode selected by the user's last shutdown.
- 5) Input detailed patient information by clicking "Edit Details".
 If you do not need to enter patient information, this step can be skipped.
- 6) Remove the reagent card from the aluminum bag and place it horizontally.
- 7) Quantitatively add the sample to the test reagent buffer and mix as required.

⚠ Note:

- Before the test, please read the operation manual of the test reagent in detail and operate as required.
- If there is no buffer in the reagent configuration, add the sample directly to the reagent sample well.
- 8) Start the test.

Standard Test: Gently push the test cartridge into the test device tray immediately after the specimen is fully absorbed. And then click "Start Test".

Quick Test: Gently push the test cartridge that is completely reacted into the test device tray. And then click "Start Test".

9) The instrument scans and analyzes the test cartridge, with its screen displaying test timing.



Fig. 6.4 Standard Test

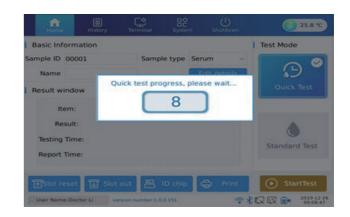


Fig. 6.5 Quick Test

10) After the stop of test timing, the test result will be shown on the screen. The test device tray will protrude after the test completes. If not, click "Slot out".

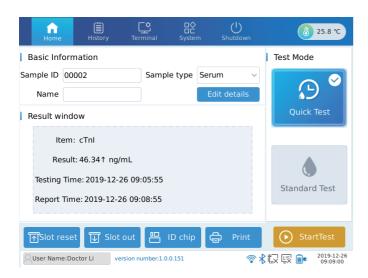


Fig. 6.6 Quick Test Result

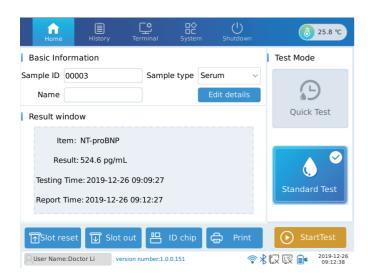


Fig. 6.7 Standard Test Result

11) Click "Print" to make a printed copy of the test result; OR
If the user ticks the box "Print automatically", the test result will be printed automatically every time after the test result is acquired.

- 12) Remove the reagent card. If in "Quick Test" mode, insert the next reagent card that has been added sample and incubated for the next test; if in "Standard Test" mode, insert the next reagent card that has just been added sample.
- 13) After the test is completed, click the "Shutdown" button to turn off the instrument.



Caution: Do not turn off the instrument while a test is in progress.

Ţ

Note:

- The room temperature should meet the incubation temperature specified in the reagent's instruction for use.
- The incubation reaction time of different projects should be determined according to the corresponding reagent's instruction for use.
- If the lot number of the reagent card and the ID chip do not match for the first test of an item, it will prompt "ID chip does not match the reagent card", click "Cancel" to stop the test. And retest it by inserting the ID chip and reagent cards with the same lot number, OR ignore the tips and click "OK" to continue the test, if you sure them are same.
- You can click the "shutdown" button in the screen, or press and hold the power switch button for more than 5 seconds to shut down the instrument.

3. History Data

The "History" function allows the user to view, edit, search, delete or export the test data.

3.1 View History Data

- 1) Click "History"
- 2) Lot number, Sample ID, the tested item, the test result, the sample type, and the time when the test is conducted are shown for each record.

If records are more than the screen can show, slide up or down on the screen to show other records.

Fig. 6.8

3.2 Search History Data

1) Click "Inquiry" under the "History" interface.

Q User Name:Doctor Li

2) Input the inquiry conditions, Finecare™ FIA Meter II Plus SE will filter test results that match the query conditions.

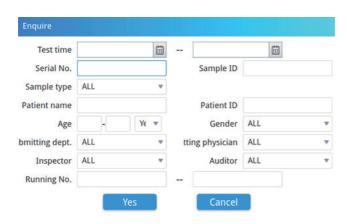


Fig. 6.9

3.3 Edit History Data

Click "Edit" and edit the patient information corresponding to the test result in the pup-up dialog box. Such as the sample ID, the patient name, the age and so on.



Fig. 6.10

3.4 Delete History Data

- 1) Select records by ticking the box in front of the record. The selected records are to be deleted.
- 2) Click "Delete". Choose "OK" to delete the selected records, otherwise click "Cancel" to quit.

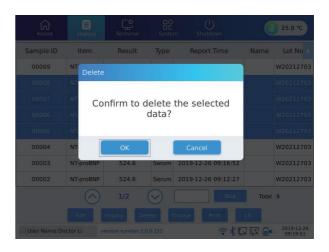


Fig. 6.11

24

3.5 Choose History Data

Click "Choose" and enter the conditions such as the range of the sample ID or the date of report in the pup-up dialog box to select the history data.

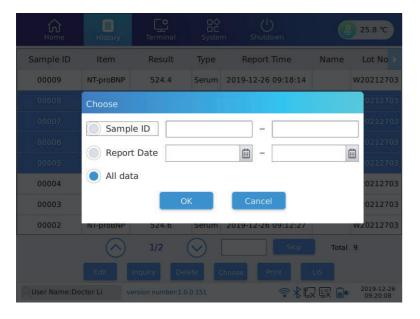


Fig. 6.12

3.6 Print History Data

- 1) Click "History".
- 2) Tick the box in the front of each record to select history data which is to be printed.
- 3) Click "Print". The instrument can print 10 records in maximum at a time.

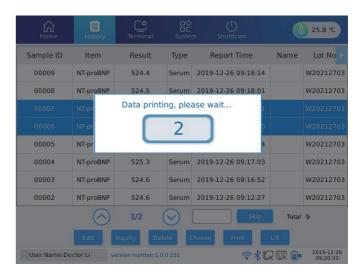


Fig. 6.13

3.7 Export History Data

It is assumed that the instrument has been connected to a LIS prior to data exportation.

- 1) Click "History".
- 2) Select records which are to be exported.
- 3) Click "LIS". The instrument will export data to the connected LIS.

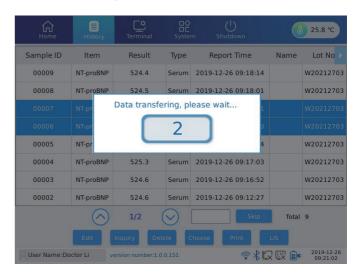


Fig. 6.14

-++4

4. Historical Data Statistics

The statistics function allows the user to get a count of the historical test data.

- 1) Click "Statistical SET." in the Terminal interface.
- 2) The user can choose "Test Account Statistics" or "Workload Statistics".

Test Account Statistics:

Choose "Count by test item", select the type of test item from a list of all test items, OR

Choose "Count by sample type", select the sample type (urine, plasma, whole blood, etc.) from the
list.

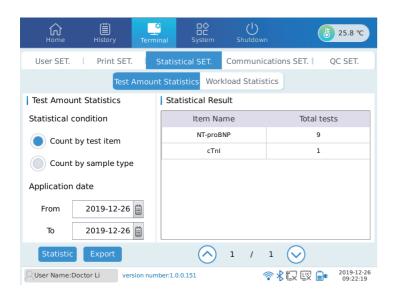


Fig. 6.15

Workload Statistics:

Check in the box prior to "Submit doct.", choose the name of the doctor from the list on the right; OR Check in the box prior to "Inspector", choose the name of the inspecting doctor from the list on the right.

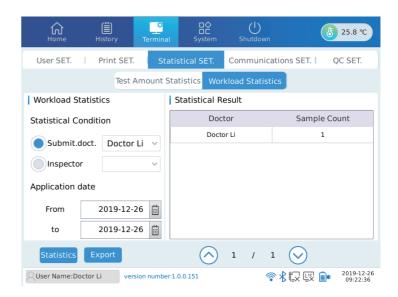


Fig. 6.16

- 1) Apply a time filter to the records by clicking From 2018-08-30 and to 2018-08-30 and input dates.
- 2) Click Statistics

5. Terminal Setting

The terminal setting includes the user setting, print setting, statistical setting, communications setting and QC setting.

5.1 User Setting

There are three different types of users, ordinary user, administrator and factory user.

- 1) Ordinary user: ordinary users can be doctors, inspectors and reviewers. The ordinary users can only perform test operations, view test results, and set general parameters of the instrument.
- 2) Administrator user: in addition to all the operations of ordinary users, the administrator user can also manage the accounts of ordinary users.
- 3) Factory user: in addition to all the operations of ordinary users, the factory user can also set the factory parameters of the instrument.

Administrator user

In the user setting interface, the administrator user can add, edit and delete ordinary user as shown below.

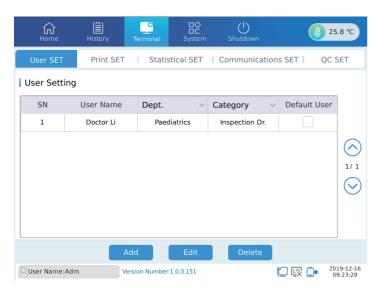


Fig. 6.17 User Setting-1

Ordinary user

In the user setting interface, the ordinary user can only modify their own password.

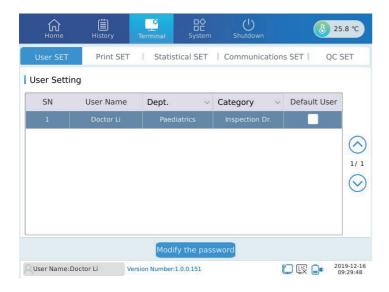


Fig. 6.18 User Setting-2

5.2 Print Setting

In the print setting interface, you can choose the printer, the size of the print paper, the print size (font), the format of report, print copies and choose whether automatic print.

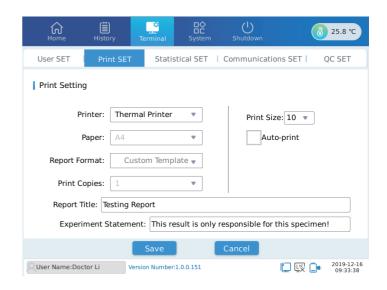


Fig.6.19 Print Setting

The four types of parameters, the size of the print paper, the print size (font), the format of report and print copies, are only applicable to external printers.

5.3 Communications Setting

In the communications setting interface, you can set the WIFI, Bluetooth, network and local setting.

5.3.1 WIFI Setting

The user can proceed WIFI setting within the communications setting as Fig. 6.20 below.

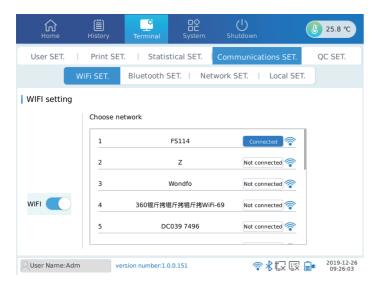


Fig 6.20 WIFI Setting

The connection and shutdown operations of WIFI are as follows:

- 1) In "WIFI SET." interface, turn on WIFI , it will display the choose network refer to Fig 6.20.
- 2) Select a network to be connected, click the "Not connected" button and enter the password in the pup-up dialog box, refer to **Fig 6.21**.



Fig 6.21 Connection

3) Disconnect the connected network, click the "Connected" button and click "OK" in the pup-up dialog box to disconnect the network, refer to Fig 6.22.



Fig 6.22 Disconnect

The WiFi function of this instrument is used to transmit test data to LIS system. Connect the WiFi network, and set the IP and port number in the "Network SET." refer to Fig.6.24, and then turn on the LIS system software of the PC, the instrument will automatically connect to the LIS system software according to the set parameters.

5.3.2 Bluetooth Setting

1) Click "Bluetooth SET." and then turn on Bluetooth. The interface will display the Bluetooth device name of the local instrument. You can proceed Bluetooth setting within the communications setting as Fig.6.23 below.

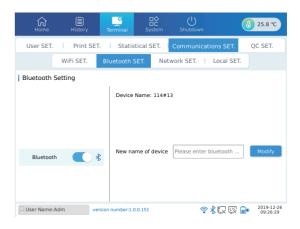


Fig. 6.23 Bluetooth Setting

2) You can modify the name of the Bluetooth device by the interface of Bluetooth setting refer to Fig 6.23. Enter a new name of device at the edit box and click "Modify" button, it will take effect after turn on the Bluetooth again.

The Bluetooth function of the instrument is used to transmit test data to other Bluetooth devices.

30

Note:

The Bluetooth function of the instrument can only be used with supporting tools and software systems, which need to be developed.

5.3.3 Network Setting

Network setting enables the user to transfer data from the Finecare™ FIA Meter II Plus SE to a Laboratory Information System (LIS) via the ethernet cable. See as Fig. 6.24 below. You can refer to Section VI for more information.

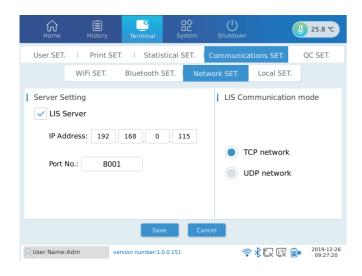


Fig. 6.24 Network Setting

5.3.4 Local Setting

The local setting is used to set the IP address, subnet mask, default gateway and Mac address of the instrument. In addition, you can set the baud rate, data bit, stop bit, parity bit and flow control of the serial port. You can refer to **Section VI** for more information.



Fig. 6.25 Local Setting

5.4. QC Setting

The quality control setting interface is used to set the quality control products and view, print the quality control data, etc. as shown in the following figure:



Fig. 6.26

32

5.4.1 QC Date

The "QC Data" interface includes the following functions:

- > Search quality control data
 - Quick search through the name of the quality control at the top and the date of the quality control data.
 - Advanced search through the "Inquiry" button at the bottom left of the interface.

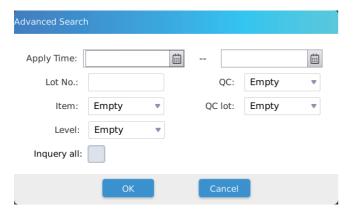


Fig. 6.27 Advanced Search

> Remarks for quality control data

Click the "Notes" button to pop up the dialog box, as shown in the figure below:



Fig. 6.28 Add Remarks

>Output the quality control data

Click the "Output" button to export the selected data to a USB flash drive.

- Upload quality control data to LIS
 Click the "LIS" button to upload the selected data to the LIS system.
- ➤ Delete quality control data

 Click the "Delete" button to pop up the delete data dialog box, as shown in the figure below.

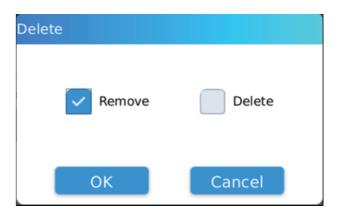


Fig. 6.29 Delete the Data

The "Remove" means to remove the data from the statistical data, but the data remains in the database. You can use the "Restore" button to restore the removed data to the non-removed state; "Delete" means to delete the data from the database.

- Restore quality control data
 Click the "Restore" button to restore the deleted data to the non-removed state.
- Print quality control data
 Click the "Print" button to print the selected data through a thermal printer.

5.4.2 QC Setting

The quality control setting interface is used to add, delete, and edit quality control items, as shown in the figure below:

Fig. 6.30 QC Setting

➤ Add QC item

Click the "Add" button to pop up the dialog box for adding quality control item, as shown in the figure below:

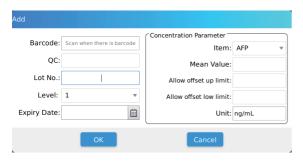


Fig. 6.31 Add QC item

> Delete QC item

Click the "Delete" button to delete the selected QC item.

➤ Edit QC item

Click the "Edit" button to pop up the edit dialog box, and modify the QC item data, as shown in the figure below:

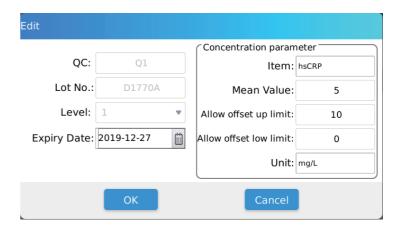


Fig. 6.32 Edit QC item

➤ QC Rule Setting

Click the "QC rule" button to pop up the QC rule setting dialog box, and set the QC rule of the QC item, as shown in the figure below:



Fig. 6.33 QC Rule Setting

5.4.3 QC Report

The QC report interface is used to search and print the QC report, as shown below:

Fig.6.34 QC Report

5.4.4 L-J Chart

The L-J chart interface is used to display the L-J graphics of the quality control data. Set the conditions in the upper selection conditions, and click the "Draw" button to start drawing the L-J chart, as shown below:



Fig. 6.35 L-J Chart

6. System Settings

There are quality control, setting, function, consumables and advanced setting in the system setting interface.

6.1 QC

The Finecare™ FIA Meter II Plus SE has a built-in quality control which aims to monitor the internal system performance of the instrument. Including quality control sample information editing, deletion, quality control operation, quality control report template setting and printing. The quality control interface is shown below:



Fig. 6.36 QC

6.2 Setting

In this setting interface, you can view the SN, set the time and date, the user mode, brightness of screen and the sample ID.

6.2.1 SN

SN code is the unique code of the instrument. This interface also displays the QR code of the SN code, is shown as follows:

38

Fig. 6.37 SN Interface

6.2.2 Date/Time Setting

You can choose the specific date and time and the date display format by clicking on the screen as **Fig.6.38** below.

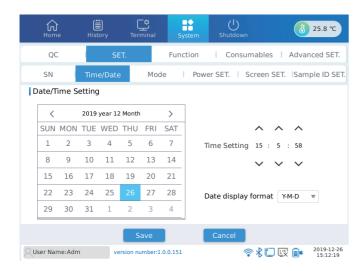


Fig. 6.38 Date/Time Setting

6.2.3 Mode Setting

The mode setting interface is used to switch the users who log in to the system by entering corresponding password.

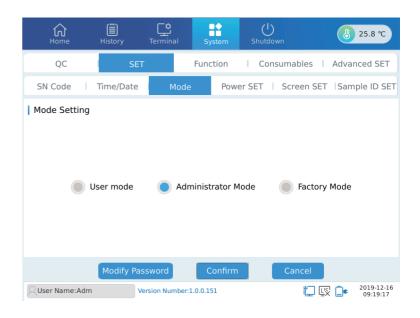


Fig. 6.39 Mode Setting

6.2.4 Power Setting

The power setting interface is used to set whether the instrument sleeps or shuts down automatically.

- 1) Click the "Enable Sleeping" box to enable the sleep function of the instrument. Enter a number in the input box to indicate the sleeping time, means that if the instrument has not performed any operations within this time and it will automatically enter the sleep state.
- 2) "Automatic shutdown setting after sleep" used to set the automatic shutdown of the instrument after a certain period of sleep. You can choose "Never", "Turn off after 1 hour", "Turn off after 2 hours", "Turn off after 4 hours" or "Turn off after 8 hours".

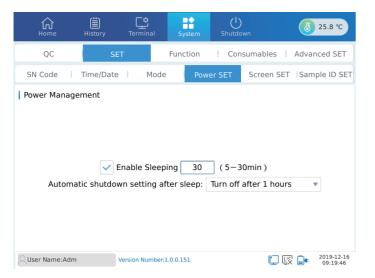


Fig. 6.40 Power Setting

6.2.5 Screen Brightness Setting

The screen brightness setting interface is used to set the brightness of the screen. Slide the button to the right, the screen gradually brightens, and slide the button to the left, the screen gradually darkens.

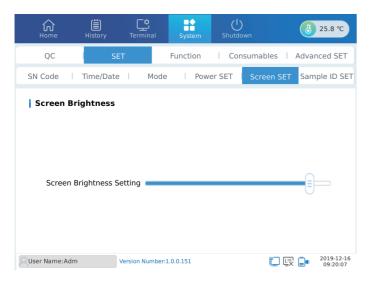


Fig. 6.41 Screen Brightness Setting

6.2.6 Sample ID Setting

In this setting interface, you can set the length of sample ID, and whether to automatically fill in "0", as shown in the following figure.

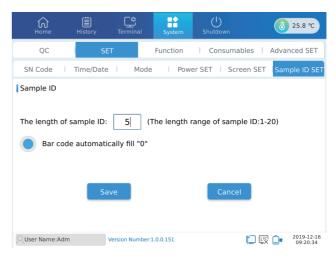


Fig. 6.42 Sample ID Setting

6.3 System Function

The system function involves configuration setting, log and version upgrade.

6.3.1 Configuration Setting

In this interface you can perform the following operations.

- 1) Check the "Uploads LIS and not display arrows" box and click "Save". When uploading the test data from the "history" interface to the LIS system, the test data does not contain the higher (↑) or lower (↓) arrows.
- 2) Check "Display the lot NO." and click "Save". The reagent lot number is displayed in the data list of "history" interface.
- 3) Click the "CRP Display Mode" box to select the display format of CRP test results, including "CRP", "hsCRP", "CRP and hsCRP", and click "Save".
- 4) Import data: copy the data folder to the root folder "pe" of the U disk, then insert a U disk into the USB interface of the instrument, and click "Data Import" to import the data to the instrument.
- 5) Export data: create a new folder "pe" in the root directory of the U disk, insert the U disk into the USB interface of the instrument, and click the "Data Export" to export the data from the instrument to the U disk.
- 6) Export log: refer to the steps of data export.

Fig. 6.43 Configuration Setting

6.3.2 Log

In this interface you can view the system logs information and operate the logs.

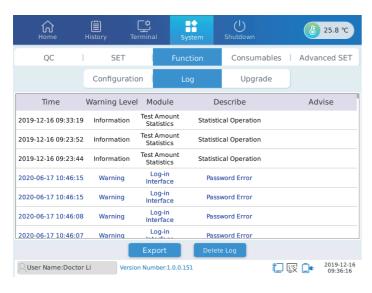


Fig. 6.44 Log

6.3.3 Version Upgrade

- 1) Enter the interface of "System-Function-Upgrade". Copy the upgrade file to a USB drive, set the new "FineCarePlus" folder, and then put the compiled host computer "FineCare114.bin" file and the lower computer "FineCarePlusMCU.bin" file in it.
- 2) Insert the USB flash drive into the USB interface of the instrument, and click "Version Upgrade" to upgrade.

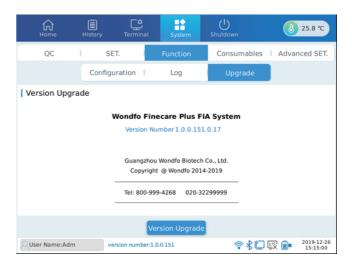


Fig. 6.45 Interface of Version Upgrade



The file format of the U disk must be FAT32.

6.4 Consumables

In this interface, you can read and view the ID chip information.

Insert the ID chip into the left front side of the instrument, enter the interface of "System-Consumables" and click "Read ID chip" to save the contents of the chip to the database, and then display the relevant information to the corresponding interface.

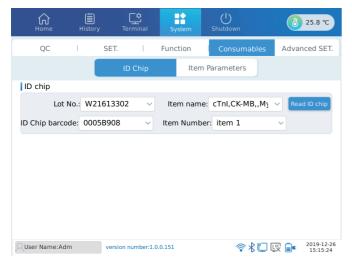


Fig. 6.46 Interface of Read ID Chip

6.5 Advanced Setting

Advanced setting mainly provided an entry port for technical support. It is a Log in interface with higher privilege level. Advanced settings must be operated by technical service personnel authorized by Guangzhou Wondfo Biotech Co., Ltd.

7. Battery

For the instrument with battery, when you insert the power adapter, the charging indicator will display the charge state of the battery: insert the adapter, charging and fill up.



Fig.6.47 Charging Indicator

Charging indicator	Red	Green	"Red" indicates whether a valid power adapter is
charging	on	on	connected; "green" indicates
Fill up	on	off	whether the battery is fully charged.

Note:

- ① There is an indicator light only for instrument with battery.
- ② No power adapter connected, the indicator light is not on.

1) When the instrument is off

- When the power adapter is not connected, the indicator is off and the power is unknown;
- > When connected to the power adapter, the red light is "on", the green light is "off", means the battery is full, and the green light is "on", the battery is not fully charged.

2) When the instrument is in normal operation

- ➤ When the power adapter is not connected and only the battery is used for power supply, there is a icon displays in the screen.
- > When connected to the power adapter and both use the battery and adaptor for power supply,
- The red light is "on", the green light is "off ", means that the battery is full and not charged, an icon displays in the screen.
- The red light is "on", the green light is "on", means that the battery is charging and ar icon displays in the screen.



For the instrument without battery, there is no LED light in the Charging indicator, and no battery icon and adapter icon displayed in the status bar at the bottom right of the main interface.

45

Section VII LIS Connecting

Here provide operational instructions on connecting **Finecare[™] FIA Meter II Plus SE** to LIS and PC. Connecting the instrument to LIS or a PC allows:

- (1) test results to be sent to LIS or a PC immediately after the test is completed;
- (2) history data stored in the instrument to be sent to the LIS or a PC.

Transfer Protocol Instruction

Finecare™ FIA Meter II Plus SE sends data to outside by UDP, click "LIS" when the test is completed every time, the current test data will be sent out.

The default connection setting is:

Finecare™ FIA Meter II Plus SE IP address: 192.168.0.3

Finecare™ FIA Meter II Plus SE Subnet mask: 255.255.255.0

Finecare™ FIA Meter II Plus SE Gateway: 192.168.0.1

Receiving IP of PC: 192.168.0.88 Subnet mask of PC: 255.255.255.0 Default gateway of PC: 192.168.0.1

PC port: 20035

Communication mode: UDP, TCP

PC Data receiving format

Start code + total number of bytes + Command block + End code + Checksum Command block content

Sample No. & Serial No. & Sample Type & Name & Sex & Age & Patient No. & Admission No. & Bed No. & Submitting Division & Submitting Doctor & Submitting Time & Tester & Test Time & Re-tester & Remark & Item Code 1 = Item 1 Results & Item Code 2 = Item 2 result \ n (End mark)

1. Connect Finecare™ FIA Meter II Plus SE to LIS/PC.

Method 1: Connect Finecare™ FIA Meter II Plus SE to a dedicated computer.

1) Connect the **Finecare™ FIA Meter II Plus SE** and the PC running LIS system by RJ45 ethernet cable.

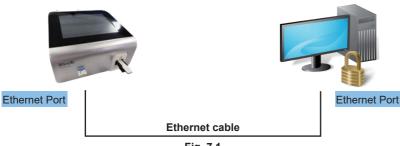


Fig. 7.1

2) Switch on the "Network connection" window on the PC, as shown in the following figure.

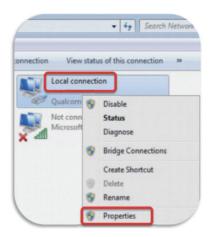


Fig. 7.2

3) Double click "Local connection" icon and click "Properties" to enter "Local Area Connection Properties" (See Fig. 7.3).

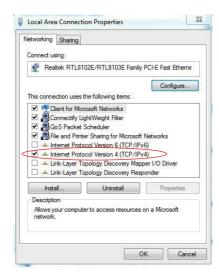


Fig. 7.3

4) Double click "Internet Protocol (TCP/IP)" to set up "Internet Protocol (TCP/IP) Properties". Set IP address as 192.168.0.88, click "OK" (See Fig. 7.4).

Fig. 7.4

Method 2: Multiple Network Interface Card

If there are multiple NIC (Network Interface Card) in the PC running LIS system, be sure that the setting IP is the IP of connected network, the method as same as Method 1 (See Fig. 7.5).

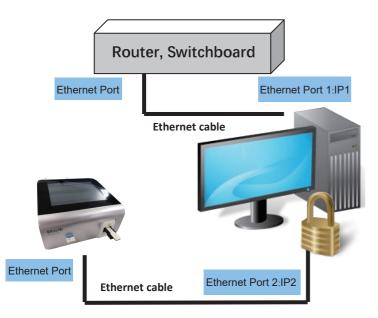
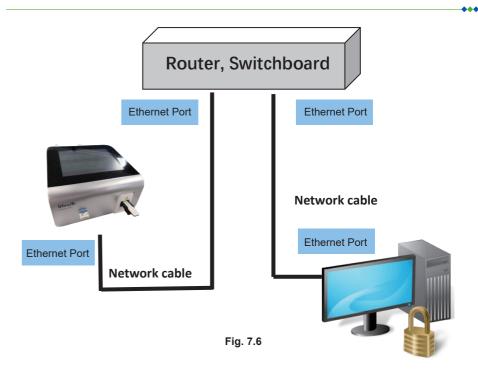


Fig. 7.5

Method 3: LAN (Local Area Network) Connection

The Finecare™ FIA Meter II Plus SE and the PC running LIS system can be connected with router or switchboard, the method as same as Method 1 (See Fig. 7.6).



Set up the connection settings in Finecare™ FIA Meter II Plus SE.

1) Navigate to the main interface of the instrument, click "Terminal", and then choose "Local SET." in the "Communications SET." interface. And make the following settings.



Fig. 7.7 Local Setting

2) Set up the network port IP address of the instrument for LIS transmission and ensure consistency with IP address of the computer terminal (See Fig. 7.8).

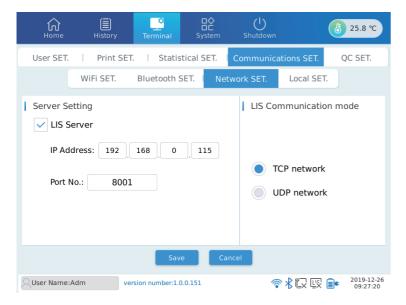


Fig. 7.8

Steps to transfer data through LIS.

- 1. Set the IP address of the instrument and PC by the above steps.
- 2. Open LIS data receiving software installed in the computer, and set up the connection mode, which can be TCP or UDP. The connection mode needs to be consistent with the instrument settings. The interface of the LIS system on PC is shown below.

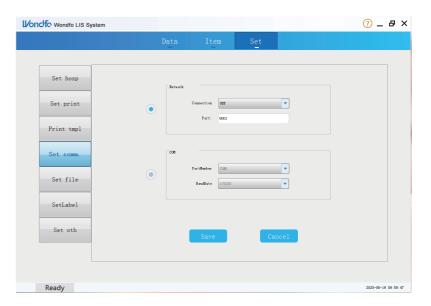


Fig. 7.9

3. In the "History" interface, upload the selected history data to PC by clicking "LIS" button. The data received by the LIS is shown in the following figure:

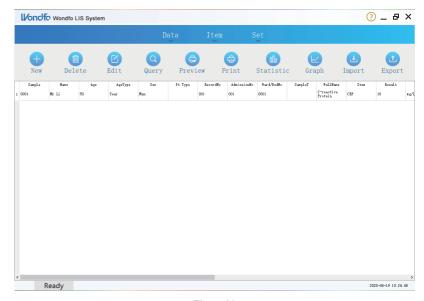


Fig. 7.10

Section VIII WIFI and Bluetooth

1. WIFI Function

The WIFI function of this instrument is used for LIS data transmission. The operation steps are as follows:

1) Set the network parameters of LIS server.

In the network setting interface, select the LIS server and enter the LIS server IP and port numbers and then choose the same communication mode as LIS server settings.



Fig. 8.1

- 2) Connect WiFi to server network, refer to "WIFI Setting" in Section VI for more connection details.
- 3) Open the LIS software in the computer, and set up the port NO. and communication mode, and then click "Save" to keep the setting, refer to **Fig. 7.9**.
- 4) Transfer the test result.

In the "History"interface, upload the selected history data to PC by clicking 'LIS' button. The interface of the receiving data in LIS software refer to **Fig. 7.10**.

2. Bluetooth Function



The Bluetooth function of the instrument can only be used with supporting tools and software systems, which need to be developed.

Section IX Maintenance and Care

1. Cleaning

Use a damp cloth with neutral detergent or 75% isopropyl alcohol to clean the external surface of the instrument.

If the instrument has been used in clinical setting and needs to be repackaged, replaced or transported, it must be cleaned. Use disinfectant and a cloth to wipe external surface of the instrument thoroughly. Spray-washing or clean any internal parts and inner surface with disinfectant are prohibited as liquid may seep inside the instrument.

\bigwedge

Note:

- Turn off the instrument and plug out all the connected wires before cleaning.
- · Avoid splashing liquid into the instrument during cleaning.
- · Connect the wires and use the instrument after the surface of it is completely dry after cleaning.

2. Maintenance

Besides regular cleaning or replacing print paper roll when needed, **Finecare™ FIA Meter II Plus SE** needs minimal maintenance. Any spillage should be cleaned when inserting a reagent card into the instrument.

When using the battery for the first time, the battery shall be charged in advance before use.

If the battery is not be used for a long time (more than two or three months), you should charge the battery first before use again.

Replace the battery: when the battery reaches its service life, or have peculiar smell or leakage, you should replace a new one. Please contact Wondfo company or local sales representative to replace the battery of the same model.

Ŵ

Warning:

- Any inappropriate operations may cause the battery become hot, catch fire, explode, destroy, or decline in battery capacity. Please read the manual and precautions carefully before use.
- You should use the same type of battery provided by Wondfo Company or local sales representative.
- The waste batteries should be returned to Wondfo Company or disposed of in accordance with local regulations.
- There are no components in the instrument can be repaired by the operator, and regular maintenance must be performed by authorized service personnel to avoid electric shock.

3. Return

Should a malfunction occur, please contact Guangzhou Wondfo Biotech Co., Ltd. or the local distributor. If it was determined that the instrument should be returned, a return authorization number will be assigned and a replacement instrument will be sent to you by Guangzhou Wondfo Biotech Co., Ltd. The return authorization number is printed on the packaging of the replacement instrument. The user is expected to utilize the packaging of the replacement instrument to return the malfunctioning instrument. Please send the instrument back to Guangzhou Wondfo Biotech Co., Ltd. as soon as possible following the receipt of the replacement meter.

4. Transportation and Storage

The original shipping container should be used to transport Finecare™ FIA Meter II Plus SE or to store it when it has not been in use over an extended period. Keep the Finecare™ FIA Meter II Plus SE, dry in upright position and in avoidance from moisture, sunlight, mechanical shocks, during transportation and storage. The specific conditions please refer to "Section III Technical Specification".

5. Disposal

Any used test devices should be disposed according to local ordinances regarding the disposal of bio-hazardous materials.

The Finecare™ FIA Meter II Plus SE, accessories and the packaging have to be disposed of waste correctly at the end of usage. Please follow Local Ordinances or Regulations for disposal.

6. Product Life

The Finecare™ FIA Meter II Plus SE is with service life as 5 years under normal use.

This is suggesting service life from Guangzhou Wondfo Biotech Co., Ltd., but it could vary according to the specific use.

Section X Trouble Shooting

Problem	Probable Cause	Remedy
	Power failure	Check the power plug.
	Run out of lithium battery (optional accessory)	Insert a valid power adapter
1. Finecare™ FIA Meter II Plus SE will not operate	Poor connection between the power adapter and the cord.	Pull out the cord and re-connect firmly.
	Main switch is off.	Turn on the main switch.
	Power adapter is damaged.	Contact Wondfo customer service for a replacement adapter.
2. No result displayed after	Excessive computation load	Wait till the computation is finished.
the test completes.	Computational abnormality	Restart the instrument.
O Took doubles Trees do se	Mechanical failure	Please contact Wondfo customer service center.
3. Test device Tray does not come out	(buzzing noise) Software abnormality.	Turn off the power and start fresh.
4. Display Screen does not	Electrostatic influence	Discharge any static electricity, reboot the system
function properly	Electric circuit failure.	Call customer service.
5. Message: Reset reagent and test again!	Test device or ID chip was not inserted.	Insert the test device or ID chip.
6. Message: Insert the corresponding ID chip	The lot number on the ID chip doesn't match the lot number of the test device inserted.	Choose "Change reagent and test again". After the test cartridge is removed from the test device tray, choose "Cancel test". Replace the ID chip with one of correct Lot number. Click "OK".
7. Message: "Optical System Fault", "Transmission System Fault", and/or "Circuit System Fault"	Internal hardware failure	Please contact Wondfo customer service center.

55

Section XI Contact Information

Guangzhou Wondfo Biotech Co., Ltd.'s expressed and implied warranties are conditioned upon full observance of manufacturer's published direction with respect to the use of Guangzhou Wondfo Biotech Co., Ltd.'s products. Under no circumstance whatsoever shall Guangzhou Wondfo Biotech Co., Ltd. be held liable for any indirect or consequential damages.

For technical assistance, call or send e-mail to us:



Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City,
Luogang District, 510663,Guangzhou, P.R.China
Tel: +86-20-32296083 400-888-5268(Toll Free)

Fax: +86-20-32296063

E-mail: Finecare@wondfo.com.cn Website: www.wondfo.com.cn



u	6	nc F	げ で

1751 1-71101 5	<i></i>
尺寸(长*宽*高): 142*210r	nm
工艺: 胶装, 封面过光胶	
改稿前编码:	

物料编码: 13006841

稿件确认签名:

颜色: PANTONE 2935 C PANTONE 361 C 其他四色印刷 材质: 封面157双铜, 内页80克双铜

修改内容: 口文字 口颜色 口尺寸 口工艺 口材质 口其他 口无 申请人:廖翠玲 设计师: 敖慧玲 设计时间: 2020.10.16

项目名称: FS-114说明书 (142*210mm) 80g铜版纸-国际版V01