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Wondfo®

Finecare

Finecare™ FIA Meter III Plus

Model No.: FS-205

Operation Manual

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Index of Symbols

Read all contents of this Manual carefully prior to use.

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

The following symbols are used on the Finecare™ FIA Meter III Plus, related components and accessories, labels are in the text of this user manual:

	Biohazard
	Caution
	Consult Operator's Manual
EC REP	European Authorized Representative
	Manufacturing Date
SN	Serial Number
	Keep Dry
	Keep away from Sunlight
IVD	For *in vitro* Diagnostic Use only
	Manufacturer
	Power ON
	Power OFF
	Protective Earthing
	Separate Collection for Waste Electrical and Electronic Equipment
	Fragile, handle with care
	This side up
	Do Not Stack
	Temperature Limitation
	Keep away from magnetic field
CE	CE Marking

Section I : Introduction

Thank you for choosing Finecare™ FIA Meter III Plus which is designed, developed, manufactured and sold by Guangzhou Wondfo Biotech Co., Ltd., The Finecare™ FIA Meter III Plus is a fluorescent immunoassay analyzer used to measure the results of tests manufactured by Guangzhou Wondfo Biotech Co., Ltd. The meter can be used in clinical laboratories and research laboratories and it is for professional use only.

This Operation Manual describes:

− Basic construction and performance characteristics of the Finecare™ FIA Meter III Plus;

− Instruction for the operation and maintenance of the Finecare™ FIA Meter III Plus;

− Basic instructions for testing samples.

The Finecare™ FIA Meter III Plus has been designed to provide the user with step-by-step instructions. The meter can display test results, menu options and instructions pertaining to the task being performed.

Intended Use:

The Finecare™ FIA Meter III Plus is a fluorescence analyzer manufactured by Guangzhou Wondfo Biotech Co., Ltd. The Finecare™ FIA Meter III Plus is for in vitro diagnostic use only and for professional use.

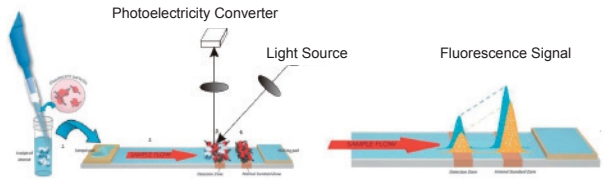
Test Principle

Finecare™ FIA Meter III Plus uses blue LED light of 470 nm as the excitation light source. The blue LED light hits a test device that has been inserted in the meter. 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 is.

After sample is added to the test device, the test device is inserted into the Finecare™ FIA Meter III Plus.

The meter measures the concentration of the analytes based on a pre-programmed calibration process.

The Finecare™ FIA Meter III Plus can measure the concentration of analytes with high sensitivity at pg/mL level.



The mechanical part of the Finecare™ FIA Meter III Plus comprises a carousel operable to rotate, a central axis and photoelectric coupling sensors to control the opening and closing of test device access. The carousel is to position and hold a plurality of test devices, controls or calibrators. Once the operator launches a Test instruction, the meter enters a preparation stage and a cover in the middle of the meter will open to reveal the test device access. Once the test device is inserted to the right position on the carousel, the photoelectric coupling sensors will detect it, the access will close and the carousel will rotate until the next position being ready to accept another test device. The operator can insert up to 20 single test devices in the carousel. The test devices are incubated inside the meter during processing.

Section II : Parts of Finecare™ FIA Meter III Plus

Hardware

The Finecare™ FIA Meter III Plus is a completely self-contained unit, intended for use with Finecare™ test devices.

The hardware contains the following elements:

- Carousel space accommodates up to 20 test devices
- A fluorometric optical system
- A mechanical system that processes the tests
- An incubation system to maintain all components at required temperature
- A central processing unit to control the entire meter
- A touchscreen and onscreen keyboard
- A thermal printer
- A scanner to read encoded information from the test device

CAUTION! Finecare™ FIA Meter III Plus can only accept test devices produced by Guangzhou Wondfo Biotech Co., Ltd.

Front View



Figure 2.1 Front view of FS-205

- Touch Screen: This is where all instructions and messages for operating the Finecare™ FIA Meter III Plus are displayed. The soft keyboard on the touch screen can convey all communications between the user and the meter.
- Test Device Slot: On the middle portion of the meter, the test device slot can accept one test device each time. Up to 20 test devices can be inserted through the slot.
- ID Card Slot: On the left of the test slot, the user can insert ID card (i.e. ID chip) through the ID card slot. The Finecare™ FIA Meter III Plus can read the batch information contained in the card.
- Printer: The Finecare™ FIA Meter III Plus is equipped with a built-in thermal printer. The printer is located on the lower part of the meter, directly below the test device slot.
- Test Device Exit: After the test finished or was stopped, the test device is expelled through the test device exit.
- Card Tray: the card tray is placed below the test device exit to collect expelled test devices.

Rear Panel

The rear panel of the Finecare™ FIA Meter III Plus contains several important hardware components. The location of these components is shown in the figure below:

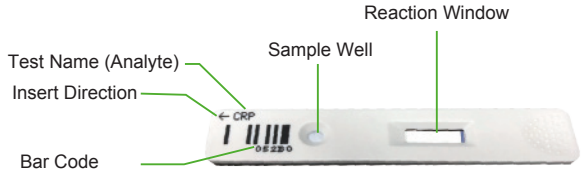


- VGA Port: Connection point for the monitor, projector or other display devices.
- USB Port: Connection point for mouse, keyboard, memory stick, barcode scanner, printer or other devices with a USB port.
- Ethernet Port: Connection point for Ethernet cable.
- COM Port: Interface to connect serial port.
- Power Connection: It includes: ON/OFF switch, receptacle for a power cord and fuse compartment.

Test Device and ID card

The test devices and ID cards are packaged separately from the meter and include instructions for running specific tests.

Note: The pictures below are for reference only. Please take in-kind as standard.



Test device



ID Card (i.e. ID chip)

Section III : Specifications

Technical Specification

Power	Power Input: 230Vac, 50Hz, 240VA Power Output: 120VA
Excitation light source	Blue LED light
Excitation spectrum wavelength (λ0)	λ0 = 470nm
Absorption spectrum wavelength (λ1)	λ1 = 525nm
Operation system	Linux 3.0.8
Detector	Photodiode
Operating System	Linux 3.0.8
Dimensions	374(L)*396(W)*480.5(H) mm
Weight	About 19.5 kg
Fuse	250V/3A, Φ5*20mm
Ports	USB×4, COM×1, Ethernet ×1, 1 VGA×1
Miscellaneous	Thermal printer 10'' touch screen USB*4, COM×1, 1 Ethernet Port, 1 VGA port Optional: can be connected to an external printer via USB port

Operating Environment

Temperature	15℃~30℃ (59℉~86℉)
Relative Humidity	20%~90%
Atmospheric pressure	86kPa~106kPa
Location	Dry, clean, flat, horizontal surface away from direct sunlight, mechanical vibration and strong electromagnetic interferences.

Storage and Transportation Environment

Temperature	-10℃~+50℃
Humidity	≤85%
Atmospheric pressure	86kPa~106kPa

Section IV : Warnings, Precautions

Please read the following information before using the Finecare™ FIA Meter III Plus. Conditions inadherent to this operation manual may lead to damage to the protective measurement of Finecare™ FIA Meter III Plus or even impairment to the device or personal health.

Warnings:

- Do not dismantle Finecare™ FIA Meter III Plus without written authorization from Guangzhou Wondfo Biotech Co., Ltd. or its representative.
- Disassembling the Finecare™ FIA Meter III Plus while it is powered on is strictly prohibited. If the user intends to change the configuration of the meter, please contact Wondfo technical support or local distributor.
- Do not spill any liquid on Finecare™ FIA Meter III Plus. Don' t immerse the meter into water or other liquids.
- Specimens are considered as carrying a risk of infection. Proper laboratory safety procedures should be followed at all times when working with patient specimens.
- Do not contact specimens, reagent or used test devices with bare hands. Gloves, goggles or other protective measures should be used when handling potential infectious materials.
- If reagent splashes into eyes, flush your eyes with clean water immediately and seek medical assistance for further treatment.
- Do not use inflammable items around the Finecare™ FIA Meter III Plus.
- The Finecare™ FIA Meter III Plus must be installed and used within the environments as specified in this manual.
- The Finecare™ FIA Meter III Plus shall be kept away from high humidity and direct sunlight. Do not freeze the meter.
- Operate the meter on a level, dry surface away from direct sunlight. Do not place the meter on an inclined surface.
- Do not drop or crash Finecare™ FIA Meter III Plus.
- Do not place the meter in environment with mechanical vibration.
- Do not place objects on the meter. This may cause compromised performance or mechanical damage to the Finecare™ FIA Meter III Plus.
- The mains outlet for Finecare™ FIA Meter III Plus shall be located in a user accessible position for easy disconnection in case of emergency.
- Earth the Finecare™ FIA Meter III Plus properly. Improper earthing may cause electric shock and test system damage.

Precautions:

- Only test devices manufactured specifically by Wondfo Biotech Co., Ltd are accepted by the Finecare™ FIA Meter III Plus. Inserting unmatched test devices into the Finecare™ FIA Meter III Plus may cause failure or wrong testing results.
- The used test devices, pipette tips and other materials must be handled and disposed carefully after single use in accordance with local regulations and procedures.

- The result of the test should be evaluated in the context of all the clinical and laboratory data available by healthcare professionals.
- Ensure the sample fluids are fully absorbed before the test device is inserted in the meter in order to prevent internal contamination of the meter.
- If liquids seep inside the meter, unplug the meter at once, contact technical support team of Wondfo Biotech Co., Ltd. or the local distributor.
- Do not write or place a label anywhere on the test device as it may interfere the meter functionally.
- Do not move the meter while a test is in process.
- Do not insert anything other than a test device provided by the manufacturer into the test device access.

Section V : Installation

1.Unpack

The Finecare™ FIA Meter III Plus and the items that come with it are provided in a single box. The test devices are packaged separately and include instructions for running specific tests. After opening the box, please check to ensure that the contents listed below are included.

Contents

No.	Item	Quantity
1	Finecare™ FIA Meter III Plus	1
2	Power cord	1
3	Operation Manual	1
4	Printer Paper	1
5	Packaging List	1
6	Quality Control card	1
7	Warranty Card	1
8	Routine Operation Instruction for Use	1

1) Remove the meter from the box and protective plastic bag.
2) Reserve the box and other packaging materials well for future transportation and storage.
3) Make sure that all the items in the packing list have been delivered. Make sure that no damage has been caused during transportation. If any item is missing, please contact your sales distributor or Guangzhou Wondfo Biotech Co., Ltd.
4) Place Finecare™ FIA Meter III Plus on a dry, clean, flat, horizontal surface. The meter must be set up in a room with an ambient temperature of 15℃ and 30°C, relative humidity of 20% to 90%, atmospheric pressure of 86kPa to 106kPa.

⚠ Mobile phone may cause electromagnetic disturbance to the meter thus lead to imprecision of measurement. Do not use mobile phone around the Finecare™ FIA Meter III Plus while the meter is in use.

⚠ The Finecare™ FIA Meter III Plus shall be used away from high-output equipments such as CT scanner system, MRI systems and X-ray machine.

Caution! The place where the Finecare™ FIA Meter III Plus is settled should be away from direct sunlight and dust accumulation.

The placement shall be easy for the user to disconnect the meter quickly and safely, as in case of emergency.

Leave sufficient clearance (at least 20cm from wall each side) around the meter for the circulation of air, which is essential to proper temperature control and for easy access to the power switch.

2. Installation of Keyboard and Mouse (Optional)

If you have purchased mouse and keyboard, please take the mouse, the mouse pad and the keyboard out of the package.

Carefully plug the keyboard extension into any ports with a ⇿ symbol in the back of the meter.

Carefully plug the mouse extension into any ports with a ⇿ symbol in the back of the meter.

Keep the keyboard, the mouse in place where is convenient for use.

3. Install External Printer (Optional)

For some Finecare™ FIA Meter III Plus not equipped with a thermal printer, an external one can be connected via a port with a ⇐ symbol.

Refer to the user manual of the printer to be connected for instructions on installation.

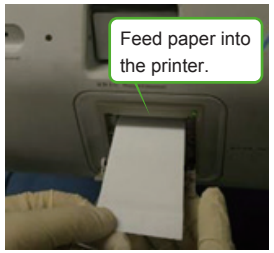
Most printers, such as HP 2010, are compatible with Finecare™ FIA Meter III Plus. Consult Wondfo for the compatibility of other printers if needed.

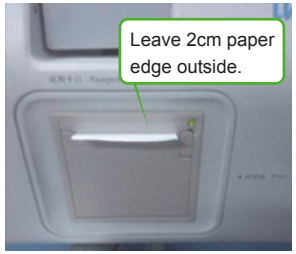
4. Install Printer Paper

For those meter equipped with a built-in printer, check whether it is necessary to replace paper before use.

1) Remove the printer cover by pulling up on the locked-lid.
2) Tear or cut a clean, straight paper edge to feed paper roll into the printer.
3) Place the paper roll into the paper compartment and adjust the tightness of the paper roll. Leave about 2 cm paper edge outside the printer cover.
4) Replace the printer cover.



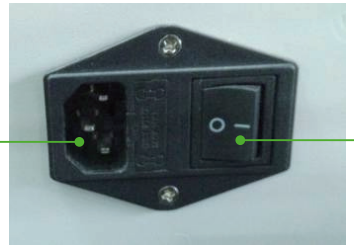




5. Connect Power Cord

1) Make sure that the power switch on the rear of the meter is on the ○ (OFF) position.
2) Plug one end of the power cord into the power source and the other end into the power cord receptacle.

Power Connection



Section VI : Getting Started

After the samples have been dispensed by the user, the Finecare™ FIA Meter III Plus automatically performs the analysis.

Finecare™ FIA Meter III Plus can be connected to a Laboratory Information System (LIS). The software processes the test device bar code and can send the test results to the LIS. The test results can be linked with the identities of patients.

1. Preparation

Please follow the instructions step by step before powering on the meter:

1) Check whether the power cord is steadily and safely plugged in the socket.
2) Check whether all the external equipments are well-connected.
3) If an external printer will be configured, please power on the printer.
4) If the meter will be connected to a LIS, please ensure that the Ethernet cable is correctly connected to the meter and a desktop computer.

⚠ **The meter must be plugged into a properly earthed, independent socket. The earthing voltage of the socket shall not exceed 0.5V.**

⚠ **Frequent power breakdown can severely affect the performance and liability of the meter. The user must sort out preventive measures, for example, installing an uninterruptible power supply (UPS), prior to use the Finecare™ FIA Meter III Plus to reduce the risk which power breakdown may bring.**

2. Starting the Meter

1) Turn on the power switch of the meter.
2) The Finecare™ FIA Meter III Plus comes from the manufacturer or distributor with a default Administrator login ID. See Fig.6.1. Log in with the ID information as below:
   User Name: Adm
   Password: 123456



Figure 6.1 Login Interface

3) The meter will check its hardware (and software) automatically. The self-check procedure takes about one minute.

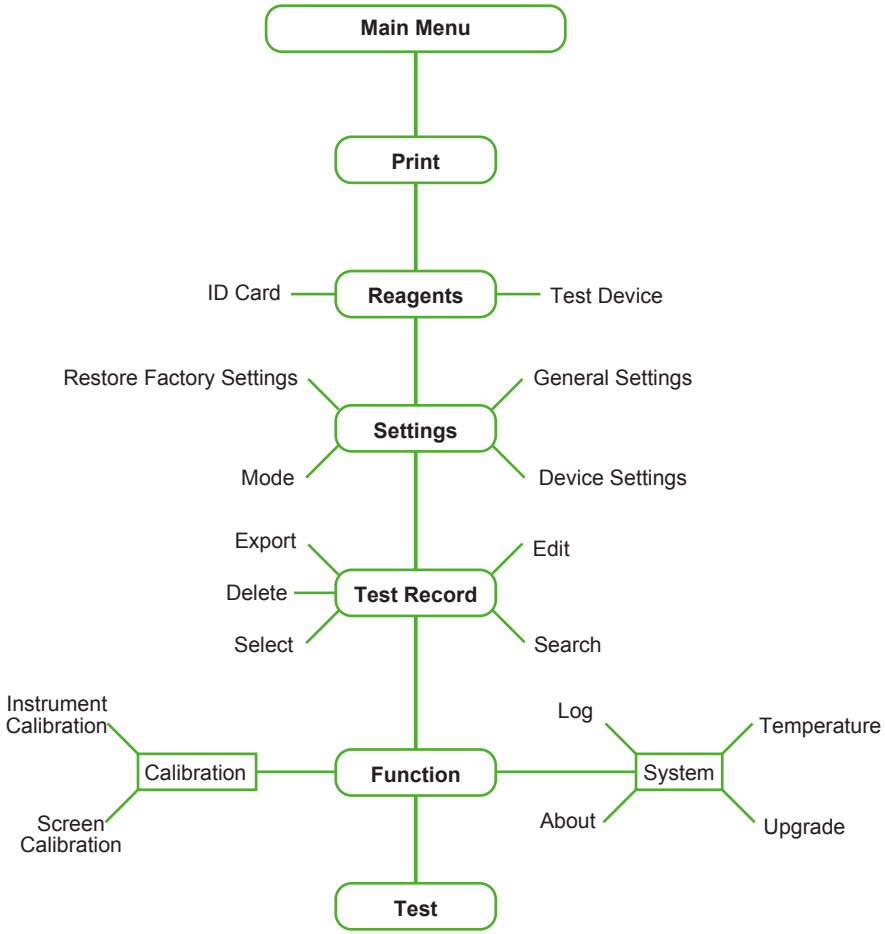
Software self-check is not noticeable.

Hardware self-check: the Finecare™ FIA Meter III Plus tests all its motors. Expect to hear noises inside the meter and if any test device is left inside the carousel, it will be kicked out by the meter from the test device exit. After the self-check, the meter can perform its tasks. Expect to see the main interface as in Figure 6.2.



Figure 6.2 Main Interface

3. Main Menu Structure



4. Settings

The parameters of the Finecare™ FIA Meter III Plus have been set up before release.

Caution! Configuration parameters should be modified by trained and qualified personnel. Any modification to settings may lead to problems or cause it to operate in an unexpected manner when the system is used. Make sure that modifications are necessary and justified.

4.1 Mode Settings

Finecare™ FIA Meter III Plus has been designed to operate in different modes. See Figure 6.3. The user can choose the User mode or the Administrator mode. The Service Mode and the Factory Mode are accessible to the staff from Wondfo Technical Support team. Unauthorized person cannot configure the settings of the meter through the Service or Factory Mode.

The default administrator ID should be changed when the meter is initially installed at the customer site.

Users without Administrator authorization have access to the following functions:

- Power on the meter
- Run test with patient samples
- Review test data

Users with Administrator authorization access can further perform the following functions:

- Load test types
- Managing users
- Load and save test records
- View user history
- View log files
- Review patient results
- Review statistics
- Change settings



Figure 6.3 Mode Settings

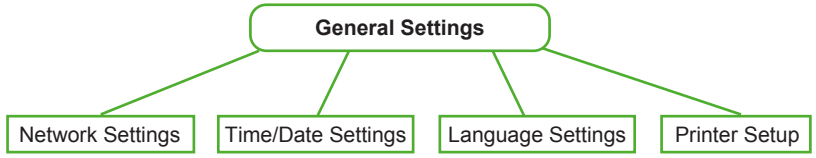
4.2 Restore Factory Settings

The user may need to restore the Finecare™ FIA Meter III Plus to factory settings to fix some problems. Follow these instructions to reset the meter:

1) From the main interface, click Settings;
2) Select Restore Factory Settings from the submenu;
3) Click Save to confirm, or click Cancel to exit.

Note: the user must back up all data and settings prior to restoring the factory settings. If you need to restore to factory settings of automatically adding samples or master control, please contact Wondfo Technical Support Team.

4.3 General Settings



4.3.1 Printer Setup

1) Choose printer: for Finecare™ FIA Meter III Plus which are equipped with built-in thermal printer, click the menu bar after Choose Printer, select Thermal Printer from the drop-down menu (See Figure 6.4).
   For a meter which is connected with an external printer, choose the suitable printer model from the drop-down menu (e.g., HP1020, HP1010, HP1108), see Fig. 6.4;
   Note: If the user needs to connect a printer that is not listed in the menu, please contact Wondfo Biotech Co., Ltd..
2) Paper: Set paper size to A4 or A5 as preferred;
3) Report Style: if the meter is equipped with built-in thermal printer, choose Default Template; if the meter is connected to an external printer, choose either Default Template or Custom Template.
4) Select Auto Print to automatically print the results after the test is finished.
5) Click Save to confirm, or click Cancel to exit without saving the settings.



Figure. 6.4 Print Option

4.3.2 Language Settings

The Finecare™ FIA Meter III Plus is capable of presenting the menu, message and other information on the screen in either Chinese or English.

1) From the main interface, click Settings, choose General Settings;
2) Select Language Settings from the submenu, See Figure 6.5.
3) Select the language preferred;
4) Click Save to confirm, or click Cancel to exit without saving the settings.



Figure 6.5 Language Setting

4.3.3 Time/Date Settings

Set Date

1) From the main interface, click Settings, choose General Settings;
2) Select Time/Date Settings from the submenu, see Figure 6.6;
3) The user can change the displayed date from as YYYY-MM-DD, MM-DD-YYYY, DD-MM-YYYY, MM/DD/YYYY, DD/MM/YYYY or MM/DD/YY. The user can upgrade the current year, month and day by selecting the parameter to change and using the (Up) or (down) button to change.



Figure 6.6 Time/Date Settings

Set Time

1) The time format is set as 24h format.
2) In the Time fields, use or to select the hours and minutes, or use numeric keyboard to enter the correct time.
3) Click Save to confirm, or click Cancel to exit without saving the settings.

4.3.4 Network Settings

This function allows the user to set network configurations. Connecting the Finecare™ FIA Meter III Plus to LIS allows (1) test results to be sent to LIS immediately after the test completes; (2) history data stored to be sent to the LIS.

Note: The operator can only configure the network settings in the Administrator Mode.

Note: Make sure that the Finecare™ FIA Meter III Plus and the Local Area Network (LAN) have been appropriately connected with an Ethernet cable.

1) From the main interface, click Settings, choose General Settings;
2) Select Network Settings from the submenu, the following screen appears, see Figure 6.7;
3) Select Use the following IP address, configure the IP Address, Subnet Mask, Default Gateway and MAC address.

   Note: the MAC address is invisible under the User mode. It has been set up when the meter is released from the manufacture, it can be left unchanged.

   Note: the IP address for the meter shall not conflict with other instruments on the LAN.
4) Click Save to save the configuration, or click Cancel to give up the modification to the network.

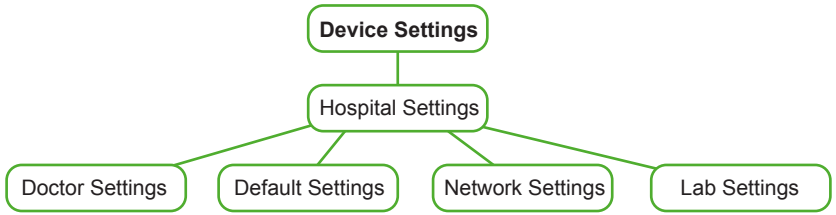
Note: If the operator needs to connect the Finecare™ FIA Meter III Plus to a Laboratory Information System (LIS), please refer to Sec. 4.4.4.



Figure 6.7 Network settings

4.4 Device Settings

This function allows the user to establish and maintain the user accounts of different accesses, to maintain the installation information of Finecare™ FIA Meter III Plus, as well as contact information of Wondfo Biotech Co., Ltd.



4.4.1 Lab Settings

This function allows the administrator to set the name of the hospital or clinical laboratory that will appear on all test result reports.

1) From the main interface, select Settings;
2) Select Hospital Settings from the submenu, see Figure 6.8.
3) Click the text box, type the information into the text box by using the touchscreen keyboard;
4) Click Confirm to save the settings, or click Cancel to exit.



Figure 6.8 Lab Settings

4.4.2 Managing Users

It is recommended that the administrator manages the user account in the initial use of Finecare™ FIA Meter III Plus. Managing User account includes adding user, editing user account, deleting user account or editing access level.

Add User

1) Select Doctor Settings from the Hospital Settings menu;
2) To add user: click New. See Figure 6.9. Text in the information for a new user in the popup Edit user window, see Figure 6.10.
3) There are four options of role for the new user to choose: Submitter, Auditor, Inspector or Laboratory Technician. Choose according to the role of the user.
4) Click Confirm to save the change, or click Cancel to exit. See Figure 6.9.



Figure 6.9 Add new user



Figure 6.10 Text in information for a new user

Edit User

1) Select the entry that is to be edited, choose click for details to view detailed information of the entry. See Figure 6.11.
2) To edit the entry, choose Edit. Then the pop-up window will show the department to which the user belongs and the shortcut for the user's name. See Figure 6.12.
3) Text in new information, i.e. department, shortcut, for the entry.
4) Click Confirm to save the change, or choose Cancel to exit.



Figure 6.11 View details of a user

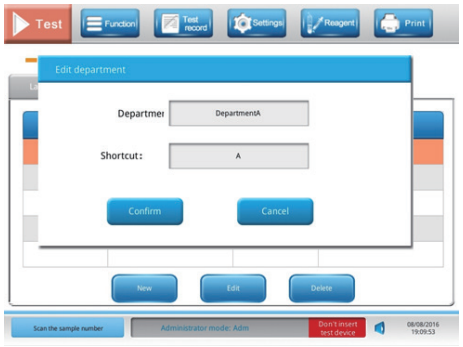


Figure 6.12 Edit information of a user

Delete User

1) Select the entry to be deleted, click Delete.
2) Click Confirm to save the change, or choose Cancel to exit.

4.4.3 Default User

All user account information and their shortcuts can be viewed in the default settings. See Figure 6.13.

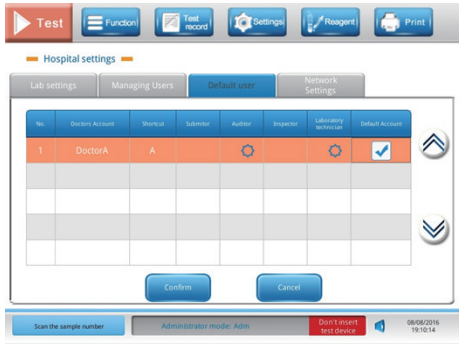


Figure 6.13 View default account

4.4.4 Network Settings

Connecting to a LIS

The LIS Server option is used if the Finecare™ FIA Meter III Plus is connected to a LIS.

1) Click Settings on the top bar, navigate to Device Settings -hospital settings —Network Settings.
2) Tick in the box before LIS Server. Text in the IP address and corresponding port number into the columns below the LIS Server option.
3) The information on Finecare™ FIA Meter III Plus can be sent via three methods: serial ports, TCP (Transmission Control Protocol) or UDP (User Datagram Protocol). The operator can choose one of these methods for communication. See Figure 6.14.
   Note: if the operator changes the communication method, it is recommended to change the port number at the same time in order to avoid port conflicts on the network.
4) Click Confirm to save the configuration, or choose Cancel to exit.

Connecting to a POCT Management System

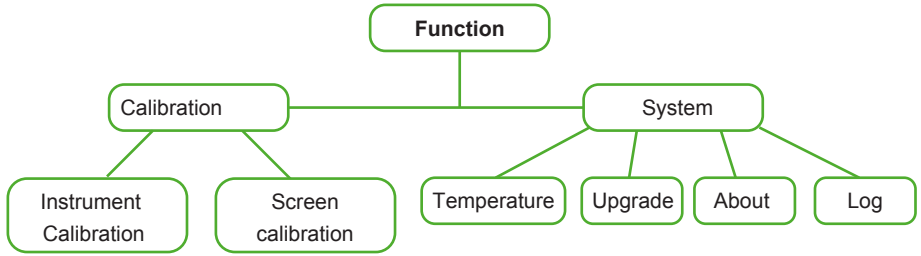
This option allows the operator to send test results, control results, requests for patient information, meter alarm message, meter to a point-of-care management system.

1) Tick in the box before POCT Management System. Text in the IP address and corresponding port number into the columns below the POCT Management System option.
2) Click Confirm to save the configuration, or choose Cancel to exit. See Figure 6.14.



Figure 6.14 Hospital network settings

5. Function



5.1 System

5.1.1 System Log

The administrator is allowed to view system log file in a defined period of time. The system log file contains all records of status or malfunction alarm.

1) Choose Function on the main menu, choose System from the submenu.
2) Define a time period by setting starting date and ending date from the dropdown menu, click Inquire.
3) The operator can choose to export log file to an external USB device or LIS by clicking Export. See Figure 6.15.

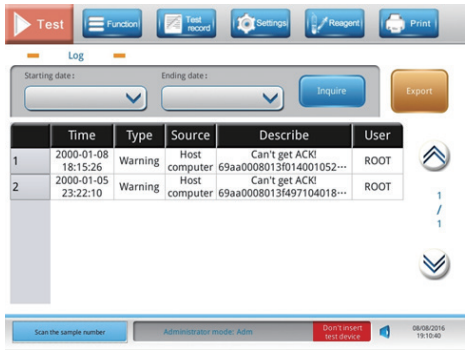


Figure 6.15 System log

5.1.2 Upgrade

This function allows the operator to manually Upgrade the software contained in Finecare™ FIA Meter III Plus either by using a USB device or updating on the Internet. See Figure 6.16.

Upgrade via USB

1) Insert the USB device into the USB port.
2) Click Function on the main menu, choose System from the submenu.
3) Choose Upgrade, then choose Upgrade from USB.
4) Click Confirm to upgrade the software, or click Cancel to exit.

Upgrade via Internet

Before choosing Upgrade via Internet, make sure that the Finecare™ FIA Meter III Plus is connected to Internet via an Ethernet cable.

1) Click Function on the main menu, choose System from the submenu.
2) Choose Upgrade, then choose Upgrade from Internet.
3) Click Confirm to upgrade the software, or click Cancel to exit.

5.1.3 About

It shows the information about the software contained in the Finecare™ FIA Meter III Plus. See Figure 6.17:



Figure 6.16 Software Upgrade



Figure 6.17 Software information

5.1.4 Temperature

Finecare™ FIA Meter III Plus can monitor and record the temperature inside the carousel. This function allows the operator to view the temperature trend in a specified period of time.

1) Click Function, choose System from the dropdown menu.
2) Choose Temperature.
3) Select preferred period of time from the dropdown menu. View the temperature trend in this period.
4) The operator can click Export to export log file to an external USB device or LIS. See Figure 6.18.



Figure 6.18 Temperature data

5.2 Calibration

5.2.1 Screen Calibration

The touch screen requires a calibration routine as to align the touch screen's coordinates to the display behind it. If a live feature on the display is to be properly activated, it indicates that the coordinates of the area touched on the screen is sufficiently close to the coordinates of the feature on the display.

1) Click Function, choose System from the dropdown menu.
2) Choose Calibration.
3) Click Confirm to start screen calibration, or click Cancel to exit. See Figure 6.19.
4) A coordinate image appears on the screen. Click on where it appears. See Figure 6.20.
5) If the screen calibration is successful, a message which reads "Calibration finished!" will appear on the screen. Click Confirm to exit.

If anyproblem occurs during screen calibration, please contact Guangzhou Wondfo Biotech Co., Ltd.



Figure 6.19 Start screen calibration

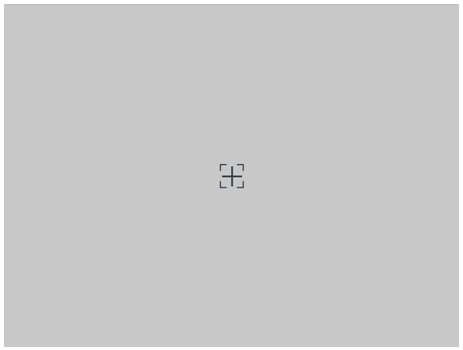


Figure 6.20 Coordinate appears on the screen

6. Shutdown

Power off the meter by using the power switch in the rear of the meter. Shutdown is completed when the screen goes dark.

Section VII : Routine Procedures

The basic work flow of Finecare™ FIA Meter III Plus includes:

Step 1: Start the meter
Step 2: Read ID card
Step 3: Plan the run
Step 4: Prepare sample
Step 5: Insert test device
Step 6: Run the test
Step 7: Print the test result
Step 8: Edit and export data
Step 9: Dispose used test devices

This section provides instructions to users on the basic work flow.

⚠ Always follow good laboratory practices and universal safety precautions when handling patient samples, test devices and other accessories.

Start the Meter

1) Turn on the power switch of the meter.
2) When the user login interface shows on the screen, touch the screen and use onscreen keypad to input user name and password, click Log in;
3) The Finecare™ FIA Meter III Plus will then enter the main interface and begins a self-check procedure. The self-check takes about one minute. After the self-check, the meter can perform its tasks.

Read ID Card

The ID card provided in each kit contains lot information and master curve. The master curve is established in manufacture for each lot of reagents. It establishes the mathematical relationship of the reference (standard) versus concentration of the analytes being tested and is provided with each kit.

1) Choose Reagent to enter the following interface.
2) Check if the information, i.e. Catalog No. and test item, matches the catalog No. and name of the test on the reagent box or package insert.
   Note: if the information does not match with that provided in the package insert, contact Guangzhou Wondfo Biotech Co., Ltd..
3) After inserting the ID card into the ID card slot, click "Read ID card" to export data from the ID card to the meter.
   Note: ID card only needs to be entered once for each lot of reagents. Once the meter recognizes the information of the card, there is no need to read ID card again for the next test, unless a new lot of test device is applied.
   Once the lot information is recognized, the ID card can be pulled out or remain inserted.
   Note: Please retain the ID card until test devices of the same lot are used up.

Plan a Run

a. When the test device access is closed

1) After starting the meter, expect to see the main interface. The test device access is closed and a message which reads “Don’t insert test device” appears on the bottom of the screen.
2) Click Test. A Start Test window will pop out. See Figure 7.1.
3) The inspector, the auditor and submit doctor are shown in the window and are not changeable. Select sample type from the dropdown menu.
4) If the operator prefers to use sample number automatically assigned by Finecare™ FIA Meter III Plus, type in a start number in the blank area after Automatically obtain sample number.
5) Click Confirm, or click Cancel to exit without saving the settings.
6) The test device access will then open. A message which reads Please insert test device appears on the bottom of the screen, which indicates that the test device access is now open.

b. When the test device access is open

1) Click Test. A window will pop out.
2) In the pop-out window, choose either Edit sample information or Sample type. Click Confirm. See Figure 7.2.



Figure 7.1 Start Test window



Figure 7.2 Edit sample information or choose sample type after the test device access opens

When choose Edit Sample Information, the operator can input sample information either by manually typing in or by scanning barcode on patient ID wristband.

If the operator has chosen Automatically obtain sample number, a sample number will be shown for an entry; otherwise the operator shall type in a sample number at first, then click Edit Sample or Scan to Add. See Figure7.3.



Figure 7.3 Edit sample information

3) Click Confirm, or click Cancel to exit without saving the settings.
4) Click Test, choose Sample type, Choose the sample type to be tested from a dropdown menu, and then click Confirm, otherwise click Cancel to exit.

c. Stop a Test

In case that the operator wants to give up a test, click Test, choose Stop test in the pop-out window. Click Confirm. The carousel will then start a mechanical reset.

Note: It is normal to hear noises during the mechanical reset.

The mechanical reset may last for several seconds. If the operator clicks Test during this process, a message which reads “The device is resetting. Please wait!” will appear. Click Confirm then wait. The used test device will be expelled through the test device exit.

Prepare Sample

Collect specimens and prepare sample in accordance with the procedure indicated in the package insert for specific assay.

Add sample into the sample well on the test device. See Figure 7.4.

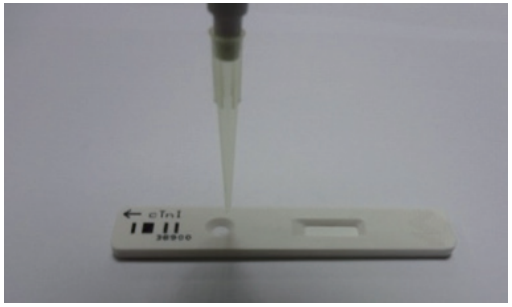


Figure 7.4 Add sample in the sample well

Insert Test Device

After adding sample into a test device, insert the test device into Finecare™ FIA Meter III Plus through the test device access.

To insert the test device, hold its handle and insert it into its assigned test position. Slide the test device all the way forward until it is seated in the position. See Figure 7.5.



Figure 7.5 Insert test device

Each test device occupies one test position on the carousel. A real-time diagram on the screen represents the occupancy of the carousel.

Once the test device is inserted, the test device access closes. The carousel rotates to transfer the test device into the test area. The bar code on the test device is then scanned. A time countdown will appear on the screen.

The carousel space can accommodate up to 20 test devices at the same time. If there is vacancy on the carousel, the operator can insert another test device 10 seconds after the last insertion.

⚠ Test devices should not be loaded in advance but just before the corresponding test is performed. In fact, preincubation in the meter can affect test results.

Note: It is important that the barcode on the test device are not covered or stained as it may make the Finecare™ FIA Meter III Plus fail to read the lot information of test device.

Run a Test

The inserted test device(s) will be incubated inside the meter under the desirable temperature for a predefined period, as indicated in the package insert of specific test.

⚠ Do not power off the meter while a test is in progress.

Print Test Result

Refer to Section 4.3.1 for print Option. With the Auto Print configuration, the test results can be automatically printed once completed.

Alternatively, after the test is completed, navigate to Test Record, select the records to be printed, click Print. See Figure 7.6.



Figure 7.6 Print test result

Edit and Export Data

Once the Finecare™ FIA Meter III Plus is connected to LIS or POCT Management System, the test result will be sent to LIS or POCT Management system every time the test is completed.

Test records can also be exported to external storage devices connected via USB ports.

The Edit function allows the user to add detailed information, such as patient's name, age, gender, bed number, inspector's name or so, to each sample.

To add detailed information for a particular record:

1) Select the record and click Edit. See Figure 7.7.
2) Type in the detailed information the user wishes to add; when finishes, click Confirm to save or click Cancel to exit. See Figure 7.8.



Figure 7.7 Select data record to be edited



Figure 7.8 Edit data record

The Inquire function allows the user to search records following specific search criteria.

1) Click Inquire, a window will pop out.
2) Set the search criteria in the pop-out window. For example, type in the patient's name, choose test date from 07/07/2016 to 09/09/2016 to retrieve records related to the patient during this time period.
3) Click Confirm to save or click Cancel to exit. See Figure 7.9.



Figure 7.9 Retrieve records using filters

The Choose function allows the user to select multiple records at one time.

1) Click Choose, then a window pops out as in Figure 7.10;
2) Type in the starting and ending number of the records to be chosen, check Select All;
3) Click Confirm to save or click Cancel to exit;
4) If the user needs to select all these records, click Choose, tick in the box before Uncheck and then click Confirm.

The Delete function allows the user to delete selected records.

To delete records:

1) Select record to be deleted by clicking on the record or use Choose function to select more than one record.
2) Click Delete.
3) Click Confirm to delete the records selected, otherwise click Cancel to exit. See Figure 7.11.



Figure 7.10 Choose multiple records



Figure 7.11 Delete record

Dispose Used Test Device

Once the test is completed, the Finecare™ FIA Meter III Plus will expel the used test devices into the device tray.

⚠ Used test devices should be considered as potentially infectious materials. Protective wearing must be applied when manipulating used test devices. Qualified laboratory personnel should follow standard procedure to deal with these biohazardous materials.

Section VIII : Maintenance and Care

To ensure accurate test results, proper cleaning and maintenance is needed for Finecare™ FIA Meter III Plus.

1. Routine Maintenance

1.1 Cleaning

Finecare™ FIA Meter III Plus requires minimal maintenance. Occasional cleaning of the exterior surface is sufficient.

1. The meter shall be plugged out prior to cleaning.
2. Use a damp cloth with 0.5% bleach, 70% isopropyl alcohol or 70% ethanol to clean the external surface of the meter. Strong bleach, oxidizing substances or solvents can cause permanent damage to the screen and other external surface materials are prohibited to be applied to the meter.
   −Only neutral detergent can be used to clean the external surface of the meter. Errosive acid, alkine or strongly volatile organic solutions such as acetone, diethyl ether or chloroform are prohibited to use.

1.2 Decontamination

Decontamination involves:

- Routine decontamination after use should be performed on a periodic basis;
- Cleaning of accidental spills should be dealt immediately.
- Decontamination before repacking and transportation of the meter, if it will not be in use for an extended period or to be returned.

1. The meter shall be unplugged prior to cleaning.
2. Use disinfectant and a damp cloth to wipe external surface of the meter thoroughly.
   Internal parts and inner surface are prohibited by spray-washing or cleaning as liquid may seep inside the meter.

1.3 Replace Fuse

1. Turn off the power switch on the rear of the meter, then pull the power cord out of the power cord receptacle. Remove the power cord from the meter.
2. With a small, flathead screwdriver or something alike, open the fuse compartment on the rear of the meter nearby the power switch.
3. Remove the old fuse from the compartment using a puller and install a new fuse.
4. Replace the fuse compartment cover.

The specification of the fuse: 250V/3A,Φ5*20mm.

1.4 Annual Maintenance

Preventive maintenance should be taken annually.

The annual preventive maintenance shall be performed only by technicians authorized by the manufacturer. Please contact our customer services prior to annual maintenance.

If the meter will not be in use for longer than two weeks or will be in transportation:

1. Switch off the power and unplug the power cord from power source.
2. Clean the power cord with damp cloth and neutral detergent, dry it in a cool place and avoid exposure to sunlight. Pack the power cord in plastic bag.
3. Place the meter and the power cord in the original shipping box of the meter.

Section IX : Return and Disposal

Return

Should a malfunction occur, please contact the sales representative via 800-999-4268 or 400-888-5268. If it was determined that the meter should be returned, a return authorization number will be assigned and a replacement meter will be sent to you by Guangzhou Wondfo Biotech Co., Ltd. The return authorization number is printed on the packaging of the replacement meter. The user is expected to utilize the packaging of the replacement meter to return the malfunctioning meter. Please send the meter back to Guangzhou Wondfo Biotech Co., Ltd. as soon as possible following the receipt of the replacement meter.

Transport

Fully packaged Finecare™ FIA Meter III Plus can be transported by ordinary vehicles. Protect the meter from moisture, exposure to sunlight and mechanic shock.

Storage

Fully packaged Finecare™ FIA Meter III Plus should be stored in well-ventilated avoiding erosive gas.

Ambient temperature: -10ºC~40ºC
Relative Humidity: 20%~90%
Atmospheric Pressure: 860hPa~1060hPa

Disposal

At the end of the life cycle of this product, dispose the product in accordance with local ordinances and regulation.

Section X : Trouble Shooting

The chart below describes some of the problems that may occur while using Finecare™ FIA Meter III Plus. In some situations, error messages may be displayed on the screen, or a warning buzzer will be heard. If any problem that hinders the normal use of the meter occurs and human intervention may be need, please follow the instructions shown below to deal with the problem. In some cases no error message will be displayed, you can also deal with the problem according to the instructions shown below.
If unable to resolve the problem after troubleshooting, please contact Wondfo Technical Support.

Problem	Possible causes	Remedy
The meter functions properly except "Start testing" failure.	Driver parameter initialization fails.	Restart the meter.
	RFID initialization fails.	
	Gateway registration Fails.	
	Thermal sensor does not function properly.	
	Temperature control initialization fails.	
The home LS or limit Sensor does not function properly.	Mechanical movement faults	Test device insertion is prohibited and an error message shows. The test device(s) which has been positioned in the incubation area will be assessed according to the grade of error whether the test continues or not.
	Sensor failure	
Test device insertion is prohibited and error message shows.	Carousel stalling occurs.	Retest until the carousel stalling is cleared.
	Abnormality in temperature monitoring.	Check whether temperature control should be reconfigured.

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 shall Guangzhou Wondfo Biotech Co., Ltd. be held liable for any indirect or consequential damages.

For technical assistance, call 800-999-4268 or 400-888-5268.

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