Finecare™ FIA Meter Plus
Operation Manual

GUANGZHOU WONDFO BIOTECH CO.,LTD

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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 Plus**, related components and accessories, labels or in the text of this user manual:

Biohazard

Caution

Consult Operator's Manual

WEEE (Waste Electrical and Electronic Equipment)

Keep Dry

Operate at 10℃~30℃

Store at -10℃~50℃

Keep away from Sunlight

For in vitro Diagnostic Use only

Manufacturing Date

CE Marking

Serial Number

Manufacturer

Authorized

Representative

Fragile, handle with care

6 identical packages can be stacked at maximum

This side up

Direct

Current ON (Power)

Off (Power)

Thank you for choosing **Finecare™ FIA Meter Plus** which is developed, designed, manufactured and sold by Guangzhou Wondfo Biotech Co., Ltd., Finecare™ FIA Meter Plus is a compact, portable fluorescent instrument used for quantitative determination of concentrations of various analytes in human blood or urine.

Test Principle:
Finecare™ FIA Meter Plus uses a LED as the excitation light source. The light from the LED 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.

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

Intended Use:
The Test device and instrument are for in vitro diagnostic use only. **Finecare™ FIA Meter Plus** is intended for professional use.
Finecare™ FIA Meter Plus can be used in a laboratory of in a point-of-care setting.

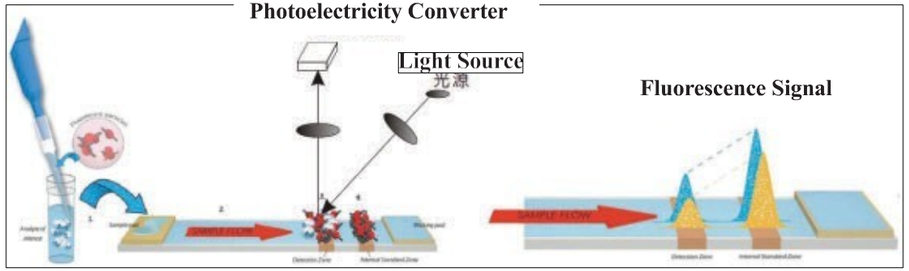


Figure 1 Working Principle

II

Unpacking

The **Finecare ™ FIA Meter 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 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.

Contents

1. List of Contents:

No.	Item	Quantity
1	Finecare™ FIA Meter Plus	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	CD Disk (electrical Operation Manual)	1
9	Packaging List	1

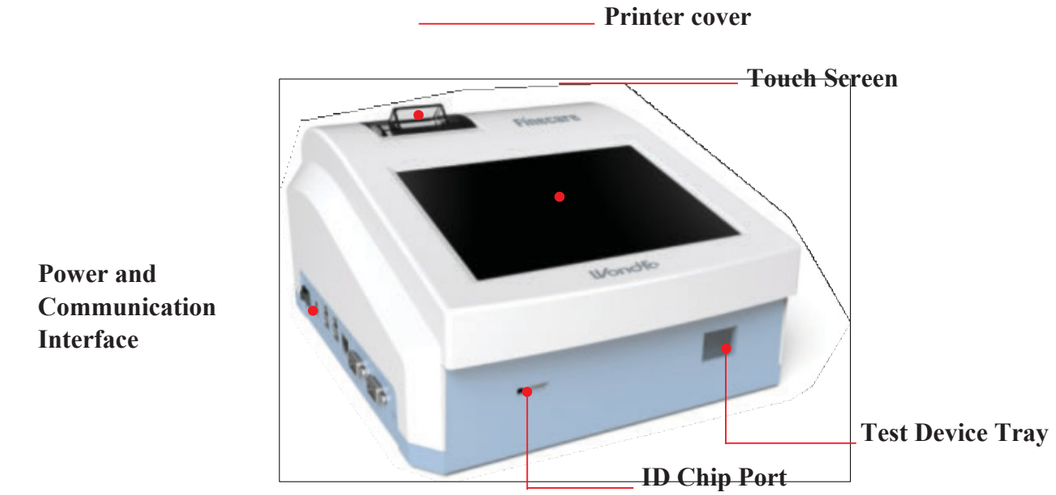


Fig. 2.1 Finecare™ FIA Meter Plus- Front View

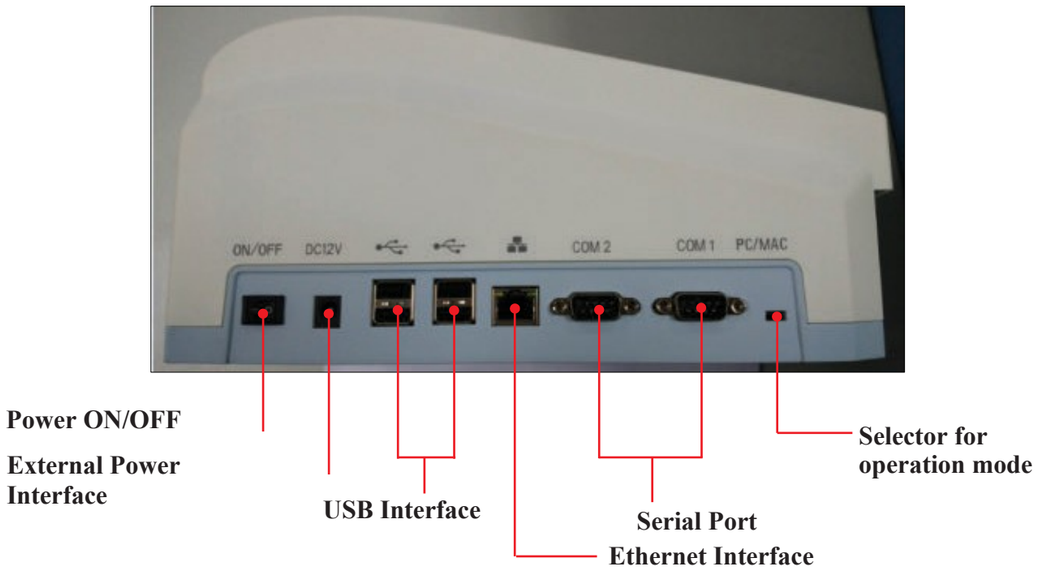


Fig. 2.2 Finecare™ FIA Meter Plus Features - Left View



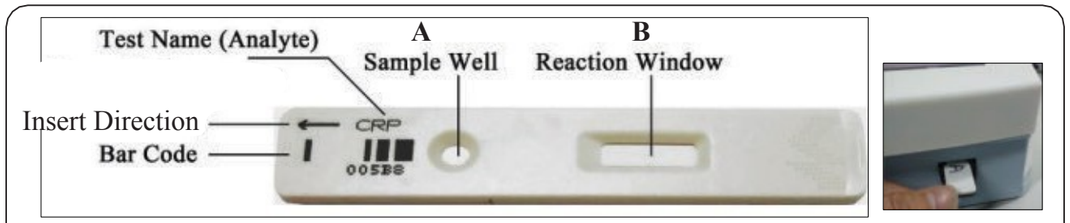
Fig. 2.3 Power Adapter



Fig. 2.4 Quality Control Card

Test Device and ID chip

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



Note: This accessory is Test Reagent's consumable

Fig. 2.5 Test device



Fig. 2.6 ID Chip

III

Basic Specification

Power	Adapter: Input: 100-240Vac, 50-60Hz, 1.4-0.7A
	Output: 12V⎓ 5.0A 60W MAX
	Power input: 12V⎓ . 45W
Excitation light source	LED
Excitation spectrum	Center wavelength λ0 = 470nm
Absorption spectrum	Center wavelength λ1 = 525nm
Specimen Type	Whole blood, serum, plasma or urine
Operation system	English and Chinese input method, customized intelligent management module
Detector	Photodiode
Storage Capacity	Up to 30,000 test results
Size	270*238*146mm
Weight	About 2.8 kg
Miscellaneous	Thermal printer LCD touch screen RS 232 computer interface port or Ethernet network English / Chinese operation interface available

Operating Environment

Temperature	10℃~30℃ (50℉~86℉)
Humidity	10%~80%
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℃ （14℉~122℉）
Humidity	≤85%

- The **Finecare™ FIA Meter Plus** must be used within the operating environment as specified in Section Ⅲ.
- Operate the meter on a level, dry surface away from direct sunlight.
- Use only the Power Adapter (including the power cord) provided with **Finecare™ FIA Meter Plus.**
- 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 meter functionally.
- Do not move the meter while a test is in process.
- 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.
- The test device tray shall be kept inside the main body of the meter all the time unless the user intends to put a test device or quality control card in it.
- The used Test device 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.
- Do not insert anything other than a test device provided by the manufacturer into the test device Tray.
- Do not spill any liquid on **Finecare™ FIA Meter Plus.** Don't immerse the meter into water or other liquids.
- Do not drop or crash **Finecare™ FIA Meter Plus.**
- Do not dismantle **Finecare™ FIA Meter Plus** without written authorization from Guangzhou Wondfo Biotech Co., Ltd. or its representative.
- Do not place objects on **Finecare™ FIA Meter Plus.** This may damage the optical alignment in turn result in compromised performance or mechanical damage.
- The mains outlet for **Finecare™ FIA Meter Plus** shall be located in a user accessible position for easy unplugging in emergency.

1. Power on

1) Place **Finecare™ FIA Meter Plus** on a dry, clean, flat, horizontal surface, with the front surface at least 10cm 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 Switch.



Power ON/OFF

External Power Interface

Selector for operation mode

2. Install Paper

1) Remove the printer cover by pulling up on the cover.
2) Tear or cut a clean, straight paper edge to feed paper roll into the printer.
3) Position the paper in a way that the paper will feed from under the roll, as opposed to over the top of the roll.
4) Insert the paper edge under the paper roller until it firmly seats or resistance is felt.
5) Place the paper roll into the paper compartment.
6) Replace the printer cover.

3. Main Interface

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

After switching on the meter, wait the meter to boot and show the main interface.
The test device tray will protrude automatically.

**Note:*
If the meter cannot log in the initial interface successfully in three minutes, switch off the meter and restart. If it still doesn't work, please contact your sales distributor or Guangzhou Wondfo Biotech Co., Ltd.

The main interface is shown as below:



A: Functions; B: Test Device Information; C: Result Display; D: Eclipses

① 【Temperature】 Display the internal temperature of the meter
② 【Test】 Choose the specific test to be run.
③ 【History】 Inquire history data
④ 【Account】 Basic statistical analysis for test data.
⑤ 【QC】 Start the self quality control process
⑥ 【Set Up】 Set parameters
⑦ 【Test Mode】 Choose test modes
⑧ 【Start Test】 Start to measure the test result

4. Set Parameters

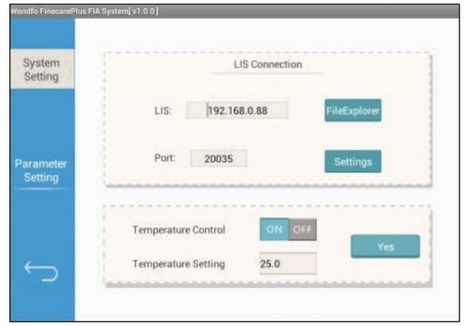
The “Set Up” function allows the user to set up parameters. To set parameters, assume that the meter is on and the screen is displaying the main interface.

4.1 Set Up LIS Connection

LIS Connection enables the user to transfer data from the **Finecare™ FIA Meter Plus** to a laboratory Information System (LIS) via the Ethernet cable, which comes with the **Finecare™ FIA Meter Plus.**

1) Click “Set Up”. The system information will be shown on the screen.
2) Input q1 in the "Authorization codes" field, click “Yes”.
3) Click “System Setting”.
4) The default setting of LIS connection is:
LIS IP address: 192.168.0.88
Port： 20035
To edit the LIS settings, type in new value in the corresponding box.





4.2 Set Up Temperature

The symbol and the temperature shown below is an indicator of the temperature inside the meter.

1) Click “set up” on the main interface;
2) Input q1 in the "Authorization codes" field, click “Yes”.
3) Click “System Setting”.
4) The default of Temperature Control is “ON”. If the temperature control is no more needed, click “OFF”.
5) The default temperature limit is 25℃. It is recommended to remain the setting as 25℃, unless different temperature preference for specific testing applies. Type in a preferred temperature value, click Enter.
6) Click “Yes” to confirm the change; otherwise click to quit.

4.3 Item Parameters

Configuring Item Parameters allows the user to add or edit test items, which will be used along with the meter, and their corresponding reference range.

To add test items:
1) Click “Add” ;
2) Type in an item name in the Item box.
3) Click “Next”, type in the “Sample Number” box, then Enter.
4) Type in the minimum limit and maximum limit of the reference range.
5) Click “OK” to save the newly added test item, otherwise click “Cancel” to quit without saving the change.
6) The newly added test item can be seen at the end of the Item parameter list.

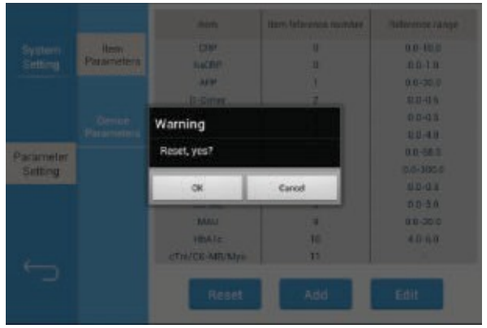




To edit the existed test items:
1) Click “Edit”.
2) The test items are listed on the left of the interface. Click on the test item to be edited, its name will appear on the ProName box.
3) Click on the Min box, delete the original value and type in the newly set value;
4) Assign a new value to Max by following the same steps as 3);
5) Click “Save” to save the change, otherwise click “Quit”.

To restore original settings:
1) Click “Reset”.
2) Click “OK” to confirm restoring original settings, otherwise choose “Cancel”.





Device Parameters:
To read the information about the following device parameters, click Read ;

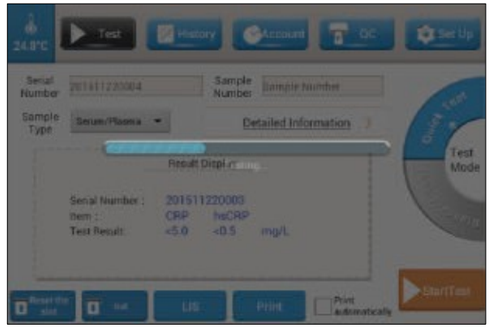
AD magnification times: Magnificating times of fluorescence signal.
Total length of the slot in running: The maximum distance running forward when motor starts with photoelectric switch.
Barcode recognition deadline: The timeout period of barcode recognition.
Sampling starting point: The starting position of fluorescence data collection.



Note:
These information are readonly to users. If you choose “Write”, a message said “Warning: Please enter password” will pop out, as users are not authorized to edit these parameters.

1. Run a Test
Run a Test to analysis a test device.
To start running a test:
1) Insert ID chip into the ID chip port until resistance is felt.
It is recommended to insert the ID chip after successful booting.
This step is necessary when a new lot of test device of specific test is applied on the meter for the first time. Once the meter recognizes the Lot information of the chip, there is no need to read ID chip again before running test, unless a new lot of test device is applied.
The ID chip can either be pulled out once the lot information is recognized or remain inserted.
2) Navigate to the main interface.
3) Click “Read ID Chip”. A message said “Warning: The ID chip ready” will prompt, click “Yes”. It indicates that the ID chip can be recognized by the meter.
4) Choose test mode by click on “Quick Test” or “Standard Test”.
5) Choose Test mode.
It is assumed that before switching Test Mode, the selector switch for operating mode, which is on the left side of analyzer, is on MAC.
Finecare™ FIA Meter Plus provides two test modes, the Standard Test mode and Quick Test mode.
Standard Test: Push the test device into the test device tray right after the specimen is fully absorbed. The analyzer acts as an incubation place for reaction for a preset time duration. Wait until the analyzer counts down to zero, the test result will be shown on the screen.
Quick Test: Push the test device into the test device tray after the reaction completes.
6) Input detailed patient information by clicking “Detailed information”..
If the user does not input a serial number for a record, the analyzer will automatically assign a serial number for it.
7) Apply the test sample on the test device according to instructions of specific test.
8) Start the test.
Quick Test: Gently push the test device that is completely reacted into the test device Tray. Click Read.
Click “StartTest”.
Standard Test: Gently push the test device into the test device tray immediately after the specimen is fully absorbed. Click Read. Click “StartTest”.
9) The meter will analyze the test device whilst the blue bar runs.





10) After the blue bar stops running, the test result will be shown on the screen. The test device tray will protrude after the test completes. If not, click“Out”.



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) Click "Read ID Chip ", **Finecare™ FIA Meter Plus** will read and keep the ID Chip information.
13) Click “Reset the slot” after the test is complete and the test device is removed from the test device tray.
14) When **Finecare™ FIA Meter Plus** is not in use, click “Reset the slot”. Turn off the meter by pressing the power switch and unplug.

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

2. History Data
The “History” function allows the user to view, to search, to delete or to export history data.

2.1 View History Data
1) Click “History”.
2) Serial Number, the tested item, the test result, the sample type, Name of the patient 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.
2.2 Search History Data
1) Click “Query” under the “History” interface,
2) Input the query conditions, **Finecare™ FIA Meter Plus** will filter test results that match the query conditions.

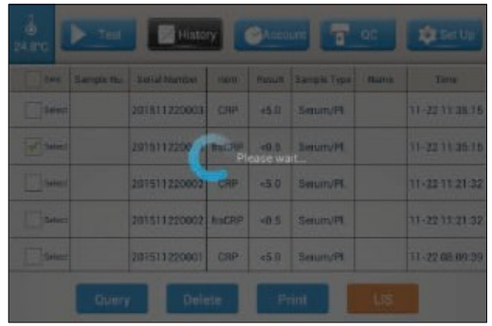




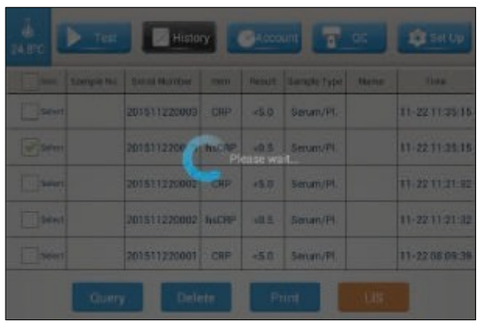
2.3 Delete History Data
1) Select records by ticking the box in front of the record. The selected records are to be deleted.
2) Click “Delete”.
3) Choose “Yes” to delete the selected records, otherwise click “No” to quit.



2.4 Print History Data
1) Click “History”.
2) Tick the box in the front of each record to select history data which are to be printed.
3) Click “Print”. The meter can print 10 records in maximum at a time.



2.5 Export History Data
It is assumed that the meter 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 meter will export data to the connected LIS.



3. Get a Count

The “Account ” function allows the user to get a count of the number of records in a query.

1) Click “Account” on the top of the main interface.

2) The user can choose “Test Account” or “Workload Account”.

Testing Account:

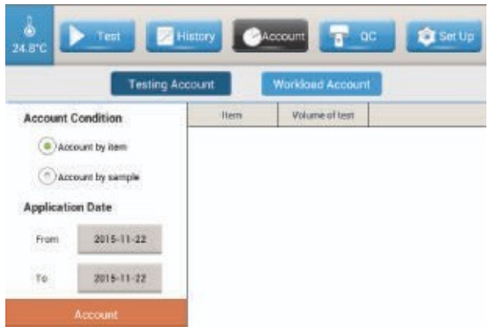
Choose “Account by item”, select the type of test item from a list of all test items, OR

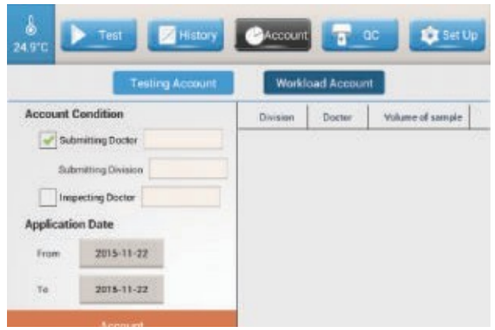
Choose “Account by sample”, select the type of sample type (urine, plasma, whole blood, etc) from the list.

Workload Account:

Check in the box prior to “Submitting Doctor”, choose the name of the Doctor from the list on the right; OR

Check in the box prior to “Inspecting Doctor”, choose the name of the Inspecting Doctor from the list on the right.





3) Apply a time filter to the records by clicking From 2015-11-22 and To 2015-11-22 and input dates.

4) Click Account .

This section provides operational instructions on connecting **Finecare™ FIA Meter Plus** to LIS and PC. Connecting the meter to LIS or a PC allows (1) test results to be sent to LIS or a PC immediatedly after the test completes; (2) history data stored in the meter to be sent to the LIS or a PC.

Transfer Protocol Instruction

Finecare™ FIA Meter Plus 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 Plus IP address : 192.168.0.3

Finecare™ FIA Meter Plus Subnet mask: 255.255.255.0

Finecare™ FIA Meter Plus 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

PC Data receiving format

For CRP: FF&test serial number&CRP test result&hs CRP test result&test time&item name&EE

Example：FF&1&<0.5&0.93&2012-07-30 13:59:33& Whole Range CRP&EE

1. Connect **Finecare™ FIA Meter Plus** to LIS \ PC.

Method 1: Connect Finecare™ FIA Meter Plus to a specific computer (see Fig. 6.1)

1) Insert one end of a network cable into the Ethernet port of **Finecare™ FIA Meter Plus** and the other end into the PC 's Ethernet port.

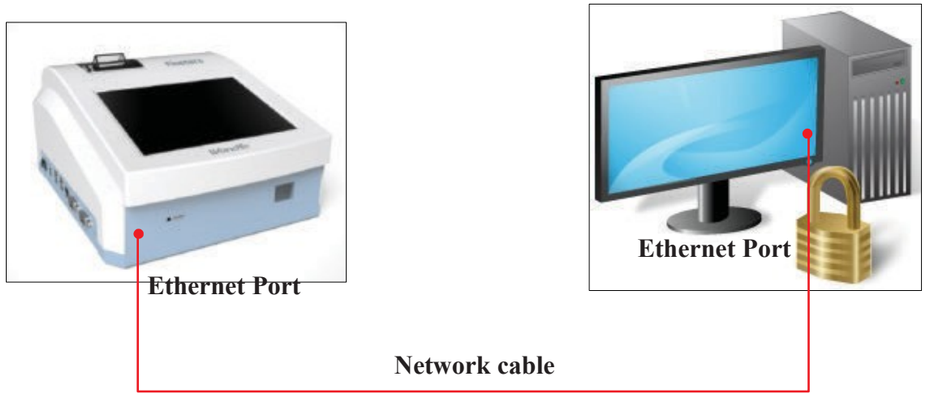


Fig. 6.1

2) Set IP address of the PC.

(1) Click “Start” -> “Routine”-> “Attachment”-> “Communication”-> “Network”; double click “local connection” and enter “Local Area Connection Status”.(See Fig. 6.2)

(2) Click “Properties” to enter “Local Area Connection Properties” (See Fig. 6.3).

(3) Double click “Internet Protocol Version 4 (TCP/IPv4)” to set up “Internet Protocol (TCP/IP) Properties”. Set IP address as 192.168.0.88，click “OK” (See Fig. 6.4).

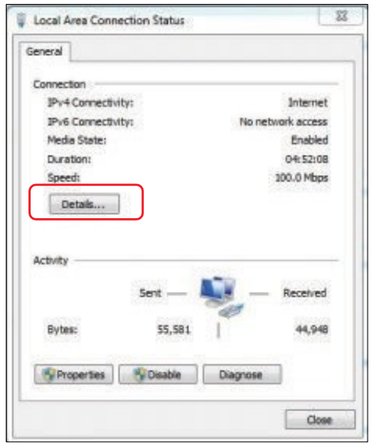


Fig. 6.2

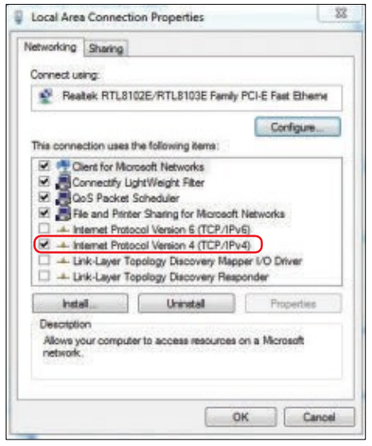


Fig. 6.3

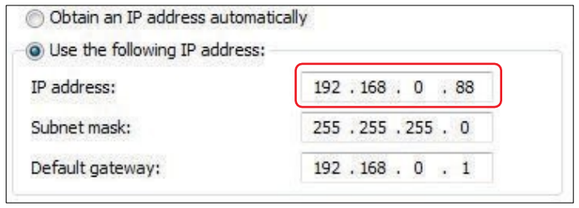


Fig. 6.4

Method 2: Multiple Network Interface Card

Install one more NIC (Network Interface Card) and corresponding driver in computer to work properly. Then use a standard network cable that can make normal PC access the Internet, one end of the network cable connects Finecare™ FIA Meter Plus’s Ethernet port, the other end connects PC 's Ethernet port of new Installed NIC. Alter the new NIC IP address in computer, the method as same as Method 1 (See Fig. 6.5).

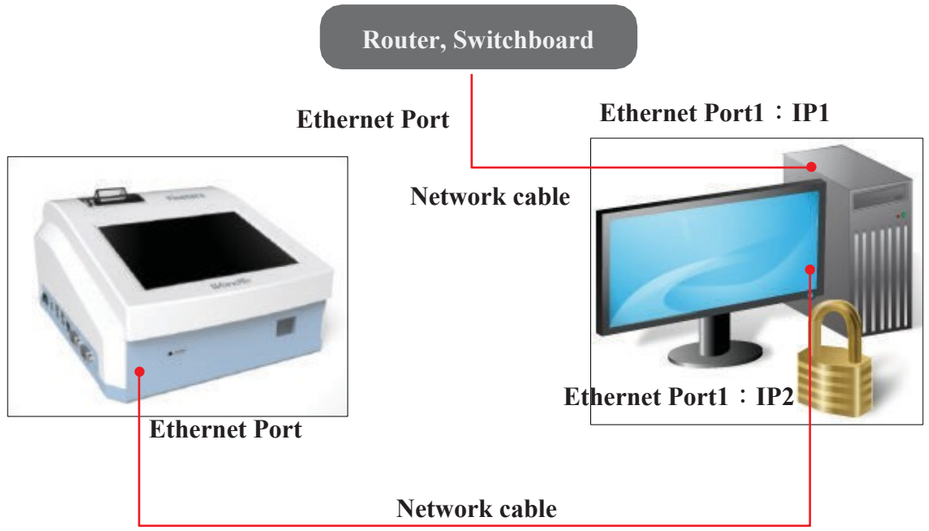


Fig. 6.5

Method 3: LAN (Local Area Network) Connection

Use standard network cables to PC access the Internet, one end of the network cable connects Finecare™ FIA Meter Plus’s Ethernet port, the other end connects Laboratory LAN(such as router and switchboard etc.). See Fig. 6.6.

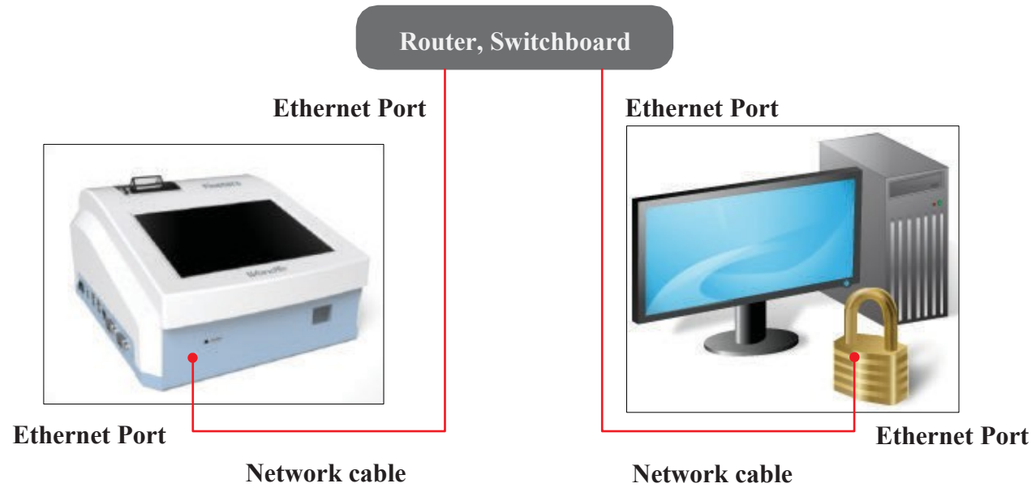


Fig. 6.6

1) Start the PC. Click “Start” -> “Routine”-> “Attachment”-> “Communication”-> “Network”; right-click “local connection”, choose “Properties” and enter to “Local Area Connection Properties”, double click “Internet Protocol Version 4 (TCP/IPv4)” . Choose “Use the following IP address” in the “Internet Protocol Version 4 (TCP/IPv4) Properties” window.

Don’t change primary IP address of PC. Example：Primary IP address：192.168.1.6.

(1) Cick “Advanced”，enter to “Advanced TCP/IP settings” (See Fig. 6.7).

(2) To add new IP address, click “Add” as indicated in Fig. 6.8.

(3) Enter the following information in the “TCP/IP address” window. Click “Add” (See Fig. 6.9).

IP address：192.168.0.88，Subnet mask：255.255.255.0

(4) Return “Advanced TCP/IP settings”, add gateway by clicking “Add…” as indicated in Fig. 6.10.

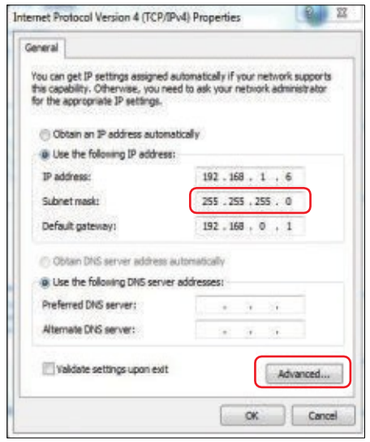


Fig. 6.7

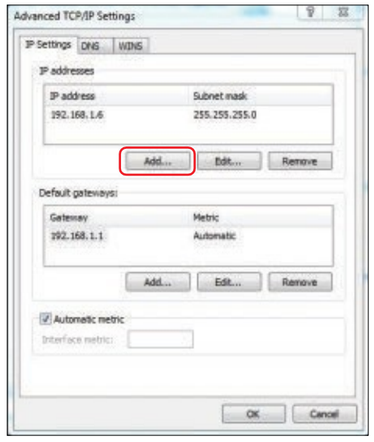


Fig. 6.8

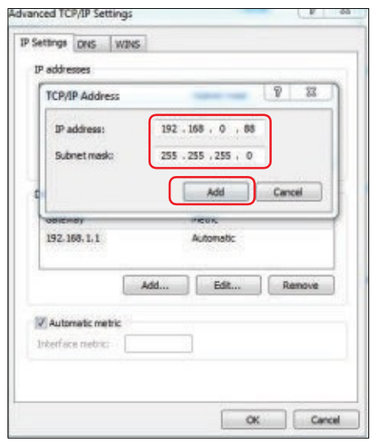


Fig. 6.9

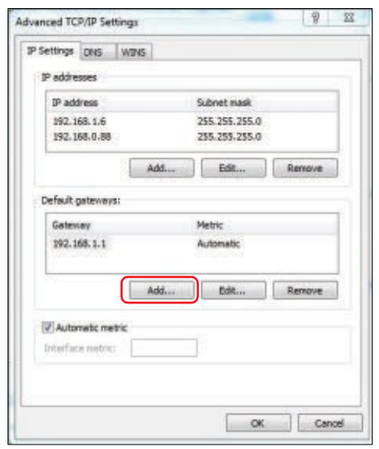


Fig. 6.10

(5) Enter gateway address in the “TCP/IP Gateway Address” window, click “Add” (See Fig. 6.11).

(6) Return to “Advanced TCP/IP settings” and click OK (See Fig. 6.12).

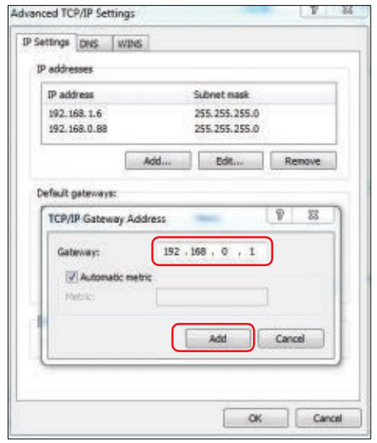


Fig. 6.11

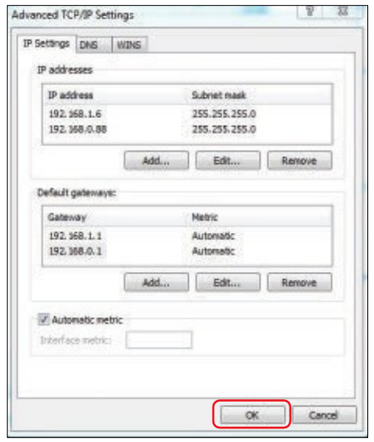


Fig. 6.12

(7) Return to IP address setting menu, click “OK” to confirm IP setting.

(8) Run ReceiveFromCRPTemp.exe. The meter will automatically send test results to the connected PC every time after a test finishes. Fig. 6.13 shows an example that the PC receives CRP test result from Finecare™ FIA Meter Plus.

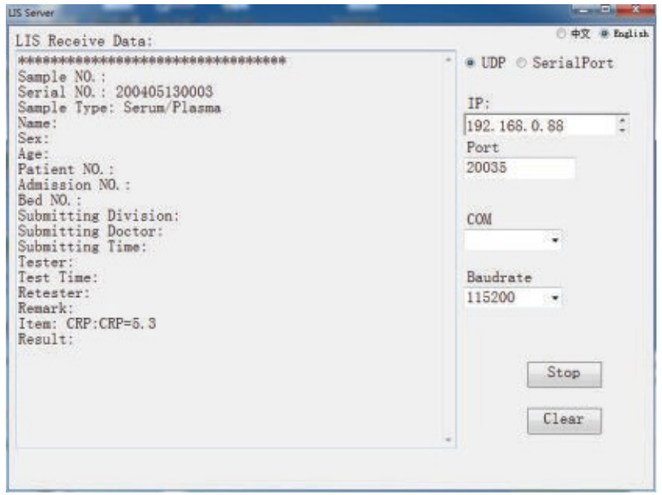


Fig. 6.13

2) Set up the connection settings in **Finecare™ FIA Meter Plus.**

(1) Navigate to the main interface of the meter, click “Setup”. Choose "System Settings". See Fig. 6.14.

(2) Click Settings , Choose “Ethernet configuration” from the menu (See Fig. 6.15).



Fig. 6.14



Fig. 6.15

(3) Tick in the box as indicated in Fig. 15 to turn on Ethernet”. Input IP address of the meter in a pop-out window. (See Fig. 6.16)

(4) Set up the network port IP address of instrument for LIS transmission and ensure consistency with IP address of the computer terminal (See Fig. 6.17).



Fig. 6.16



Fig. 6.17

3) Open LIS data receiving software installed in the computer, select "network port". Click “Start” (See Fig. 6.18).

Note: Choose UDP as communication networks. Don’t choose “SerialPort”.

4) After the meter finishes testing, the test results will be sent automatically to the PC data receiving software. If the user didn’t input detailed information, such as name and sample types, on the Finecare ™ FIA Meter plus, they will be left blank on the computer terminal (See Fig. 6.19). OR:

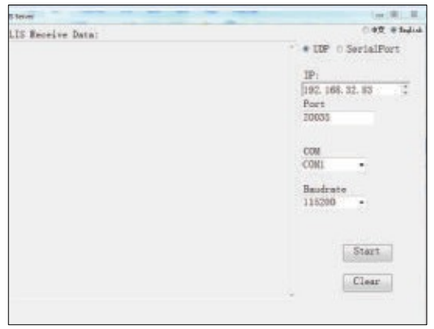


Fig. 6.18

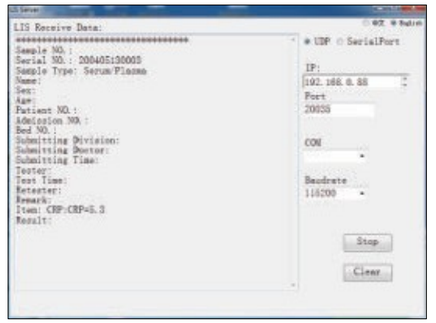


Fig. 6.19

5) Upload selected history data to PC by clicking ‘LIS’. (See Fig. 6.20 and Fig. 6.21)



Fig. 6.20

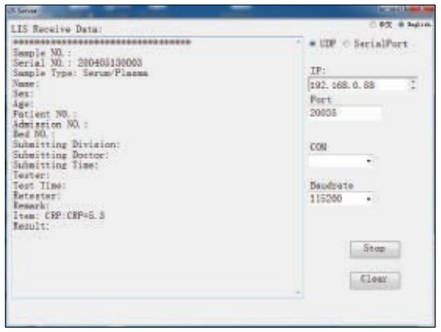
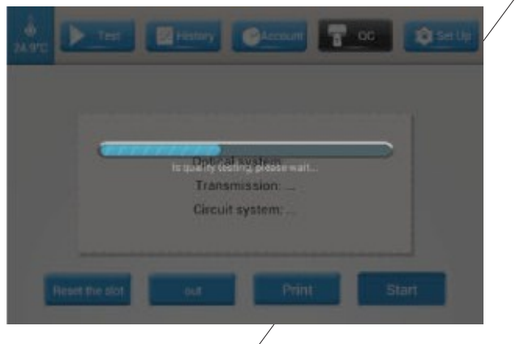


Fig. 6.21

The **Finecare™ FIA Meter Plus** has a built-in quality control which aims to monitor the internal system performance of the meter. .
The quality control should be run on and initial use and each day of patient testing.
To run the Quality Control:

1) Navigate to the main interface, click “QC”. The test device tray will protrude. If the tray does not protrude automatically, click “out”.
2) Gently insert the quality control Card into the test device tray, push the tray inside the meter until resistance is felt.
3) Click “Start”.



4) Wait until the blue progress bar runs to the end. The result of Quality Control will be displayed as below. If the result of quality control is not shown as below, contact the distributor or Guangzhou Wondfo and report the problem



5) Click “Reset the slot”,to draw back the test device tray.
6) Click “Print” to make a printed copy of the quality control result if needed.

Maintenance
Besides regular cleaning or replacing print paper roll when needed, **Finecare™ FIA Meter Plus** needs minimal maintenance. The instrument shall be plugged out prior to cleaning.

Cleaning
Use a damp cloth with 0.5% bleach, 70% isopropyl alcohol or 70% ethanol to clean the external surface of the instrument. Strong bleach (bleach concentration over 0.5%), oxidizing substances or solvents can cause permanent damage to the screen and other external surface material thus are prohibited to be applied to the meter.

If the meter has been used in clinical setting and needs to be repackaged, replaced or transported, it must be cleaned. Use disinfectant (e.g. bleach concentration lower than 0.1%) 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 meter.

Return
Should a malfunction occur, please contact Guangzhou Wondfo Biotech Co., Ltd. or the local distributor. If it were 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.

Transportation and storage
The original shipping container should be used to transport **Finecare™ FIA Meter Plus** or to store it when it has not been in use over an extended period. Keep the **Finecare™ FIA Meter Plus**, dry in upright position and in avoidance from sun, mechanical shocks, during transportation and storage.

Disposal
Any used test device should be disposed according to local ordinances regarding the disposal of bio-hazardous materials.
The **Finecare™ FIA Meter Plus,** accessories and the packaging have to be disposed of waste correctly at the end of usage. Please follow Local Ordinances or Regulations for disposal.

Problem	Probable Cause	Remedy
Finecare™ FIA Meter Plus will not operate	Power Failure	Check the Power Plug.
	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 Customer Service for a replacement adapter.
No result displayed after the test completes.	Excessive Computation Load	Wait till the computation is finished.
	Computational Abnormality	Restart the meter.
Test device Tray does not come out	Mechanical Failure (Buzzing Noise)	Call Customer Service.
	Software Abnormality.	Turn off the power and start fresh.
Display Screen does not function properly	Electrostatic Influence	Discharge any static electricity, reboot the system
	Electric Circuit Failure.	Call Customer Service.
Message: Reset reagent and test again!	Test device or ID chip was not inserted.	Insert the test device or ID chip.
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 device is removed from the test device tray, choose "Cancel test". Replace the ID chip with one of correct Lot number. Click "OK".
Message: "Optical System Fault", "Transmission System Fault", and/or "Circuit System Fault"	Internal hardware failure	Please contact Wondfo Customer Service Center.

XI

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.

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