

WONDFO BIOTECH  
WeAreWorkingForYourHealth



# OCG-102

REF W958

Wondfo

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## Optical Coagulation Analyzer

Operation Manual

13909282

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## Index of Symbols

The label on the back of the instrument, the Operation Manual and other packaging material may contain the following symbols or abbreviations:

	Caution		<i>In vitro</i> diagnostic medical device
	Consult Instructions for Use		Manufacturer
	CE Marking		Date of Manufacture
	Authorized representative in the European Community/European Union		Serial number
	Fragile, handle with care		Keep Dry
	This way up		Keep Away from Sunlight
	Stacking limit by number		Warning: Biological hazard
	Temperature limit		Importer
	Model number		Unique device identifier
	Use-by date		Device for near-patient test
	Device not for self-testing		Do not roll
	Direct current		This WEEE flag indicates that this device is classified as an obsolete electrical or electronic device under the EU WEEE directive.
	Catalogue number		General warning sign

## Section I Notice for Use

Thank you for choosing Optical Coagulation Analyzer (  OCG-102), which is designed, manufactured and sold by Guangzhou Wondfo Biotech Co., Ltd.

The manual describes the construction and performance characteristics of Optical Coagulation Analyzer, as well as the instructions for operation and maintenance of the instrument.

The Optical Coagulation Analyzer is designed to provide its user with step-by-step instructions. Please read the manual carefully before operating the analyzer.

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the installation, use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.



# Section II Introduction

## 2.1 Basic Information

Product Name: Optical Coagulation Analyzer

# OCG-102

Basic UDI-DI: 69332898CE1114EP

REF W958

## 2.2 Intended use

The Optical Coagulation Analyzer is an in vitro diagnostic device used for the quantitative determination of concentration of various coagulation factors in human whole blood.

The specific sample type is subject to the instructions for use of coagulation test card that used along with and manufactured by Guangzhou Wondfo Biotech Co., Ltd.

The Optical Coagulation Analyzer is for in vitro diagnostic use only. It is intended to be used by healthcare professionals in laboratories as well as Near-Patient Testing (NPT). It is not intended for self-testing.

## 2.3 Test Principle

Optical Coagulation Analyzer is a battery-powered or adapter powered, portable instrument that performs POC coagulation test on human whole blood.

The test is performed by inserting a test strip into the instrument and applying a drop of blood to the sample well of the test device. The instrument contains a test chamber which warms the test strip to the required temperature, and it performs all operation after the test is started by the operator.

The disposable test device contains a rotating, spoked wheel that draws the sample into the reaction well after it is applied to the sample receptacle. The spokes rotate across the path of an infrared light beam and mix the liquid sample with the reagent which is dried in the reaction well. When the sample clots, the clot is picked up by the spokes, interrupting the path of the light beam that is detected by the instrument. An internal timer measures the elapsed time between the start of the test and the clot formation.

During the test, the clotting time (in seconds) is displayed. PT results are also displayed as the International Normalized Ratios (INR).

⚠ The Optical Coagulation Analyzer can be only used according to the usage described by the manual.

⚠ The Optical Coagulation Analyzer is only for in vitro monitoring and not for the diagnosis of corresponding diseases.

## Definitions and Terms

POC	Point of Care
PT	Prothrombin Time
INR	International Normalized Ratio
ACT	Activated Clotting Time
APTT	Activated Partial Thromboplastin Time
EQC	Electronic Quality Control (System Verification)
QC	Quality Control
FIB	Fibrinogen
TT	Thrombin Time

## Section III Product Overview

### 3.1 Unpacking

The Optical Coagulation Analyzer and the items that come with it are provided in a single box. The test strips 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. Make sure that no damage has been caused during transportation. If any item is missing or damaged, please contact your sales distributor or Guangzhou Wondfo Biotech Co., Ltd.

Note: Do not discard the packaging material. It should be kept for shipping the analyzer to the manufacturer, if repair is necessary.

#### List of Content

Item	Quantity
Optical Coagulation Analyzer	1
Power Adapter	1
User Manual	1
Warranty Card	2
Product Certification	1
Quick SOP	1
Packing List	1
Printer	1
Electronic Control Card	5
Electronic Control Card Operation Guide	1
Ethernet Cable	1
Lithium battery	2

#### Material Needed But Not Provided

Item	Catalog No.
Prothrombin Time PT/INR Reagent Kit (Clotting)	WN01P0001 WN02P0001
Activated Clotting Time (Non-anticoagulated) Reagent Kit (Clotting)	WN03P0001
Activated Clotting Time (Citrate) Reagent Kit (Clotting)	WN04P0001
Activated Partial Thromboplastin Time Reagent Kit (Clotting)	WN05P0001
Fibrinogen Reagent Kit (Clotting)	WN06P0001
Thrombin Time Reagent Kit (Clotting)	WN07P0001
Pipette or capillary tube	/

#### Notes:

- Do not use accessories not provided or recommended by our company.
- If any components missing or damaged, please contact Guangzhou Wondfo Biotech Co., Ltd and local sales in time. Detailed contact information is in chapter XIII of the manual.

### 3.2 Features

- The main function of Optical Coagulation Analyzer: after inserting the test strip into the analyzer, the analyzer will preheat the test strip. Then add blood sample into specific zone. After adding sample, it will display the results when tests finish, and the test time will vary depending on different items. The test results will save automatically for checking in future.
- LIS connect function: It can connect to the LIS in hospital by Ethernet port and upload the test data
- Print function: QC and patient test results can be printed via a printer provided with the analyzer.
- Bluetooth function: The Bluetooth can pair and connect external devices.
- WIFI connect function: It can search WIFI and establish communication.

### 3.3 Hardware

#### 3.3.1 Optical Coagulation Analyzer structure and components

It consists of a host, a power adapter and embedded software, and the host includes a detection unit, a control unit, a data processing unit, a display unit and a scanning unit.

##### Front view



##### Rear view:



##### Rear view:



##### Top view



- ⚠ Do not use the analyzer if it works abnormally or is damaged such as falling down or falling into the water.
- ⚠ Guangzhou Wondfo Biotech Co., Ltd. has made every reasonable effort to ensure that all the information contained in this manual is correct at the time of printing. However, Guangzhou Wondfo Biotech Co., Ltd. reserves the right to make any changes necessary without notice as part of ongoing development.

## Section IV Specification

### 4.1 Operating Conditions

<b>Temperature</b>	15 °C~32°C
<b>Relative Humidity</b>	10% ~ 80% (without condensation)
<b>Placement</b>	Operate on a level, vibration-free surface.

### 4.2 Non-Operating Storage and Transport Condition

<b>Temperature</b>	-10°C~50°C
<b>Relative Humidity</b>	10%~90% (without condensation)

### 4.3 Specification

Memory	300 test results and 12 QC test results
Memory	3.5-inch color touch screen
Adapter	Adapter Input: 100-240Vac, 50/60Hz, 0.5A Max Adapter Output: 9V $\overline{---}$ , 2A
Power	9V $\overline{---}$ , 18W
Main supply voltage fluctuations	±10%
Battery Operation	Two 3.6V lithium batteries
Battery Life	300 complete charge-discharge cycles, depending on the frequency of use
Dimensions	243 × 184 × 134 mm
Weight	about 860 grams (without batteries)
Printer	Printer with USB interface
Use Environment	Indoor use
Altitude	Use not exceed 2000m
Pollution Degree	Pollution Degree 2
Service life	5 years under normal use

### 4.4 Network Security

#### 4.4.1. All functions and software versions of the software

This software is not used as an independent software, but only as a component of the Optical Coagulation Analyze to realize its test function.

Software release version: V1

#### 4.4.2. Software operating environment

<b>Hardware Configuration</b>	CPU: STM32f407, 168MHz main frequency, 5 12KB Flash, 192kB RAM memory;
<b>Software Environment</b>	uCOS operating system
<b>Network conditions</b>	Wi-Fi, Bluetooth, wired network

#### 4.4.3. Data interface

The wired network is connected to the LIS server through the TCP/IP protocol, and the test results can be uploaded to the corresponding LIS system server, and the transmission format is determined by the LIS system server.

The data interface includes network port, WIFI, USB2.0 port, and serial port. Among them, the network port and WIFI are used to transmit test related data, the serial port is used for software upgrade, and the USB2.0 port is used to connect to an external printer. User Access Control

#### 4.4.4. User Access Control

Boot into the default user mode without a password.

#### 4.4.5. Security software

It runs on the uCOS operating system, so there is no need for related anti-virus at present.

#### 4.4.6. Security Software Updates

This software runs independently in the uCOS operating system, and no other third-party software runs at the same time.

### 4.5 EMC

- Optical Coagulation Analyzer (  $\square$  OCG-102) has been tested and found to be in conformity with EN 61326-1 and EN 61326-2-6.
- Please check the EMC report of Optical Coagulation Analyze for detailed information.
- It is the user's responsibility to ensure the electromagnetic compatibility environment of the analyzer so that the equipment can work properly.
- It is recommended to evaluate the electromagnetic environment before using the analyzer.
- Do not use this analyzer near strong radiation sources (such as unshielded radio frequency sources), which may interfere with the normal operation of the analyzer.

## Section V Operating Precautions

The Optical Coagulation Analyzer is only for in vitro diagnostic use.

To ensure that the Optical Coagulation Analyzer functions correctly, read carefully following warnings before use.

- Do not dismantle the instrument.
- Do not use test strips which are NOT provided by Guangzhou Wondfo Biotech Co., Ltd.
- Do not use test strips, which are beyond the expiration date or have been improperly stored.
- Do not use excessive force in inserting test strips or ID chip.
- Do not drop the instrument.
- Do not spill any liquid on the instrument.
- Do not use the instrument near a strong electro- or magnetic field, such as mobile phone, microwave oven, as this may interfere with the instrument's proper operation.
- Please balance the analyzer, test strip and sample at room temperature before use.
- The instrument should be operated on a horizontal and vibration-free surface. Don't hold the instrument in hands during testing.
- Don't move or touch the analyzer or test strip during testing.
- The test strip is for single use only. Don't reuse the test strip or add additional sample to a test strip. These operations may lead to wrong results.
- Do not switch the power mode during testing (adaptor supply, battery supply).
- Testing at low battery level may lead to inaccurate or wrong results. If the battery is running low, stop testing and connect to power supply.
- When performing blood sample testing and other related operations, the operator should abide by the safety operation regulations and take safety protection measures (such as wearing protective clothing and gloves, etc.).
- The analyzer should not be close to the wall, and there should be a distance of at least 20cm to ensure the ventilation of the analyzer and the space required by the operator for safe and effective maintenance.
- There are test samples left on the used test card, which is a potential biological hazard. It should be recycled as medical waste or disposed of in accordance with the regulations of the local administrative department.

### Note:

- The instrument should be operated by trained professionals from medical institutions.
- When the instrument is working normally, the detection channel may be touched, and there are potential risks. Please operate according to the instructions.

## Section VI Getting Started

### 6.1 Power on

- Insert the power cord into the analyzer and then connect the external power supply. Alternatively,
- Use the two rechargeable lithium ion batteries.

After connecting the power supply, turn on the power switch and the analyzer will start.

The Optical Coagulation Analyzer is only for in vitro diagnostic use.

To ensure that the Optical Coagulation Analyzer functions correctly, read carefully following warnings before use.



### 6.2 Stand-by Mode

The Optical Coagulation Analyzer saves power by automatically enter stand-by mode, i.e. sleep, after 10 minutes of inactivity, unless the operator presses the Sleep button to wake up the analyzer.

If the analyzer is not to be used temporarily, the operator can press the  button to make the analyzer enter stand-by mode.

### 6.3 Install, Replace and Charge Batteries

#### 6.3.1 Install (or Replace) the Batteries

(1) Open battery compartment:

With the meter powered off, turn it over. Press the latch gently inward and lift the battery compartment cover. Remove the old batteries, if necessary.

(2) Insert new batteries:

Position the batteries according to the diagram inside the battery compartment.

(3) Replace the battery compartment cover. Turn the meter back over.



### 6.3.2 Charge the Batteries

The Optical Coagulation Analyzer uses two 3.6V rechargeable lithium batteries. The batteries should last for approximately 300 full charge/discharge cycles.

When a message saying “Low Battery” appears on the screen, charge the batteries by inserting the power cord into the analyzer and then connect the external power supply.

The charge indicator will glow constantly red while charging. When the batteries are fully charged, the charge indicator turns green.

#### **Note:**

1. When replacing the battery, please replace two new batteries at the same time.
2. Be sure to replace with the correct type of battery: rechargeable lithium battery; installing an incorrect type of battery may present a risk of explosion or fire.
3. When installing or taking out the battery, it is forbidden to touch the battery interface with hands or metal objects, so as to avoid causing short circuit and endangering personal and battery safety.
4. When the battery fails, such as liquid leakage, rupture, etc., please stay away immediately. If the electrolyte accidentally seeps into the skin or clothes, just rinse with clean water. If the electrolyte gets into the eyes accidentally, do not rub the eyes, please wash them with clean water immediately and seek medical treatment.

### 6.4 Connecting Printer

- (1) Connect one end of the printer cable to the mini-USB port.
- (2) Connect the other end of the printer cable to the printer.
- (3) Long press the on/off button of the printer until its blue indicator light glows. The printer will beep before it turns on.

### 6.5 Connecting to a PC

Optical Coagulation Analyzer can be connected to a PC using a standard network cable.

- (1) Obtain a network cable.
- (2) Connect one end of the cable to the Ethernet port, which is on the rear of the analyzer.
- (3) Connect the other end of the cable to an Ethernet port on the computer. Note the location of the port.
- (4) Set the IP address and Port number of the PC as described in Sector 7.6.

### 6.6 Power off

Press the power switch at the back of the analyzer.

 Whenever the power cord is connected to a power supply, the battery is charged even after the analyzer is switched off.

If the analyzer is not to be used for a while, please turn off the analyzer and disconnect the analyzer from power supply.

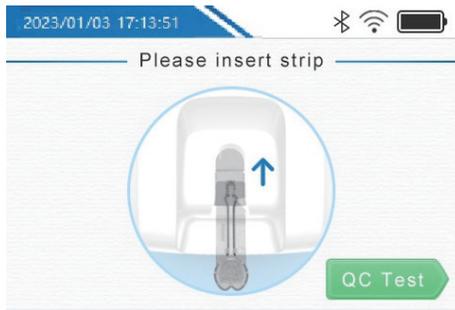
Please take the batteries out of the battery compartment if the analyzer is not going to be used for a long time.

## Section VII Device Settings

Follow the instructions below to set up the Optical Coagulation Analyzer ( [ # ] OCG-102).

### 7.1 Enter Setting Interface

- (1) The analyzer starts up and show the starting up picture when the operator connects it to power supply and press the switch. Three seconds after the starting up interface shows, the analyzers prompts the operator to insert test strip, indicating it is ready to work.



- (2) Press the SET button. The following menu will appear on the screen.

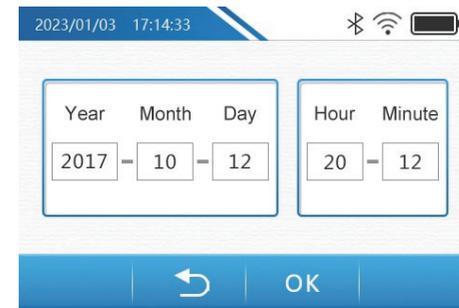


### 7.2 Time setting

Click on  .

Click on the blank under Year/Month/Day or Hour/Minute, change the time by choosing  or  .

Click OK to confirm, or click  to give up the change and go back to the device setting menu.



### 7.3 Language setting

Click on  .

Click on the preferred language.

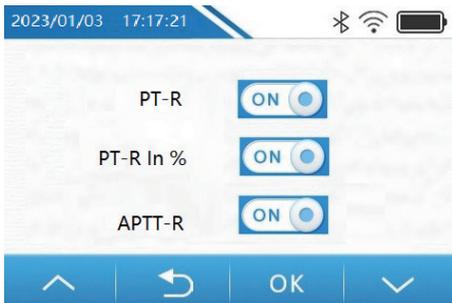
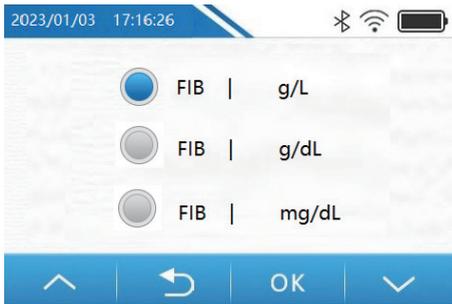
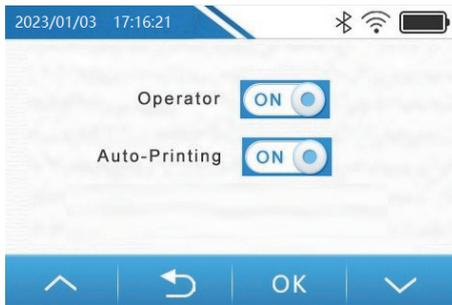


Click OK to confirm, or click  to give up the change and go back to the device setting menu.

### 7.4 System Setting

Enter the system Settings and slide the interface icon  to open and close the Settings of operator, auto-printing, FIB, PT-R, PTR In % and APTT-R.

Select whether to add operator information, auto-printing, unit of FIB, and display of PT-R, APTT-R and PTR.



## 7.5 Parameter Settings

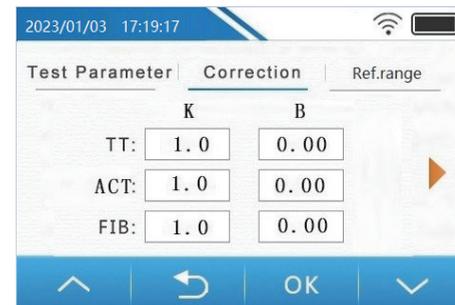
Parameter setting includes test parameter, correction parameter and reference range setting.

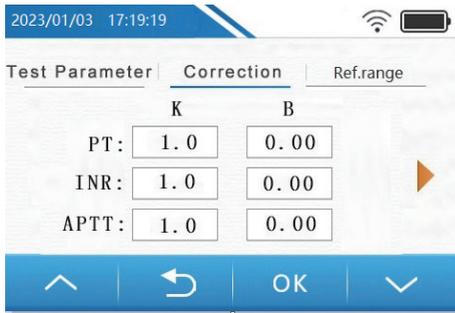
### 7.5.1 Test parameter setting

PTnormal and APTTnormal are set by the analyzer. PT test results can be shown as INR and in seconds or a percentage value. INR (international normalized ratio) is calculated by formula  $INR = (PT_{test}/PT_{normal})^{ISI}$ . ISI is provided by test strip barcode. Then click OK to complete this setting.

### 7.5.2 Correction parameter setting

The following parameters can be corrected, K for slope and B for intercept. The user can adjust the slope and intercept of the parameter according to the need. Then click OK to complete this setting.





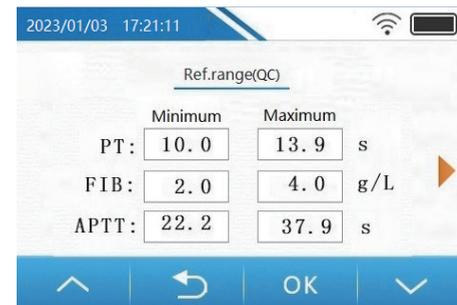
### 7.5.3 Reference range setting

The following parameters can be set according to the reference range established by the laboratory. Then click OK to complete this setting.



### 7.5.4 Reference range of QC setting

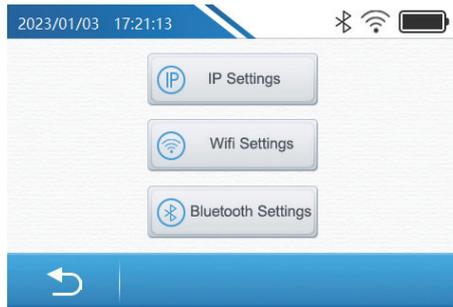
The following parameters can be set according to the QC reference range established by the laboratory. Then click OK to complete this setting.



## 7.6 Network settings

The Optical Coagulation Analyzer allows connection to the LIS or a computer via IP setting, WIFI setting or Bluetooth setting.

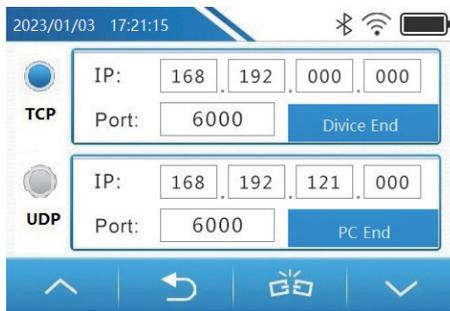
Click on . The following menu appears on the screen.



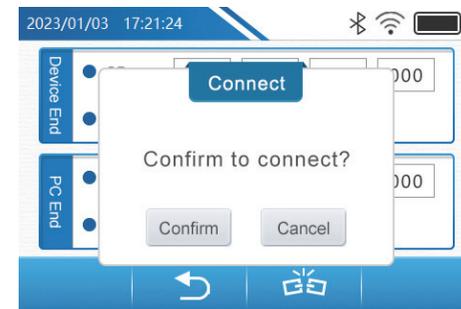
### 7.6.1 IP settings

Connect the analyzer to the computer with a network cable, and an IP address can be assigned to the Optical Coagulation Analyzer.

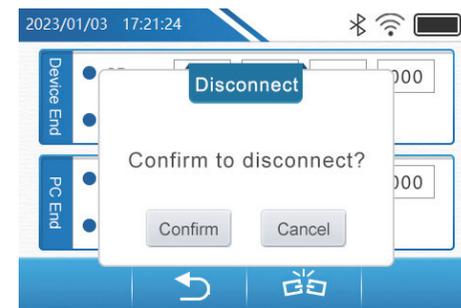
- (1) Click on .
- (2) Assign an IP address and port for the analyzer. Enter the IP address and Port in the on-screen keyboard.
- (3) Enter the IP address and port of the PC end of the LIS.



- (4) Click  to connect, otherwise click  to exit.



- (5) If you wish to disconnect an existing WIFI connection, click , and click  to disconnect, otherwise click  to exit.



### 7.6.2 WIFI setting

- (1) Click on  .
- (2) Slide the WIFI switch to the ON position.
- (3) The analyzer will automatically search nearby WIFI. Choose the WIFI to be connected, click on  .
- (4) Enter password in the popup window.



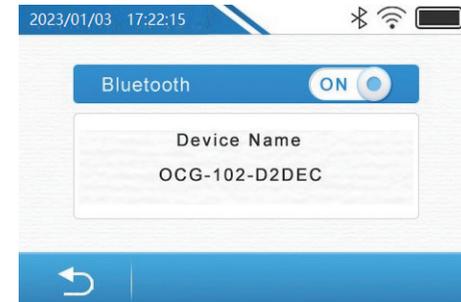
- (5) Enter password then click **Confirm**, otherwise click Cancel to exit.



 Note: Only letters and numbers are allowed for WIFI name input.

### 7.6.3 Bluetooth setting

- (1) Click on  .
- (2) Slide the Bluetooth switch to the ON position.
- (3) The analyzer then searches for nearby device equipped with Bluetooth. The Bluetooth logo appears at the top right of the screen
- (4) If the operator needs to disconnect, slide the Bluetooth switch the OFF position.



### 7.7 Software Information

The version of Optical Coagulation Analyzer Detecting System can be found through “about” in the setting.

For future software updates, please contact Wondfo technical support team.



## Section VIII Performing a Test

Please read carefully the manual before using the Optical Coagulation Analyzer. The test should be conducted in 15°C~32°C.

### 8.1 Preparing for a Test

Gather the following items before performing a test:

- ✓ Optical Coagulation Analyzer
- ✓ Test strip
- ✓ ID chip (only available for Fibrinogen test)
- ✓ Blood specimen
- ✓ Pipette or capillary tube



The Optical Coagulation Analyzer can only recognize test strips manufactured by Guangzhou Wondfo Biotech Co., Ltd. Test strips are for single use. They cannot be reused.

### 8.2 Insert ID Chip

Each box of Fibrinogen Reagent Kit (Clotting) comes with a ID chip which contains standard curve for each batch of the test strip. Every time opening a new box of Fibrinogen Reagent Kit (Clotting), replace the old ID chip with the new one. With the ID chip label facing down, insert the ID chip into the ID chip slot until it snaps into place. If an error message saying “Invalid ID chip” appears, it means the lot number information contained in the ID chip and test strip does not match. Insert a new test strip. If the problem still exists, contact your local distributor. If no ID chip is inserted when testing FIB, the analyzer will remind the user to insert ID chip.

### 8.3 Perform a Test

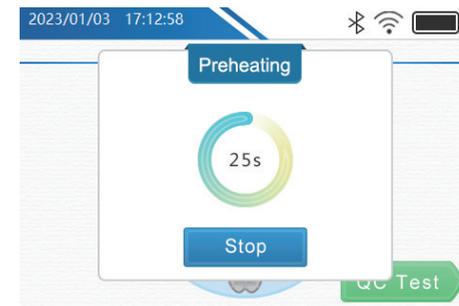
#### 8.3.1 Insert Test Strip

- (1) When it shows “please insert test strip” on the screen, take a test strip out of the pouch. Slide the test strip into the test strip slot in the direction as shown on the screen. If an old test strip is left in test strip slot, a message saying “please eject test strip” will appear on the screen. Pull out the old test strip and the message will disappear.

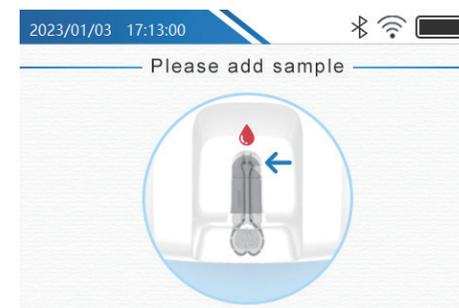


⚠ Once the pouch is opened, use the test strip within 15 minutes.

- (2) The analyzer will identify its corresponding test item from the barcode printed on it and show the test item on the screen. If an error message saying “Invalid barcode” appears, it means that the analyzer does not detect correct barcode information. In this case, pull out the test strip and reinsert.
- (3) After confirm the test item, the analyzer starts preheating the test strip. As the countdown timer shown on the screen, the preheating takes about 25 seconds. If the operator needs to stop preheating, click  .



- (4) When the preheating finishes, the analyzer will remind the operator to add sample into the sample well. Please add the sample according to the package insert of specific test strip.



#### 8.3.2 Add Sample

- (1) Use a capillary tube or pipette to collect blood specimen. Apply the blood specimen to the test strip. Do not use non-siliconized glass capillary tubes or capillary tubes containing EDTA, heparin or oxalate anticoagulant.

(2) After adding sample, the analyzer automatically starts testing. Wait until the testing finishes, or click to terminate a testing.

⚠ Do not move the meter or add more blood during testing.



⚠ An error message saying "Adding sample has timed out" will appear if the user does not add sample within 2 minutes after inserting the test strip. The user needs to take the test strip out of the slot and reinsert.

### 8.3.3 Read the Test Result

(1) The test result, along with the time when the testing was conducted, appear on the screen when the test finishes. The analyzer will then remind the user to eject test strip.



(2) The test result is then stored in the memory automatically after the testing finishes.

(3) If the analyzer has been connected to LIS via WIFI or network cable, the test result can be automatically transferred to LIS.

### 8.3.4 Print Test Results

Make sure the analyzer is connected to the printer before printing.

(1) Select the record(s) to be printed, click .

(2) Click to print, otherwise click to exit.



### 8.3.5 Dispose of Used Test Strip and Other Materials

After testing, pull the used test strip out of the slot. Discard the used test strip along with capillary tube or pipette according to infection control guidelines.

## 8.4 Test result Interpretation

When testing PT (prothrombin time), the test result can be reported both in INR or in seconds. When testing APTT (activated partial thromboplastin time), TT (thrombin time) or ACT (Activated clotting time), the test result is reported in second. When testing FIB (fibrinogen), the concentration of fibrinogen in the blood specimen is reported in g/L.

The reportable range of each test is indicated in the package insert of the corresponding test strip. If the test result falls outside the reportable range, the analyzer displays "No Clot Formation Detected". In this case, refer to the test strip package insert and repeat the test.

## Section IX Quality Control

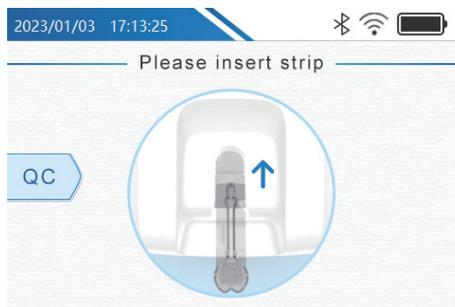
Routine quality control testing should be part of the quality assurance program to maintain reliable performance of the Optical Coagulation Analyzer. QC tests will be saved in memory as Test Result (QC). The analyzer can store up to 12 QC records.

### 9.1 Quality control liquid quality control test

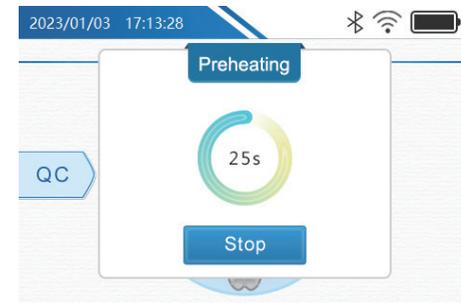
(1) Turn on the analyzer then click **QC Test**.



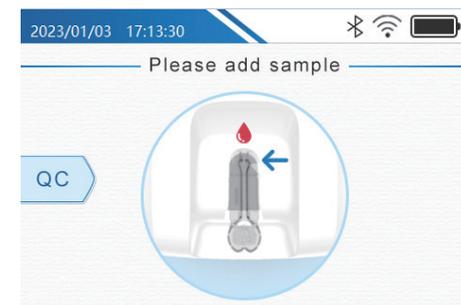
(2) Insert a new test strip when the following image appears on the screen.



(3) Insert the test strip. The analyzer starts preheating to reach a predefined temperature.



(4) When the preheating finishes, add quality control in the sample well of the test strip.



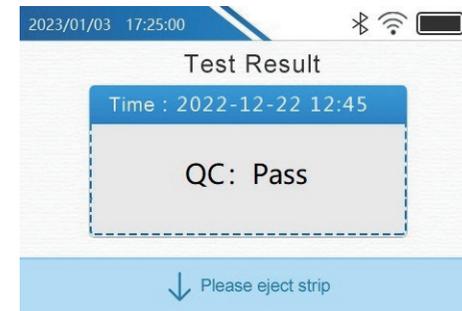
(5) Wait until the testing finishes, or click to terminate a testing.



- (6) The test result, along with the time when the testing was conducted, appear on the screen when the test finishes.



- 3) When the testing is completed, the result will be displayed on the screen. The analyzer will remind the user to pop up the test strip, and the screen shows "Please eject strip"



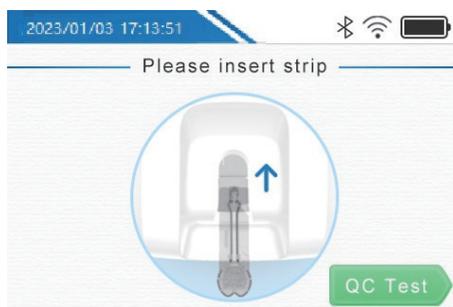
- (7) When the testing is completed, the result will be displayed on the screen. The test result is then stored in the memory automatically after the testing finishes. To access QC results in the memory, Refer to Section XII.
- (8) After testing, pull the used test strip out of the slot. Discard the used test strip according to laboratory procedures.

- ⚠ If the QC fails, repeat the quality control testing process or contact Wondfo Technical Support Team for assistance before testing patient samples. For additional contact information, refer to Section XIV.

## 9.2 External electronic quality control test

Guangzhou Wondfo Biotech Co., Ltd. provides a special external electronic quality control card for the semi-automatic blood coagulation analyzer detection system to verify the system performance.

- 1) Turn on the analyzer then click "QC Test" at the bottom right of the main test interface to conduct quality control test.



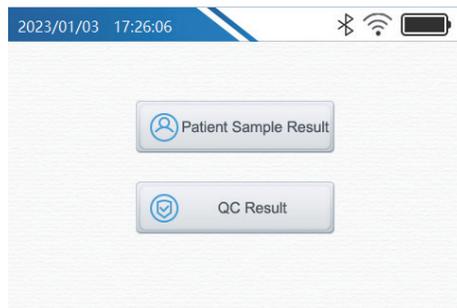
- 2) After entering the quality control interface, the screen shows "Please insert the card". At this time, please insert the external electronic quality control card into the test slot, and the system will conduct external electronic quality control test automatically.

# Section X Memory

The test results, both QC results and patient test results, are automatically stored in memory. The Optical Coagulation Analyzer stores up to 300 patient test results and 12 QC results.

## 10.1 View the Memory

- (1) Press the MEM button.
- (2) Click  to review patient test results, or click  to review QC results.



- (3) The records stored in the memory appears. Every record contains test time, date, and test result. All records are ranked by test time in a descending order. The most recent test result is shown on the top. Each page shows up to four records. If there are more than 4 records stored in memory, use "" or "" to access earlier records.



Time	Result ( QC )
2022-06-21 12:22	INR:0.96 PT:10.6s

## 10.2 Erase Memory

Test results in the memory should be periodically erased to prevent overwriting. **Caution:** Results cannot be retrieved after they have been erased from the memory. Do not erase test results until they have been transferred to a laboratory computer or other physical storage hardware.

- (1) Select the test results which is to be deleted, click .
- (2) The user can either erase all test results or delete individual test results.
- (3) Click  to erase either the entire memory or selected test results; or to exit without erasing the results, click .

## 10.3 Print Records

Make sure the analyzer is connected to the printer before printing records.

- (1) Select the record(s) to be printed, click .



- (2) Click  to print, otherwise click  to exit.

## 10.4 Transfer Records

Records in the memory can be transferred to LIS. Select the record(s) to be transferred, then click .

## Section XI Maintenance and storage

To ensure accurate test results, proper cleaning and maintenance is needed for Optical Coagulation Analyzer. Please follow the instruction carefully for the maintenance procedure.

### 11.1 Clean

#### 11.1.1 Clean the Exterior

- The analyzer shall be plugged out prior to cleaning.
- Use a damp, lint-free cloth with clean water to clean the exterior of the analyzer. Do not use any other cleaning/disinfecting solutions on the exterior as they may cause damage to the analyzer surface material.
- Do not let liquid accumulate near any opening. Make sure that no liquid enters the analyzer.

#### 11.1.2 Clean the Test Strip Slot

- The analyzer shall be plugged out prior to cleaning.
- Use a damp, lint-free cloth with clean water to clean the test strip slot. Do not use any other cleaning/disinfecting solutions on the test strip slot as they may result in damage to the analyzer.
- Allow the test strip slot to dry thoroughly before next use.

#### 11.1.3 Clean the Heater Band

- The analyzer shall be plugged out prior to cleaning.
- Dirt accumulated on the heater band may interrupt the signal detection. Use a damp, lint-free cloth with clean water to clean the test strip slot. Do not use any other cleaning/disinfecting solutions on the test strip slot as they may result in damage to the heater band.
- Under no circumstances shall the analyzer be washed with water.

#### **Note:**

- Users should strictly follow the instructions of this manual to clean the Analyzer.
- Do not use cleaning agents that chemically react with equipment parts or materials contained in the equipment to cause danger.
- If there is any doubt about the compatibility of the cleaning agent with the equipment parts or the materials contained in the equipment, the manufacturer or its agent should be consulted.
- Never dismantle the analyzer without written permission of Guangzhou Wondfo Biotech Co., Ltd. If problems occur during the use of the Optical Coagulation Analyzer, please contact the distributor or technical support.
- Instruments should be cleaned regularly by trained healthcare facility professionals

### 11.2 Maintenance

#### 11.2.1 Maintenance of Battery

- 1) When the battery is used for the first time, the battery shall be charged in advance to prevent the battery from being unable to use due to insufficient power. After the first use, the battery

can be charged only by connecting the AC power supply.

- 2) If the battery is not used for a long time (more than two or three months), the user should charge the battery before using it again.
- 3) 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 (more than six months).

#### **Warning:**

- Improper operation may cause the battery to become heat, fire, explode, and destroy or attenuate battery capacity. Before using the battery, please read the instruction and notices carefully.

#### **Note:**

- The battery reached its service life must be treated as special garbage and should be disposed of in accordance with local regulations.

#### 11.2.2 Maintenance of Printer and Print Paper

The following requirements should be noted for the storage of the print paper:

- 1) Print paper should be kept in a dry and cool place, avoiding high temperature, humidity and direct sunlight.
- 2) Avoid being put under fluorescent light for a long time.
- 3) The storage environment of the print paper cannot place PVC plastic, otherwise it may cause the print paper's color change.

### 11.2 Non-Operating Storage and Transport Conditions

- Temperature: -10°C~50°C;
- Relative Humidity: 10%~90% (without condensation).

## Section XII Troubleshooting

Message	Possible Causes	Remedy
Please eject strip	A test strip is left inside the analyzer.	Pull out the test strip from the test strip slot.
Invalid barcode	The analyzer cannot detect correct barcode information.	Please reinsert the test strip or replace a new test strip.
Please reinsert strip	The test strip was not inserted in place.	Reinsert a test strip.
No Clot Formation Detected	No clot detected in the time range of the specific test.	Retest with a new test strip
Ambient temperature is too low to run a test	The environment temperature is out of operation range.	Please operate in suitable environment.
Low battery	The battery is low.	Charge the battery or temporarily use AC power.
Invalid ID chip	The information contained in the ID chip does not match the lot number of test strips.	Use the ID chip which comes with the test strips.
Adding sample has timed out	Operator hasn't added sample within two minutes after inserting the test strip.	Retest with a new test strip.
Strip Expired	The test strip is beyond expiration date.	Contact your local distributor.

## Section XIII Return, Disposal and Warranty

If service or repair is needed, please call: 800-999-4268 or 400-888-5268.

The Wondfo does not need special maintenance except regular cleaning. It will make the analyzer work normally to wipe the analyzer shell with dry cloth.

### 13.1 Return

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

### 13.2 Transport

Fully packaged Optical Coagulation Analyzer can be transported by ordinary vehicles. Protect the analyzer from moisture, exposure to sunlight and mechanic shock.

### 13.3 Storage

Fully packaged Optical Coagulation Analyzer should be stored in well-ventilated avoiding erosive gas.

Ambient temperature: -10~50°C

Relative Humidity: 10%~90%

Atmospheric Pressure: 860hPa~1060hPa

### 13.4 Disposal

The Optical Coagulation Analyzer, accessories and the packaging has to be disposed correctly at the end of usage. Disposal of used analyzer should be in accordance with local ordinances and regulations.

### 13.5 Warranty

Guangzhou Wondfo Biotech Co., Ltd warrants, to the original purchaser only, that Wondfo Optical Coagulation Analyzer shall be free from all defects for a period of one year from the date of purchase.

Please use the analyzer carefully by following the manufacturer's instructions for use.

Wondfo is prepared to compensate for faulty material or malfunctions within the limitations of the warranty. Tampering with the internal components, damage due to operating errors, misuse and overlooking essential information with respect to warnings and precautions described in this User Manual will invalidate the warranty.

Products will be repaired with charge during the warranty period in following cases.

- 1) Improper use or misuse.
- 2) Consumer's intentional abuse or neglect of the products.
- 3) Unauthorized repair or parts replacement.
- 4) Other faults not caused by the product itself

After the expiration of the warranty, the company can continue to provide fee-based services during the service life;

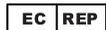
## Section XIV Contact information

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 support, call 800-999-4268 or 400-888-5268.



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Website: en.wondfo.com  
E-mail: sales@wondfo.com.cn



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PAS 257  
2440 Geel  
Belgium

## Appendix 1 Bibliography

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物料编码: 13909282

项目名称: OCG-102仪器说明书(142\*210mm)IVDR英文V01

尺寸(长\*宽\*高): 142\*210mm

颜色:  C100 M40 其他四色印刷

材质: 封面157双铜, 内页80克双铜

工艺: 胶装, 封面过光胶

修改内容: 文字 颜色 尺寸 工艺 材质 其他 无

改稿前编码:

申请人: 吴烁琳

设计师: 敖慧玲

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