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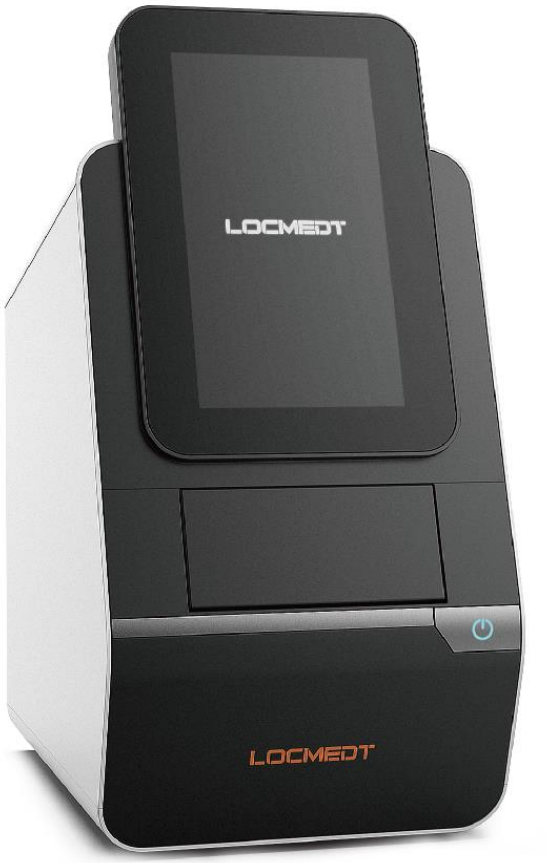
Automatic Biochemistry Analyzer

LOC-200

Operator's Manual

For In-Vitro Diagnostic Use Only



Tianjin LOCMEDT Technologies Co., Ltd.

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Notice for Use

Dear Customers:

We appreciate your selection of Automatic Biochemistry Analyzer LOC-200 (hereinafter referred to as the "Analyzer") of Tianjin LOCMEDT Technologies Co., Ltd.. For a better overview of the Analyzer, we provide this *Operator's Manual* which will guide you through installation, operation and maintenance of the analyzer. The user manual also explains how the analyzer works, describes the quality assurance system and assists you in troubleshooting.

For analysing patient samples or controls, please also read the test specific information given in the package inserts following the LOCMEDT Test Disc Kits.

It is recommended that you become familiar with these user instructions before you start operating the LOC-200 Analyzer.

Please strictly follow "Notes" and "Warnings" (in bold) in the *Operator's Manual* to ensure that the Analyzer functions well, and the test results are accurate and reliable.

To correctly use this, the users (personnel) who have received the operation training provided by Tianjin LOCMEDT Technologies Co., Ltd. or authorized dealers of Tianjin LOCMEDT Technologies Co., Ltd..

EXAMINING THE PACKAGE CONTENTS

When unpacking, check the contents against the list below and examine the components for signs of shipping damage.

Packing list

Name of Article	Unit	Quantity
Analyzer	/	1
Power adapter	/	1
Power cable	/	1
Certificate of Conformity	Piece	1
Operator's Manual	Piece	1
Installation training record	Piece	1
Thermal printing paper	Roll	2
Pipette	100 μL each	1
Tip	200 μL each	50
Anti-dust sponge	/	1

If the package unit is found incomplete, please report missing items or shipping damage to your supplier. It is recommended to keep the shipping box in case of later transportation of the analyzer.

THE ILLUSTRATIONS PROVIDED HEREIN ARE EXAMPLES, WHICH MAY BE DIFFERENT FROM THE ACTUAL PRODUCT. IN CASE OF ANY DIFFERENCES, THE ACTUAL PRODUCT SHALL PREVAIL.

 **Note**

Please ensure that the Analyzer is used under the conditions specified in the *Operator's Manual*. Otherwise, the Analyzer may not function well and the test results may be unreliable.

 **Warnings**

- **The Analyzer shall not be used in the damp environment or the environment containing corrosive gases.**
- **In case of a peculiar smell or smoke in the use of the Analyzer, please timely cut off the power supply, unplug the power cord, and notify the manufacturer or the agent to repair the Analyzer.**
- **The operators shall avoid contact with the electronic circuit of the Analyzer. Only the qualified individuals can repair the Analyzer.**
- **Users shall ensure the electromagnetic compatibility of the Analyzer to make it function well.**
- **The analyzer conforms to the emission and immunity requirements of the equipment in EN 61326-1:2013, EN 61326-2-6:2013.**
- **The analyzer is designed and tested according to class A device in CISRP 11:2010.**
- **The Analyzer shall not be used near strong radiation sources (such as unshielded radio frequency sources), otherwise it may not function well.**

Chapter One Product Overview

1.1 Appearance of the Product

Figure 1-1

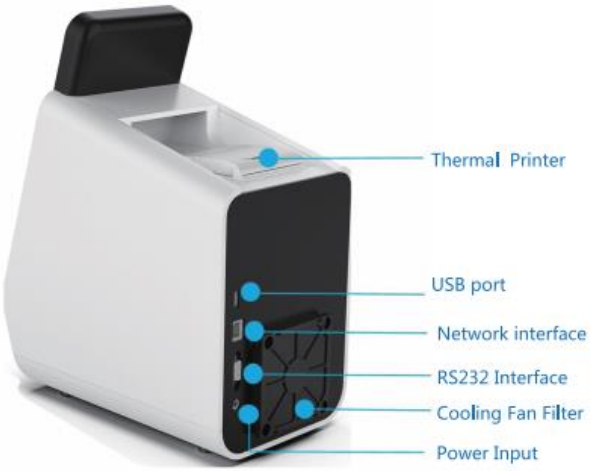


Figure 1-2

Touch screen: Human-computer interaction	Drawer: Place/take out test disc
Power button: Turn on/off power of the instrument	Thermal printer: Print test reports
USB port: For instrument software upgrades	Network port: For delivery test of the instrument (Users should connect the instrument to the network by themselves)
RS232 port: For connection to LIS of hospitals	Cooling fan filter: For cooling the instrument
Power input: Direct current power supply interface of the instrument	

1.2 Brief Introduction

Instrument name: Automatic Biochemistry Analyzer LOC-200

Specification/Model: LOC-200

Automatic Biochemistry Analyzer LOC-200 is highly integrated, intelligent, and convenient, which can simultaneously analyze multiple indicators of a sample.

Intended purpose:

Used with the kit produced by Tianjin LOCMEDT Technologies Co., Ltd., Automatic Biochemistry Analyzer LOC-200 provides quantitative in-vitro determinations of clinical chemistry analytes in human Lithium-heparinized whole blood (Including but not limited to venous blood and capillary blood), heparinized plasma, or serum and is supposed to be used for clinical auxiliary diagnosis. The Analyzer is suitable for use in a laboratory environment, near patient (NPT) or point of care setting (POCT). The Analyzer is intended for use only by trained professionals such as physicians, nurses, therapists, health care assistants and pharmacists.

Requirements on operators: Doctors and medical practitioners with clinical laboratory skills and knowledge, who should receive the operation training provided by the Company or its dealer before use.

1.3 Testing Principle

Based on the Beer-Lambert law, Automatic Biochemistry Analyzer LOC-200 adopts the testing principle of

absorption spectroscopy. LOC-200 system consists of a portable analyzer and single-use disposable reagent discs. Each reagent disc is a self-contained, clear, plastic disc, 7.8cm in diameter and 0.68cm thick. Working principle: lyophilized reagent beads are pre-installed in these cuvettes along the perimeter of reagent disc to form the independent reaction chambers. To perform an analysis, operators only need to add the blood sample (lithium-heparinized whole blood, heparinized plasma or serum) into the disc through the sample port, then place reagent disc into the analyzer drawer, input patient information, and the analyzer automatically performs the testing. The centrifugal force and capillary force of the disc are generated under the drive of motor, the reagent disc spins and the whole blood is separated into plasma and blood cells. Then the required amount of diluent and plasma are precisely measured and combined at the mixing chamber. Centrifugal and capillary forces distribute the diluted plasma to the reaction chambers (cuvettes) along the perimeter of reagent disc. Serum and heparinized plasma samples are processed in a similar manner. The sample and reagents in the disc are mixed well, and chemical reactions occur. According to the Beer-Lambert law, when a beam of white light irradiates the liquid to be tested, the light signal which passes the liquid to be tested is converted to the electrical signal, the operations of the converter are performed, and the content of a certain chemical component in the liquid to be tested is obtained by reference to the standard curve. Based on the micro-channel design of the reagent disc, the operations above are automatically completed in the reagent disc with the speed regulation of a motor.

The lyophilized reagent beads in the reaction chambers (cuvettes) of the reagent disc is dissolved by the diluted plasma (serum), and biochemical reactions occur. The Analyzer determines the absorbance of the solution by the spectrophotometry, and the concentration of the analyte is calculated based on the changes or the change rates of the absorbance. The calibration information of a certain biochemical reaction is stored in the QR code of the reagent disc. After the tests, the test results will be displayed on the screen, and the test report will be printed by the thermal printer. The test report includes results of test items of each reagent disc, normal reference ranges of items, and the sample information. The database of the Analyzer for storing the test results can be connected with the data management systems of the hospitals for easy data management.

1.4 Structure and Composition of Product

Main structure and composition of the Analyzer:

- Variable speed motor (driving and controlling the reagent disc)
- Spectrophotometer (measuring the light signal of the reaction chamber of the disc)
- Microprocessor (constant temperature and temperature control components, QR code scanning and collection components for system control, data acquisition and calculation)
- Color touch screen (performing the communication between the analyzer and the operator)
- Thermal printer (printing out results)
- Embedded software system (human-computer interaction operating software)

1.5 Standard

- The electrical safety performance of the products is fully in accordance with EN 61010-1:2010 *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.*
- This product conforms to EN 61010-2-101:2017 *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment,* and EN 61010-2-010:2014 *Safety requirements for electrical equipment for*

measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.

- The environmental test of the product meets the requirements of GB/T14710-2009 *Medical Electrical Environment Requirements and Test Methods*.
- The main performance indicators of the product are designed and manufactured in strict accordance with YY/T0654-2017 *Automatic Biochemistry Analyzer.*

1.6 Technical Parameters

Test specimen	human lithium-heparinized whole blood, heparinized plasma or serum
Sample size	100 μL
Barcode identification	QR code (reading automatically)
Test time	8-12 min/sample
Testing principle	Absorption spectrocolorimetry
Analytical procedures	Endpoint method, rate method
Precision of temperature control	37±0.2℃
Linear range of absorbance	0-3.5 Abs
Cross-contamination rate	0
Operating environment	Temperature: 10°C-30°C, humidity: 40%-85%
Light source	Xenon flash lamp, up to 10^9 times of exposure
Power supply	Input: AC 110V-240 V, 50Hz-60Hz 1.3A; Output: 24Vd.c 3.75A
Main Unit	24Vd.c 3.75A
Optical system	First absorption, then spectrophotometry, with 9 wavelengths, 340, 405, 450, 505, 546, 600, 630, 700 and 800 nm, simultaneously tested
Operation interface	7-inch capacitive touch screen, Multi-language
Memory space	Max 500,000 results
Printer	Built-in thermal printer
Data interface	1 USB port, 1 network port and 1 RS232 port
Weight	Weight per instrument: 4.5 Kg
Dimension	172 mm (width)*256 mm (thickness)*350 mm (height)

Chapter Two Installation Instructions

2.1 Packaging Inspection

The Analyzer should be strictly inspected by professionals of the Company before packaging and transport, and it should be transported to the installation site by the specified transport company.

Upon receipt of the Analyzer, the user should carefully inspect whether the outer packaging has the following damages before unpacking:

- Obvious deformation
- Water stains
- Impact marks
- Signs of being opened before

In case of any damages above, please do not unpack, and immediately notify the after-sales service personnel of the Company or the local dealer.

2.2 Unpacking Inspection

The Analyzer is a piece of precision equipment, which should be handled gently. After unpacking, please inspect the articles in the packaging box according to the packing list. In case of any missing or damage, please contact the after-sales service personnel of the Company or the local dealer. See Page 1 for the packing list.

When all articles are available, take out the Analyzer from the packing box and place it on a horizontal table. After the installation, assist the equipment installation personnel in completing the *Installation Training Record*. The guarantee period starts from the installation date of the Analyzer.

 **Note**

- **Ambient temperature of the instrument: 10℃-30℃**
- **Ambient humidity of the instrument: 40%-85%**
- **Atmospheric pressure: 86.0KPa-106.0KPa**
- **Supply voltage: AC 110V-240V, 50Hz-60Hz**
- **Input power: 120W**
- **The power supply should be well grounded. The accessories and the adapter provided by the Company are recommended, they should be connected to the power supply, and the grounding voltage should be less than 5V.**

2.3 Equipment Installation

2.3.1 Placement of Analyzer

The placement of the Analyzer has direct effects on the normal operations of the equipment and the accuracy of the test results. Place the analyzer on a level surface that is free of hair, dust, and other contaminants.

 **Note**

- **The Analyzer shall be horizontally placed, and the drawer shall not be covered.**
- **The Analyzer shall be far away from dust environment.**

- **Avoid direct sunlight and be away from other potential heat sources.**
- **More than 30 cm away from surrounding objects to ensure good heat dissipation and easy connection with the power supply or other equipment and do not install in a position where it is difficult to disconnect the power.**

2.3.2 Installation of Printing Paper

The thermal printing paper, 30*57 mm, should be used for the Analyzer. See Figure 2-2 for the internal structure of the printer.

Figure 2-2

The installation steps are as follows:

1) Pull the lock cover to open the printer cover as shown in Figure 2-3;
2) Remove the outer packing of the printing paper and put the printing paper in the slot. Pay attention to the front and back sides of the thermal printing paper, do not put the back side out when installing;
3) Hold the front of the paper roll, bypass the printer shaft and out towards to the back of the analyzer, make sure several inches of paper extend out of the printer slot;
4) Close the printer cover, lock up, and the installation is completed.

⚠ **Note: The printing paper is installed when the Analyzer leaves the factory, and the user should follow the steps above when the printing paper is used up.**

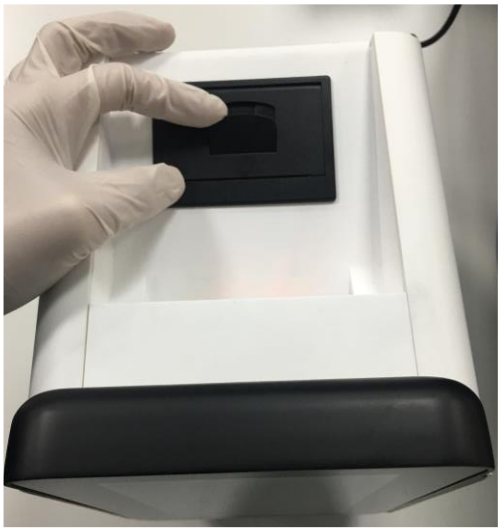


Figure 2-3

2.3.3 Power Supply Connection

Attach the DC power cord of the power adapter to the back of the analyzer, plug the AC power cord of the power adapter to the grounded electrical outlet. Make sure all connections are secure.

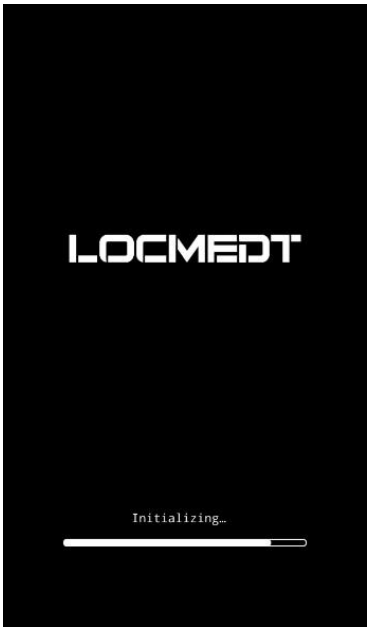
Note: To prevent power surges or drains, the Analyzer shall not share same circuit with a centrifuge or any other high-current devices. A surge protector of the same type used for computers is recommended to protect the clinical chemistry analyzer.

2.3.4 Turning on the Analyzer

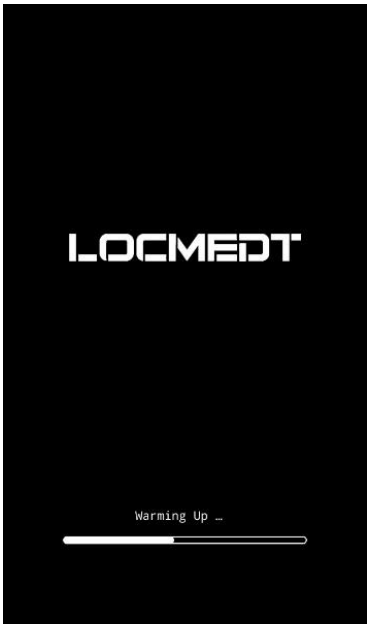
Note

The analyzer screenshots displayed in this manual are for illustration only, and may differ from system displays during actual operations.

Press the power button to turn on the analyzer after connecting the power. The following display appears:

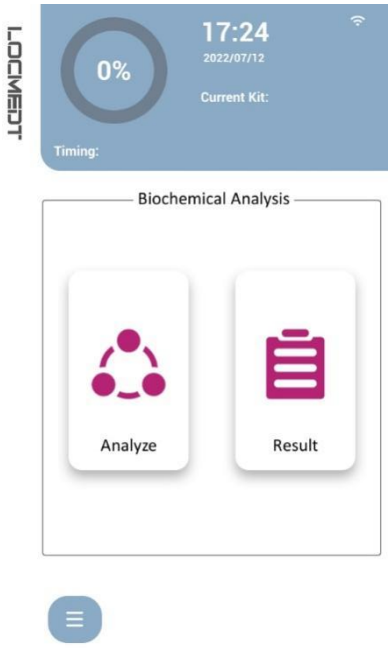


During the initiating process, the system launches the warming procedure and system self-testing to reach to the operating temperature.



Note: It takes 1-2 minutes for the Analyzer to reach the operating temperature when the room temperature is normal; and it may be longer if the room temperature is low. Please ensure that the ambient temperature is 10℃-30℃.

When the Analyzer reaches the operating temperature, the system will automatically enter the main interface as shown in the figure below:



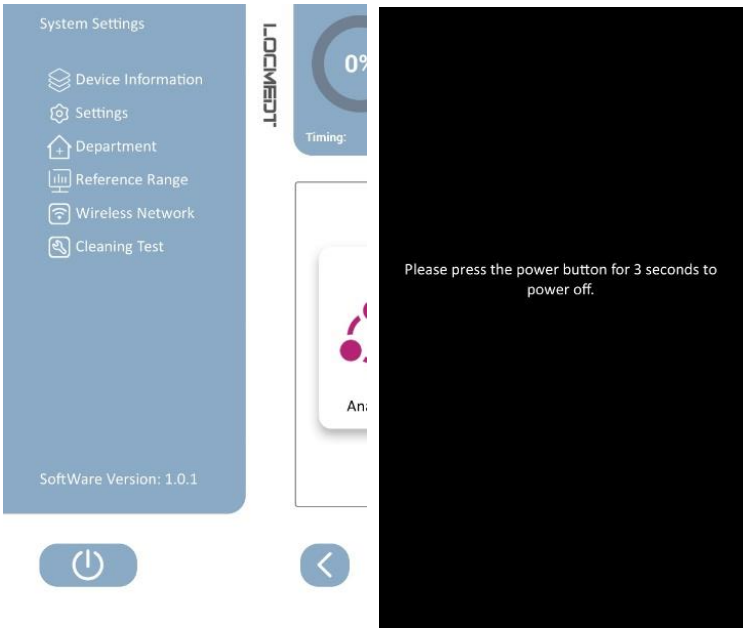
Note: The operators can communicate with the analyzer by the touch screen.

2.3.5 Turning off the Analyzer

Click " " button on the main screen, the system setting screen pops up as shown in the figure below.

Click " " button on the screen, a power off screen appears.

Touch the power button at the bottom right corner of the screen of the Analyzer and hold for 3 seconds, the Analyzer shuts down.



Chapter Three Sample Testing and Results

3.1 Sample Requirements

The analyzer required lithium-heparinized whole blood, lithium-heparinized plasma or serum for testing. The amount of sample required for one panel test is 100 μL, and 90-120 μL is acceptable. It is recommended that the blood collection volume should be not less than 250 μL for retest.

When collecting the sample in lithium heparin collection tubes, fill the tube at least halfway so the anticoagulant does not become too concentrated in the sample as high concentration of anticoagulant will affect the result. Sample preparation can directly affect the accuracy of the test results. Samples incorrectly prepared can even cause failed tests in some cases. Therefore, please operate in strict accordance with the following requirements.

 **Warnings**

When handling blood samples and operating analyzers, users should strictly comply with general and medical laboratory biosafety specifications.

 **Note**

- **The anticoagulant used in the samples of the Analyzer shall be heparin lithium. Do not use EDTA (lavender top test tube) for any samples to be tested on the Analyzer.**
- **Make sure whole blood samples are homogeneous before adding the sample to the reagent disc. Gently invert the collection tube 5-7 times before filling the transfer device. Do not shake vigorously the collection tube; shaking vigorously can cause hemolysis.**
- **Whole blood must be analyzed within 60 minutes of collection, or separated into plasma or serum. The prepared plasma or serum samples after centrifugation should be stored at room temperature for no more than 5 h, and should be tested timely. If not analyzed immediately, plasma or serum can be stored at a capped tube at 2-8 °C (36-46 °F) for no more than 24 hours or store it at –20°C± 2°C for up to 5 weeks in a freezer without self-defrost cycle. If the conditions above cannot be met, the concentrations of the analytes may be changed, and the test results have no actual clinical significance.**
- **The reference ranges of most clinical biochemical indicators are set based on the data of healthy populations in the fasted state. To prevent the interference of meals, the blood collection for some items should be performed after at least 12 hours of fasting.**

3.2 Preparation of Reagent Disc

The associated reagent disc of Automatic Biochemical Analyzer LOC-200 is 7.8cm in diameter and 0.68cm in thickness. The disc is disposable and made of plastic with a diluent container in the center. Lyophilized reagent beads are pre-installed in the cuvettes located along the perimeter of the disc.
The disc shelf life is 12 months, the users should not use the expired discs.

The reagent disc adopts the disposable single-piece packing and the independent channel design, which can avoid cross contamination.

3.2.1 Storage and Handling of Reagent Disc

To ensure the stability of the reagent disc and the accuracy of the test results, the reagent disc should be stored at 2-8℃ as specified on the label of the reagent, use only reagent Discs that have not expired. The Analyzer automatically rejects expired disc.

- The reagent disc can be used immediately after taking out from the 2-8℃ refrigerator without warming.
- Do not expose discs in or out of their foil pouches to direct sunlight or to temperatures above 30℃ (86 ° F).
- Check the unopened foil pouch for any damage, tear or puncture before use. Never use a disc from a damaged foil pouch, as the reagent beads in the damaged pouch may deteriorate, it may reduce the disc performance.
- The reagent disc should be handled gently. After removing the reagent disc, check the reagent disc for damage. Do not attempt to knock the reagent disc. Do not use dropped or damaged reagent discs.
- The reagent disc should be used within 20 min after the aluminum foil bag is opened. The accuracy of the test results will be affected if the aluminum foil bag is opened for a long time. do not place the disc back in the refrigerator for later use.

Open the aluminum foil pouch at the notch on the edge of the package and remove the reagent disc from the pouch. Handle the disc only along the edges with fingers (it would be better to wear disposable plastic gloves) and place it flat on the table.

Note: Do not touch the area around the cuvettes on the surface to prevent any stains which may affect the accuracy of the test.

Sample port, marked by the red circle on the disc, provides the access to the sample chamber. Shown as the below Figure 3-1:

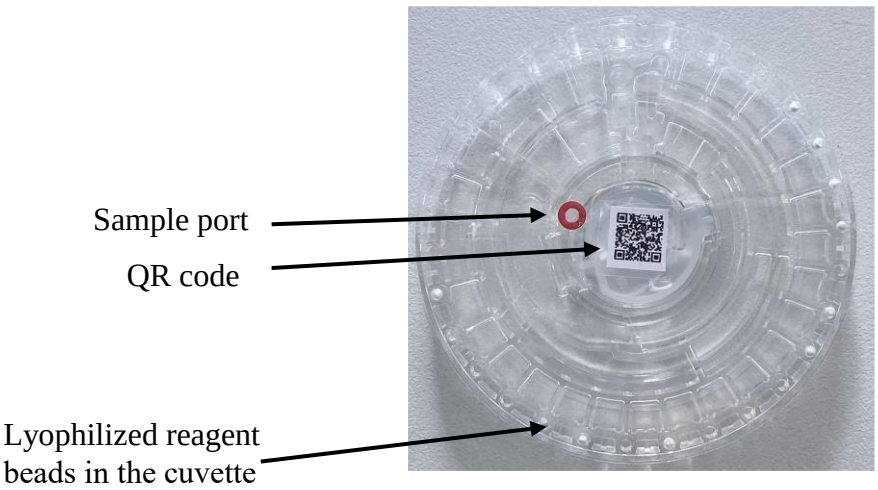
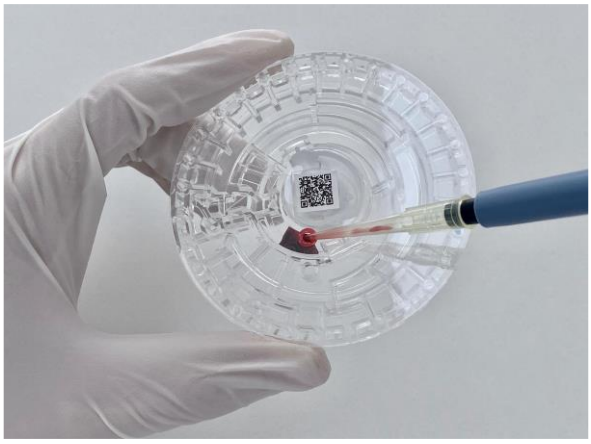


Figure 3-1

3.2.2 Adding Sample to the Disc

(1) Use a fixed 100 μL Volume Pipette and attach a new tip to the end of the pipette. Do not touch the tip to prevent contamination.

(2) Draw 100 µL sample (lithium-heparinized whole blood, lithium-heparinized plasma or serum) by pipette then place the pipette tip into the reagent disc's sample port, tilt the pipette tip at an angle of 45° from the disc (shown as below). Gently and smoothly release the sample to the sample chamber. Do not release the sample too fast, otherwise sample will overflow. Excess blood may contaminate the analyzer.



(3) To avoid cross contamination, the pipette tip is for single use only.

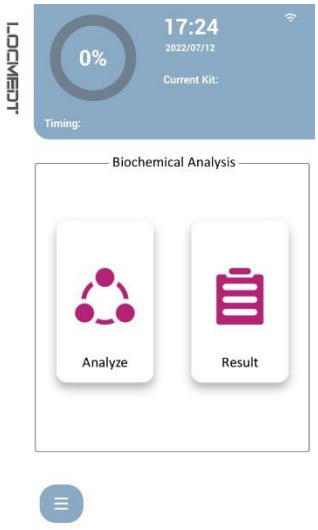
(4) Hold the reagent disc by its edges and keep it in a flat position while carrying it to the drawer of the analyzer.

Note

- **Make sure there is no contamination or damage on the QR code on the center of the disc.**
- **Immerse the pipette tip 2-3mm below the surface of the sample and make sure there is no air bubbles in the pipette tip after drawing sample.**
- **Do not remove the sample in the sample port and try to reintroduce it into the disc.**
- **Discard the used pipette tip in the biological dustbin.**

3.3 Running a Test

(1) Turn on the Analyzer and it starts up and performs self test. When the Analyzer reaches operating temperature, the analyzer displays the home screen as shown in the figure below:

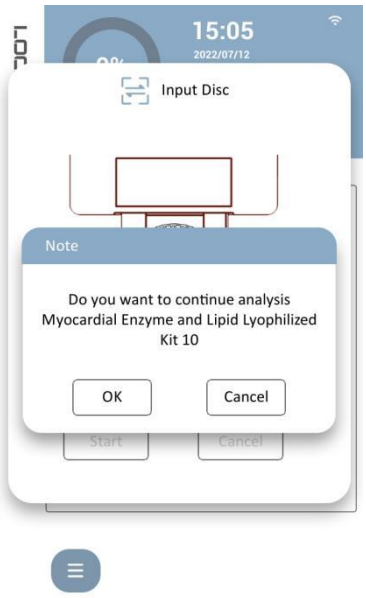


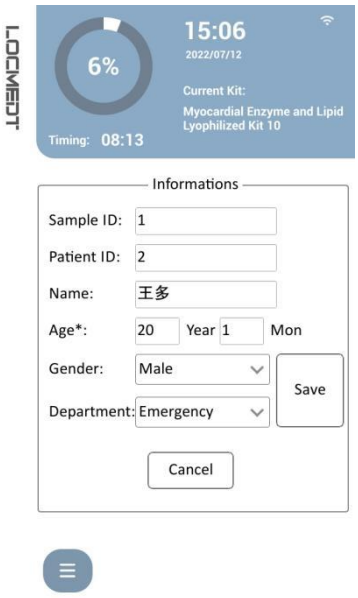
(2) Click the Analyze "" button on the screen to open the drawer. The analyzer displays the screen shown as below. Then place the reagent disc in the drawer as shown in the figure below.

Note: Now insert the reagent disc into the drawer smoothly and make sure the rim of the disc fits the drawer edge marked by red line shown on the picture.

(3) Press "**Start**", the drawer will be closed. The analyzer reads the disc information by scanning the QR code on the disc, the confirmation screen of the reagent disc will appear. If the information of the reagent disc is correct, click "**OK**", then it displays the screen shown as below.

Note: Please do not put your hands in the drawer when it is going in and out, or your hands may be clamped.





Note: If the QR code cannot be scanned, a prompt box will automatically pop up as shown in the figure below.

(4) When the "QR Code Error" prompt pops up, please click "OK" button. Take out the reagent disc when the drawer is opened, and view whether the QR code is damaged or contaminated. If there is no damage or contamination on the QR code, place the reagent disc into the Analyzer once again at a different angle, and start analysis. If the QR code is damaged or contaminated replace the reagent disc and test.

Remarks:

1) When "QR Code Unidentified" prompt pops up, take the disc out and confirm whether the QR code on the disc is the original one when the disc leaves the factory;

2) "Used Disc" prompt means this disc is used, please remove the reagent disc from the drawer, and prepare a new reagent disc for testing;

3) When "Expired Disc" prompt pops up, please check the expiry date on the foil pouch of this disc. If it is expired, please prepare a new disc for testing.

Note: The QR code on the reagent disc contains the ID code of the reagent disc, the production lot No., the expiry date and the calibration information, etc. Make sure the QR code is clean without any damage or contamination before using the disc for testing.

(5) During the test, the user inputs the sample information. Then click "Save". If it is necessary to modify the sample information, click "Modify" to operate.

(6) When the analysis is completed, the system will store the analysis results and display them on the touchscreen as shown below, the report is printed automatically (the automatic printing mode should be set). Click "^" (page up) and "v" (page down) buttons to see the last or the next page.

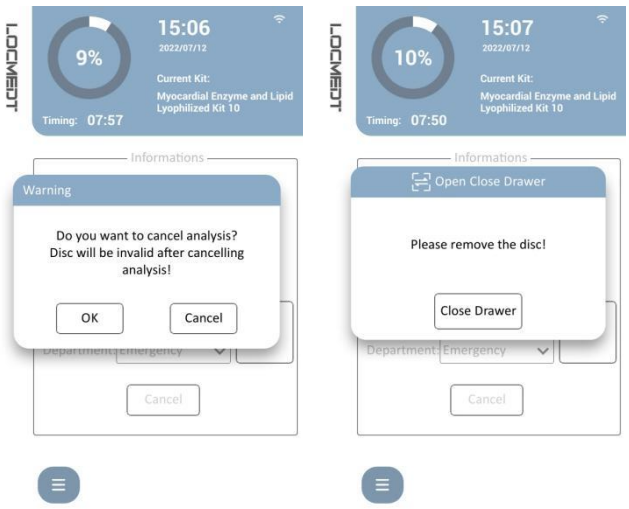
(7) After the test, the drawer of the Analyzer opens automatically. Take out the reagent disc, and discard it according to the laboratory biosafety levels. Click "Continue" button return the analyzer to the home screen, then place a new disc for the next analysis. Click "Finish" button to close the drawer, and the system returns to the main screen.

3.4 Canceling Analysis

In case of special circumstances, the current analysis has to be cancelled. The operation steps are as follows:

- Click "**Cancel**" button on the analysis countdown screen, and the confirmation screen will appear as shown in the figure below.
- Click "**OK**" button, the Analyzer will cancel the analysis after the motor completes the centrifugation step. According to the state of the Analyzer, it may take 1-2 min for the motor to stop running, and then the drawer opens automatically.
- Remove the reagent disc and discard it according to the laboratory biosafety requirements.
- Click "Close Drawer" button, the drawer of the Analyzer will be closed, and the system will go back to the home screen and ready to perform the next analysis.

Note: When the analysis is cancelled, the reagent disc is invalid and cannot be used in the next analysis.



3.5 Report Interpretation

The picture shows the format of the analysis report which printed by the thermal printer of the Analyzer. The heading of the report includes information about the disc name, sample type, patient ID, reagent disc serial number, gender and age. The report section contains four columns, kit, Result, Indicator, Reference Range and Units.

Biochemical Analyzer Test Report
Myocardial Enzyme and Lipid Lyophilized Kit 10

Sample ID: 23
Patient ID: 23
Department: id1
Name: 23
Gender: Male
Age: 20 years and 1 months
Lot ID: 220501-53-305

Kit	Result		Reference Range	Unit
AST	13	↓	15-40	U/L
CHOL	4.71		3.1-5.7	mmol/L
CK	35		10-200	U/L
CK-MB	8		≤ 24	U/L
HCY	7.1		≤ 15	umol/L
HDL-C	2.08	↑	1.16-1.42	mmol/L
LDH	165		120-250	U/L
TG	1.3		≤ 2.1	mmol/L
a-HBDH	116		90-230	U/L
LDL-C	2.04		≤ 3.37	mmol/L

Operating Physician:
Auditing Physician:
2022-07-12 16:52
The result are only representative of the samples submitted

The bottom of the report contains the information such as the test date and time, and blank areas for operator and reviewer to sign.

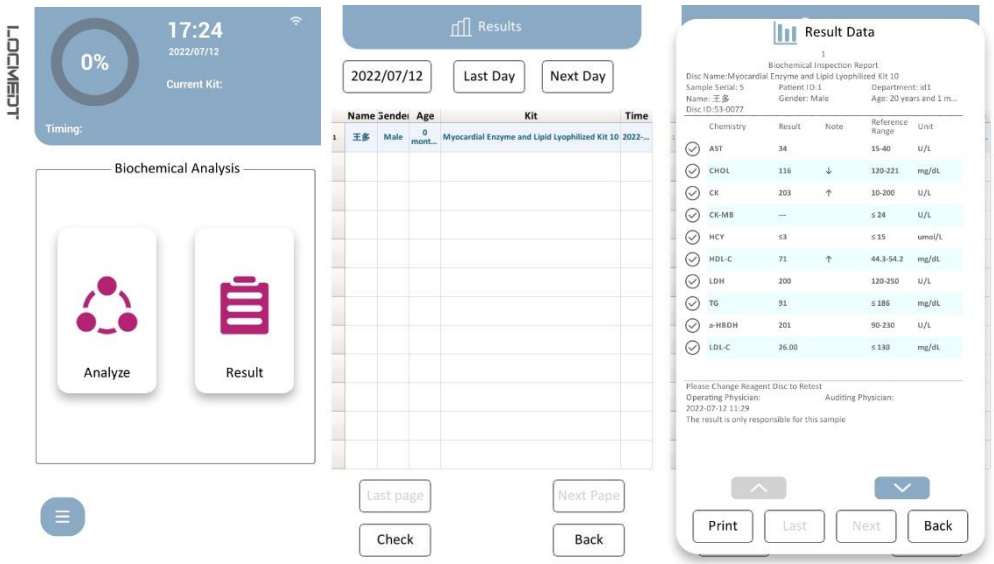
- If the results are outside the reference range, the results will be marked with symbols printed next to the analyte concentration ("↑" indicates the result is above the upper limit of the reference range and "↓" indicates the result is below the lower limit of the reference range).
- If the results are outside the dynamic range, a 'less than or equal' symbol ≤ printed next to the lowest value of the dynamic range, or a 'greater than or equal' symbol ≥ printed next to the highest value of the dynamic range.
- Any abnormal test results due to abnormal blood samples (hemolysis, lipemia, or icterus), pollution of blood samples or diluent, exogenous interference factors, medication residue, and the concentrations outside the processing capacity of the Analyzer can be automatically judged by the Analyzer. In case of abnormalities, the symbol "---" appears in the place of numbers of result. If the symbol"---" appears for the first time, please retest, and if it still exists, please contact the after-sales service technician of the Company.
- If the test results are abnormal due to hemolysis, lipemia, or icterus of the sample to be tested, "Hemolysis", "Lipemia" or "Icterus" will be printed at the bottom of the report to indicate that the sample is abnormal. The abnormal sample will affect the testing of some particular analytes, and the test results are for reference only.
- The whole blood sample with hematocrit in excess of 70% packed red cell volume may give inaccurate

results and cause disc errors. In this case, it is recommended to centrifuge the blood samples into plasma, replace the reagent disc and test once again.

- During the analysis, the Analyzer can intelligently detect the sample volume. If the sample volume injected into the reagent disc does not meet the volume requirements, the Analyzer will prompt error code EM201 at the end of analysis. In this case, a new reagent disc should be used, and required enough volume sample should be added, see the details in "3.2 Preparation of Reagent Disc".
- In very rare cases, the samples injected into the blood sample chamber of the reagent disc may be not mixed properly with the diluent, or the mixture cannot successfully enter the reaction chamber of the reagent disc, then the corresponding error will be prompted on the test report. At this time, please confirm whether the operation process meets the requirements of this *Operator's Manual*. Use a new reagent disc and test once again, and call the local dealer or the after-sale service department of the Company.

3.6 Recalling Result

The test results are stored in the database of the Analyzer, click " " on the main interface to view and print the results. Select the test date and the item to be viewed, and click "Check" button.



In the result query screen, press " " before each test item to select the items to be printed. Click "Print" button, the Analyzer will print the results of the selected items.

3.7 Calibration

The Automatic Biochemistry Analyzer LOC-200 is calibrated by the manufacturer before shipment. The analyzer is self-calibrating whenever the power is switched on. The lyophilized reagent beads used in the disc are calibrated by the reference Method or reference material provided by the manufacturer prior to shipment. QR code printed on the reagent disc contains the calibration data and provides analyzer information to measure analyte concentrations.

3.8 Quality Control

It is necessary to run the control on the analyzer to verify the performance of the analyzer or reagent disc. A control is a biological sample or solution that is analyzed for purposes of quality control.

It is recommended that the quality control test be performed:

1. Whenever there is a significant change to the laboratory environment.

2. When there is staff training.

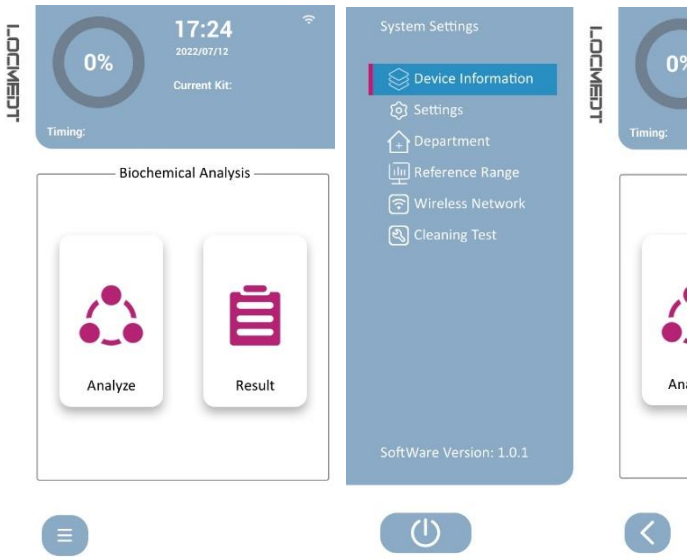
3. When test results are inconsistent with patient symptoms or diagnosis.

4. If this is not the case, a quality check is recommended every 30 days up to a maximum of 90 days, which it must be carried out.

Samples and controls are analyzed identically by the analyzer. We recommend that the users should run RANDOX quality control on the analyzer. Please contact LOCMEDT for assistance in interpreting control results.

Chapter Four Configuring the Analyzer

Click "" button on the main screen to enter the system setting screen as shown in the figure below:



4.1 Device Information

Click "**Device Information**" button, the system screen will display "Device ID", "Software Version" "Hardware 1 Version "and "Hardware 2 Version". Click "**Check Update**" button to update the "Software Version" and "Hardware Version" of the Analyzer to the latest ones as shown in the figure below:

Note: To improve the user experience, the Analyzer will regularly release hardware and software upgrade packages. When the Analyzer is connected to the server, there will be notification on the analyzer screen. Click "OK" in the notification dialogue box to upgrade, or just wait for several seconds, it will update automatically without pressing any button.

4.2 Settings

Click "**Setting**" button at System Settings screen. Set in the pop-up dialog box as shown in the figure below.

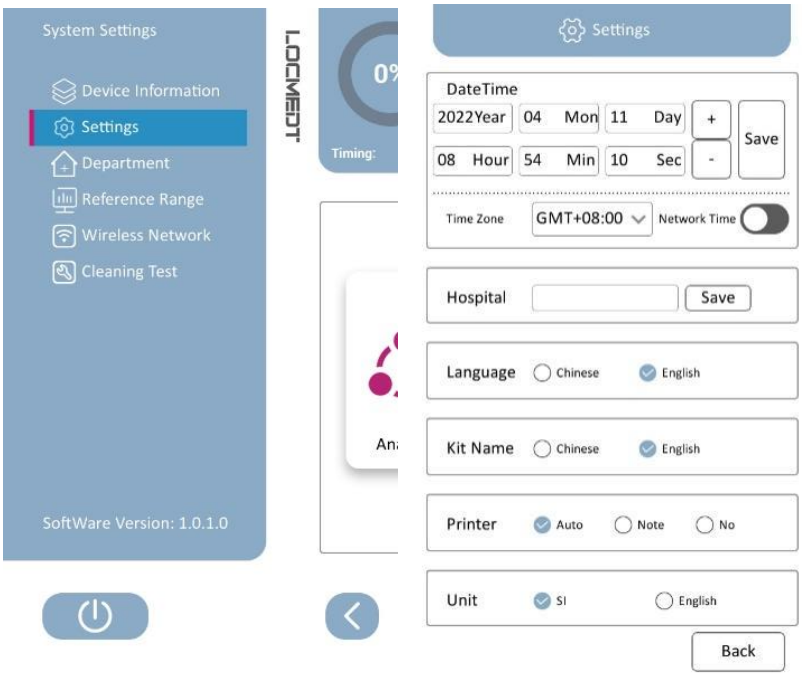
[Language] Select the system language of the Analyzer.

[Date Time] The date and time is factory preset to Beijing Time (UTC+8). Reset the date and time according to the user's time zone when setting up the analyzer.

[Hospital] Input the hospital name and then click "Save".

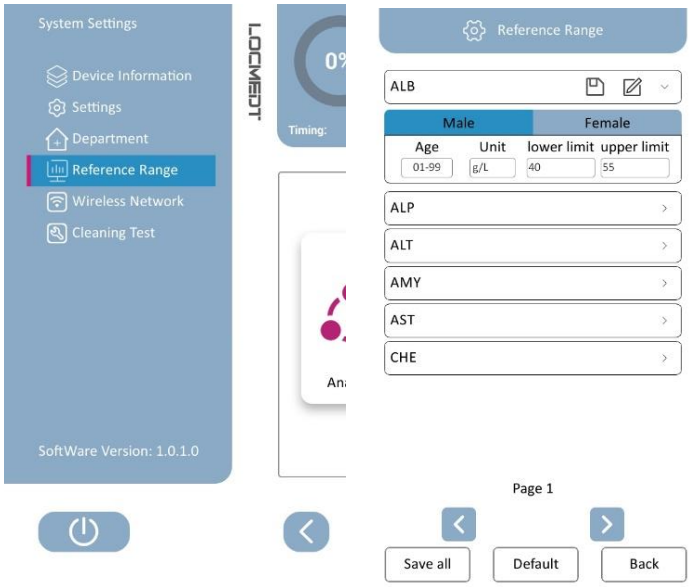
[Printer] There are 3 modes, "Automatic", "Note" and "No", in the print settings. If "Automatic" mode is selected, the results will be printed automatically after the test is completed; if "Note" mode is selected, "Do you want to print the result?" prompt will pop up after the test is completed; and if "No" mode is selected, the printer will not print the result, but the user can search the result and then print it. See the section 3.6 Recalling Results for details.

[Unit] The user can select the concentration unit "International unit" or "English Unit".



4.3 Reference Range

The upper and lower limits of reference ranges of test items can be set in the Analyzer according to the clinical requirements of the end users. Click "Reference Range" button to enter the reference range setting screen as shown in the figure below. Select [Gender] and [Age]. The first white box represents the lower limit and the second white box represents the upper limit. Click the number boxes of the lower limit and the upper limit. When the cursor blinks in the selected box, select the box and modify the figure and press "Save".

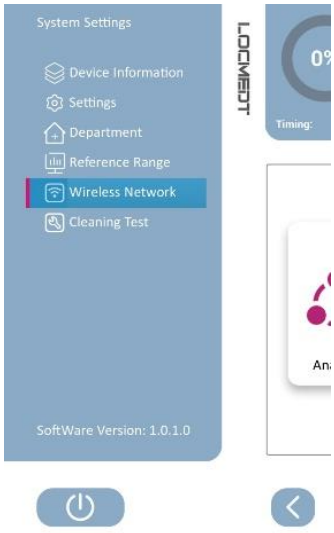


Note: Click "Default" button to set the reference range to its factory default values.

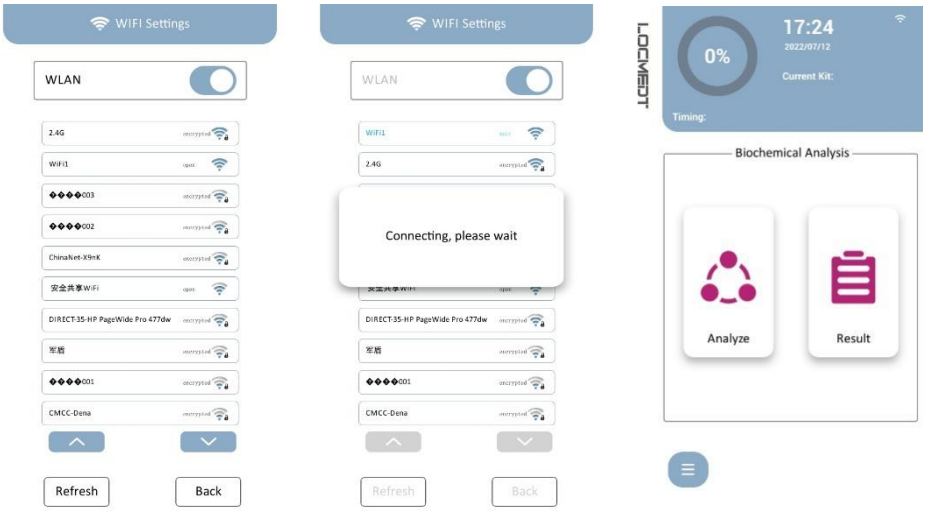
4.4 WIFI Connection

The analyzer has built-in WiFi network module, which is convenient for users to optimize and upgrade the software and upload the error log to Cloud server. The technicians can review the status of the analyzer by analyzing the error log and help solving the problems remotely.

Click "**Wireless Network**" button on the setting screen to enter the network setting screen as shown in the figure below:



Click "**WLAN**" button to enter the screen below. Select the wireless network available and input the password. Click "Connect" button, wait for the wireless network to be successfully connected, and then go back to the main screen. There is a WiFi identification in the upper right corner of the screen as shown in the figure below:



Chapter Five Error Code and Troubleshooting

5.1 Error Code

The analyzer can display warnings, error codes and messages if there any problems occur during running the test. These error codes indicate the user error type and help after-sales service technicians to diagnose the problem.

If the analyzer displays an Error code, find the code in the following pages, and try the suggested solutions in the order presented.

5.2 Electrostatic Discharge

If there is strong electrostatic discharge during the sample testing, the Analyzer may crash. In case of timeout (or countdown stops), the analysis should be cancelled immediately. Turn off the Analyzer for several minutes and then restart, the Analyzer will return to normal.

5.3 Analyzer Error Code and Troubleshooting

Error Code	Probable Cause	Solutions
EM101	Circuit Error	1.Restart the analyzer and check whether the analyzer can be powered on through the self-test. 2.If the problem persists, please contact the authorized technical support department.
EM102		
EM103		
EM105		
EM111	Optics Error	1. Click the menu to enter "Cleaning Test" interface and then clean the inside of the analyzer according to the prompts on the page. More details please check 6.2 section on user's manual. 2. After the cleaning is complete, perform the "Cleaning test" to check the cleaning results. 3. Failed to pass the test for three times， please contact the authorized technical support department.
EM121	Open Drawer Error	1.Make sure the hardware and software are the latest versions. 2.Turn the analyzer upside-down carefully and gently pat the drawer if there is a disc inside the drawer. Then open the analyzer. 3.If the problem persists, please contact the authorized technical support department.
EM122	Lock Disc Error	
EM123	Close Drawer Error	1. Make sure the adapter is supplied by LOCMEDT and Check whether there are foreign bodies in the drawer. 2. If the problem persists, please contact the authorized technical support department.
EM131	Expired Disc	The disc is expired, please use a new reagent disc.
EM132	QR Code Error	1.Inspect the QC Code to see if it is damaged or contaminated. If there is no damage or contamination on the QR code, still place this disc into the drawer for testing but in a different direction. If the QR code has been damaged and contaminated, please prepare another reagent disc for testing. 2.If the problem persists, please contact the authorized technical support department.
EM133	Used Disc	Please remove the reagent disc from the drawer, and prepare a new reagent disc for testing.
EM134	No Related Disc Information	1.Make sure the hardware and software are the latest versions. 2.If the problem persists, please contact the authorized technical support department.
EM135	QR Code Info Error	Inspect the QC Code to see if it is damaged or contaminated. If the QR code has been damaged and contaminated, please prepare another reagent disc for testing.

EM142	Locating signal Error	1. Click the menu to enter "Cleaning Test" interface and then clean the inside of the analyzer according to the prompts on the page. More details please check 6.2 section on user's manual. Perform Cleaning Test to check whether the test passes. 2.If the problem persists, please contact the authorized technical support department.
EM143	Collecting Error	1.Restart the analyzer. 2.If the problem persists, please contact the authorized technical support department.
EM144	Abnormal Light intensity value	
EM161	Hardware 1 Error	
EM171	Hardware 2 Error	
EM181	No upgrade package in the USB flash disc	1.When the analyzer is started, insert the USB flash disc and remove it.
EM182	Hardware 1 Update Failed	1.Restart the analyzer. 2.If the problem persists, please contact the authorized technical support department.
EM183	Hardware 2 Update Failed	
EM184	Software Upgrade Failed	1.Press Wireless Network on System Settings Screen to connect the WiFi. Then press the Device Information on System Setting Screen to check the update version and perform the updating. 2.If still failed, please try to connect another WiFi to update, or connect a mobile hotspot to download a software upgrade.

5.4 Disc Error Code and Troubleshooting

Error Code	Probable Cause	Solutions
EM201	Insufficient Blood Sample	1. Make sure to add 100μL of sample (only 120μL plasma for Critical Care Panel 13) without any air bubbles. Please insert a new reagent disc to retest. 2. Inspect the blood sample whether it is clotting or too thick. If so, it is recommended to centrifuge the whole blood sample into plasma, and then prepare a new reagent disc for testing.
EM202	Insufficient Diluent	1.Restart the analyzer and test a new disc. 2.If the problem persists, please contact the authorized technical support department.
EM203	Disc Analysis Error	1.It is recommended to centrifuge the whole blood sample with mild hemolysis or lipemia problem into plasma and use plasma to retest. 2. Hemolysis, lipemia, or icterus adversely affect the results. To make sure the accuracy of the result, it is suggested to re-collect the qualified sample to perform the test if the whole blood sample has serious hemolysis, lipemia or icterus problems.

Service information

The laboratory must notify the manufacturer of this test system of any performance, perceived or validated, that does not meet the performance specifications as outlined in the instructions.

The manufacturer provides a toll free line for technical support: +86-22-58601276

Before asking for assistance, please record the following information:

• Automatic Biochemistry Analyzer LOC-200 serial number (SN) – see label on the analyzer

• Software version number – see Device information.

• Test type • Test kit name and kit lot number – see the package of the kit

• Control identification and lot number – see the control kit label

• Control results obtained

• Description of the problem with reference to information error codes or messages

Chapter Six Maintenance and Software Update

The analyzer requires minimal maintenance. In order to keep the analyzer in good working order, the analyzer requires maintenance regularly:

- Weekly: Wipe the outer surface of the Analyzer using mild detergents and soft cleaning cloth;
- Monthly: Clean the touch screen using mild detergents and soft cleaning cloth;
- Monthly or as instructed: Clean the fan filter;
- Every six months or as instructed: Wipe the lens of the optical module of the Analyzer.

Note:

- **It is recommended to use 75% alcohol as the cleaning detergent. Do not spray the detergent onto the analyzer, just dampen the cloth instead. Protect the analyzer from any grease solvents and corrosive substances.**
- **If there is any doubt about the compatibility of the stain remover or cleaner, consult the manufacturer or its agent.**
- **It is the user's responsibility not to use decontamination or cleaning agents that may cause danger due to reactions with equipment parts or materials contained therein.**

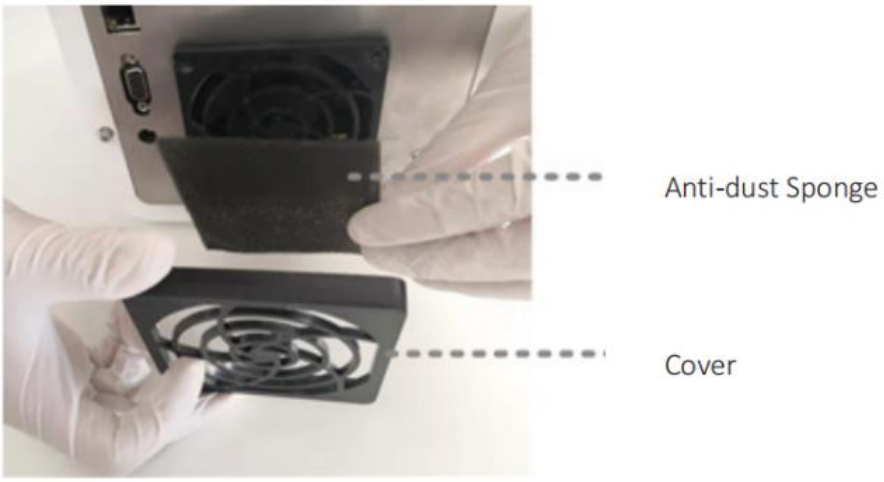
Warning: The power of the Analyzer shall be cut off during the cleaning!

6.1 Cleaning the Fan Filter

Accurate temperature control is crucial to the normal operations of the Analyzer. Please replace the fan filter at the back of the Analyzer monthly to keep the cleanliness and air permeability of the fan filter and ensure the normal temperature control of the Analyzer.

The replacement steps are as follows:

1) Unplug the power cord back of the Analyzer, open the cover of the fan filter, and take out the black anti-dust sponge (as shown in the figure below);



2) Take out the replacement anti-dust sponge from the accessory box and put it into the analyzer and snap the filter cover into the place over the filter;

3) Wash the dirty anti-dust sponge with soapy water to remove the dust and any other debris. Dry the anti-dust sponge and put it away for next replacement.

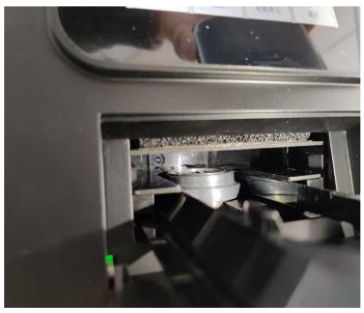
6.2 Cleaning the Optical Lens

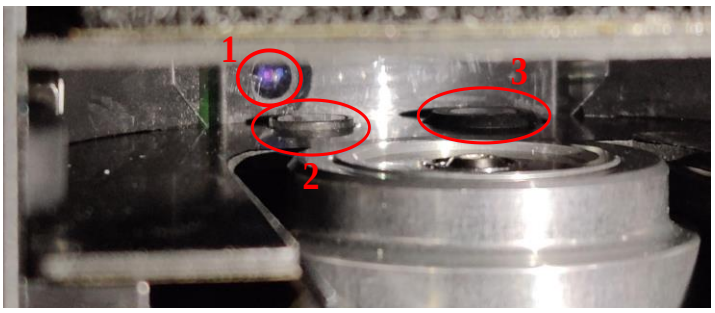
The optical module is the core component of the Analyzer. In order to ensure the normal operation of the analyzer and obtain accurate detection results, please clean the lens of the optical module every six months.

The operation steps are as follows:

Prepare the following cleaning items: ① Cotton swab (18 cm in length); ② 75% alcohol;

1) Turn on the analyzer, the analyzer displays the home screen, press the menu icon " " to enter system settings. And then press “Cleaning Test” and "Open Drawer". The drawer opens.
2) Unplug the power adapter to power off the analyzer. Cleaning will be done under the state of power off. And now the drawer still keeps open and we will begin the cleaning process.
3) The below picture shows the inside of the analyzer drawer where we should clean. Dampen the sponge swab with the 75% alcohol, and clean the three locations marked by number 1,2,3 in the below picture. Please make sure there is no alcohol dropping from the sponge swab.
4) After wiping, plug the power adapter in and restart the analyzer to enter the home screen. Click the menu button to enter the "Cleaning Test" interface again. Click "Open Drawer" and put the cleaning test disc into the drawer, click the "Start" button.
5) Then wait for the cleaning test results. If the test fails, please clean it again. If the symptom persists, please contact the after-sales service.





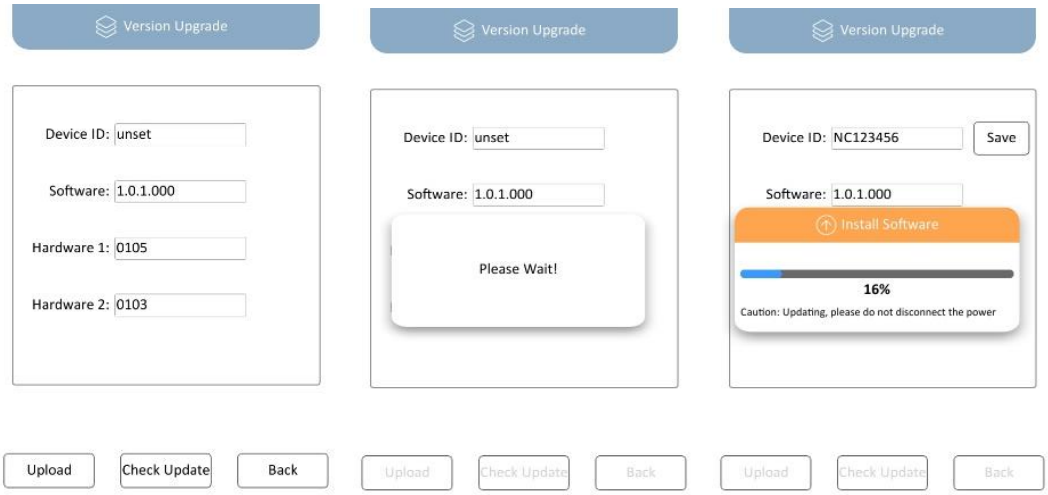
6.3 Software Update

According to the market demand and customer feedback, the Company will irregularly optimize the software of the Analyzer to ensure that the user has a good experience: "faster analysis, better performance, and more convenient operations." If it is necessary to update the version of the software, the after-sales service personnel of the Company will contact the users timely and update the software via network or USB flash drive.

Note: It is recommended to update the software and store the test results using the special USB flash drive provided by the Manufacturer or via wireless network to prevent virus infection of the Analyzer.

6.3.1 Updating via WIFI

Click "**Wireless Network**" button (see "**4.4 WIFI Connection**" for details) and connect the Analyzer to the wireless network. Go back to the system setting screen, click "**Device Information**" button to enter the device information screen, and then click "**Check Update**" button to update the software.



Warning: Do not cut off the power or the network during the software updating to avoid failure.

6.3.2 Updating via USB Flash Drive

If the WiFi is not available, the user can connect the after-sales service or the local agent to get an update U disc. Connect the U disc to the USB port at the back of the analyzer and then press the device information button on the system settings screen. Then press the check update button on the device information screen to update the software.

Warning: The USB flash drive for updates can only be inserted to the Analyzer to avoid virus infection of the Analyzer.

6.4 Returning the Analyzer for Service

If it is confirmed that the Analyzer should return to the manufacturer for repair, please contact the courier service company designated by the Company to transport the Analyzer. Before the transportation, please contact the after-sales service.

Chapter Seven Packaging, Transport and Storage

7.1 Packaging

The inner box of analyzer is strong foam box with shock proof function. The outer box is standard shipping carton. The package is strong enough and suitable for long distance sea or air transportation.

It should be guaranteed that the outer packaging box should not be damaged and should be protected from water and rain during the transportation and storage.

7.2 Transportation

Please make sure the analyzer is well protected against dampness and rain and if necessary, please cover the analyzer box with a waterproof material during transportation.

The goods on the carrier vehicle should be piled in order, compactly, reasonably, safely and reliably to prevent damage to the goods due to sways during the transportation.

This product shall not be transported on the same vehicle with inflammables, explosives, and perishable items, and the components of this product shall be protected from rain, snow or liquid substances or mechanical damage.

7.3 Storage

- Ambient temperature for storage: 0℃ - 40℃.
- Ambient humidity for storage: No more than 85%.
- The product shall be stored in the original packaging box to maintain original protection.
- Damp-proof, dust-proof, shake-proof, anti-corrosion and other measures should be taken in the warehouse of this product. It is recommended that there should be air conditioners and lighting equipment, etc. installed in the warehouse.

Chapter Eight Quality Assurance and Safety Precaution

Any company, organization or individual other than the Company does not have the rights to test and repair the Analyzer. The Company undertakes to provide 12-month free quality assurance services (excluding consumables) for users of the Analyzer upon installation with the following exceptions:

1、The Analyzer is not used in strict accordance with the *Operator's Manual* or standard supporting consumables are not used;

2、Injuries are caused by human factors;

3、The Analyzer is dismantled without the permission of the Company, etc..

The quality assurance services above are provided exclusively to the original users of the Analyzer, which shall not be transferred to or shared with others.

Safety Precautions

To safely and effectively use the Analyzer, the following precautions should be followed:

Correctly Place and Operate the Analyzer

The Analyzer shall be installed in the environment specified in the *Operator's Manual*, and it shall be operated according to the *Operator's Manual*.

Prevent Electric Shock

The enclosure of the Analyzer shall not be opened without the permission of the Company to prevent liquid splashes to the Analyzer. To prevent electric shock and other accidents, please timely contact the customer service staff of the Company if liquid enters the Analyzer before it is used.

Prevent Sample Pollution

Protective gloves shall be worn when biochemical tests are conducted. Direct contact with the samples to be tested without protective gloves may pose potential risks of biological infections. If used discs are not undergone biological safety treatment, it can also pose potential biological safety problems. In case of direct contact with the skin, please clean and disinfect the contact site immediately, and consult the doctor.

Correctly Operate the Reagent Disc

Reagent beads may contain corrosive substances or ingredients. Please operate in strict accordance with the *Operator's Manual*. The operators will not contact the reagent beads which are sealed in the reagent disc during normal use. Unless the reagent disc is broken, the reagent beads will not be leaked. In case of leakage of reagent beads, avoid direct contact with the reagent as much as possible.

Correctly Dispose of used Reagent Discs

Used reagent discs contain human blood samples. Please strictly adhere to laboratory practices when handling blood and body fluid samples; Dispose of used reagent discs according to the biological medical waste disposal regulations of the locality.

Contact Information

Manufacturer: Tianjin LOCMEDT Technologies Co., Ltd.

Address: Floor 4, Building B3, Huaming High-tech Industrial Zone, No.6 Huafeng Road, Dongli District, Tianjin, 300300, China

Tel: +86-22-58601276

Email: service@locmedt.com

EC REP Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Email: peter@lotusnl.com

Revision date: Apr. 26th. 2024 Rev: 05

Symbols used in Analyzer

⎓	**Direct current (DC)**
	Biohazard: In accordance with standard Laboratory practices: All samples, quality control products, associated containers and used reagent discs should be disposed of according to the appropriate biosafety level, taking into account the potential for infection of all human samples
IVD	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
CE	Appears on the instrument and indicates that the instrument meets the requirements of the Related EU directive
EC REP	Indicates the authorized representative in the European Community/ European Union
	Indicates the need for the user to consult the instructions for use
	Identifies the terminal connected to the outer protection conductor to prevent electric shock in case of failure
	Indicates the medical device manufacturer
	Indicates the date when the medical device was manufactured
SN	Indicates the manufacture’s serial number so that a specific medical device can be identified
	Indicate the range of humidity to which the medical device can be safely exposed
	Indicates the temperature limits to which the medical device can be safely exposed
CC	To identify the country of manufacture of products