乐普医疗
LEPU MEDICAL

CE 0123

Cholesterol Analyzer

LP-M3-11

Instruction for use

Lepu Medical Technology (Beijing) Co., Ltd.

Statement

Thank you for choosing products manufactured by Lepu Medical Technology (Beijing) Co., Ltd.

Before using the Cholesterol Analyzer for the first time, please be sure to read carefully all documents accompanying the product. This will help the product be used better. If this product is not operated according to the instructions and requirements of this manual, or the product is misused due to misunderstanding or other reasons, Lepu Medical Technology (Beijing) Co., Ltd. (hereinafter referred to as "Lepu") will not be liable for any loss arising therefrom.

Lepu has carefully reviewed and verified this manual, but we cannot guarantee that this manual has no errors or omissions. If any errors and inadequacies are found, please contact the company's customer service staff.

Lepu is committed to continuously improving product performance and service quality, and reserves the right to make changes to any product and software program described in this manual, and the contents of this manual, without prior notice.

The purpose of this manual is to guide use of the product correctly. It does not represent any description of the hardware and software configuration of this product. For product configuration, check the contract (if any) related to this product, the packing list of the product, or consult the dealers who sold the product. Pictures in this manual are for reference only. If there is a discrepancy between an individual picture and the actual state of the product, the actual state of the product will prevail.

During use, any inconsistency between the actual status of this product and the content described in this manual or inquiries about any issues related to use of this product and the latest product information or provide valuable opinions and suggestions, please contact the company directly. Contact information is as follows:

Lepu Medical Technology (Beijing) Co., Ltd.
Address: No. 37, Chaoqian Road, Changping District, Beijing
Production address: Building 7-1, No. 37, Chaoqian Road, Changping District, Beijing
Postcode: 102200
Customer service hotline: 86 10-80120666
http://www.lepumedical.com

Contents

1、Product Introduction

1.1 Product description

Product name: Cholesterol Analyzer
Product model: LP-M3-11

1.2 Intended use

The Cholesterol Analyzer is intended for quantitative determination in vitro of total cholesterol (CHOL), high-density lipoprotein cholesterol (HDL) and triglyceride (TRIG) in human whole blood (venous blood or capillary blood) using light reflectance principle.
A CHOL/HDL ration and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the Cholesterol Analyzer.
Indications: It is intended to be used by medical professionals or non-professionals (or their families) with hyperlipidemia under the guidance of doctors. It can be used in hospital or for self-testing. Test results should not be used for diagnostic or therapeutic decisions. Consumers should communicate relevant questions or doubts to medical staff after obtaining test results.
Contraindications: Not found.

1.3 Principles of test

After the sample is added to the Lipid Profile Test Strip, the sample quickly and uniformly infiltrates the reaction layer. After the test substance reacts with the enzymes and chemicals, intensity of the color is proportional to the concentration of the tested substance. The Cholesterol Analyzer (photochemical method) measures the change in color intensity before and after reaction to calculate total cholesterol (CHOL), high-density lipoprotein cholesterol (HDL) and triglyceride (TRIG) concentrations, and calculates the CHOL/HDL ratio and the low-density lipoprotein cholesterol (LDL) value, simultaneously. When the unit is mmol/L, the calculation formula for low-density lipoprotein cholesterol (LDL) is LDL = CHOL-HDL-TRIG / 2.2. When the unit is mg/dL, the calculation formula for low-density lipoprotein cholesterol (LDL) is LDL = CHOL-HDL-TRIG / 5.
Low-density lipoprotein cholesterol (LDL) and CHOL/HDL ratios are non-measured values and are for reference only.

1.4 Safety instructions

- Read the instructions carefully before use.
- The Cholesterol Analyzer is to be used in conjunction with the Lipid Profile Test Strip (manufactured by Beijing Lepu Medical Technology Co., Ltd.).
- Keep the Cholesterol Analyzer and Lipid Profile Test Strip out of the reach of children.
- Disinfect blood collection devices and the blood partaking needle.
- Do not reuse Lipid Profile Test Strip or blood collection devices.
- The used Lipid Profile Test Strip and blood collection device should

be disposed properly.
● Do not use the Cholesterol Analyzer if it does not work properly or has been damaged.
● Do not use the Cholesterol Analyzer outdoors.
● This product is not applicable to the newborn.

1.5 Precautions, sample requirements, limitations, warnings, and the statement on electromagnetic compatibility

1.5.1 Precautions
● Observe routine safety operating rules of the laboratory. The used Lipid Profile Test Strip should be disposed as biological waste and placed in a special receptacle.
● Used batteries should be recycled according to local requirements.
● Before testing, check whether the code displayed on the Cholesterol Analyzer is consistent with that on the packaging of the CODE card.
● Precautions for using quality control card: a. Do not use expired quality control cards. The shelf life of the packed quality control card is three years. b. The quality control card must be stored in a sealed cartridge at 0-50°C away from direct sunlight. c. After removal, the quality control card should be used as soon as possible. After used, it should be placed back in the cartridge as soon as possible, with the cartridge lid tightly closed. d. Do not touch the surface of the test area during use. e. The quality control card can be tested before each test.
● It is used for in vitro diagnosis only. This test method cannot be used for the diagnosis and screening of diseases such as hyperlipidemia and atherosclerosis, nor other lipid tests related to lipid metabolism disorder, but only for testing of blood lipid levels of hyperlipidemic patients.
● Modification of medical device is prohibited.
● Maintenance personnel, not authorized by the Lepu, shall not disassemble the instrument and perform maintenance.

1.5.2 Requirements for samples
● Applicable sample type: whole blood (venous or capillary blood).
● If the sample contains anticoagulant, this product is only applicable to the whole blood containing heparin anticoagulant. Avoid using the plasma containing EDTA anticoagulant and samples containing other anticoagulants.
● Blood samples not containing anticoagulants should be tested as soon as possible after being collected. Blood samples containing anticoagulants should be tested within 8 hours after being collected. Capillary blood should be tested immediately.
● Mix the sample in its blood collection container thoroughly and evenly before it is tested.

1.5.3 Limitations of the test method
Like all experimental tests, any diagnosis or treatment decision cannot be based on a single test result or method.

1.5.4 Warning
Do not use this device near strong radiation sources (such as unshielded RF sources). Otherwise, they may interfere the normal operation of the device.

1.5.5 Statement on electromagnetic compatibility
● The device meets the emission and immunity requirements of IEC 61326-1:2012 and IEC 61326-2-6:2012 group Ⅰ class B.
● It is recommended to evaluate the electromagnetic environment before using the device.
● Do not use this device near strong radiation sources (such as unshielded RF sources). Otherwise, they may interfere the normal operation of the device.

1.6 Packaging composition

The items contained in the package are as follows:

No.	Name	Unit	Quantity
1	Cholesterol Analyzer	Set	1
2	Quality control card	Cartridge	1
3	Instruction for use	Copy	1
4	Quick operation manual	Copy	1
5	Certificate of Conformity	Piece	1
6	1.5V AAA Battery	Piece	4

2、Product Composition

2.1 Product structure

The Cholesterol Analyzer consists of a host (liquid crystal display (LCD), shell, optical test module, control main board), accompanying software, 1.5v AAA batteries and a quality control card.

2.2 Product diagram

Figure 1 Product exterior diagram

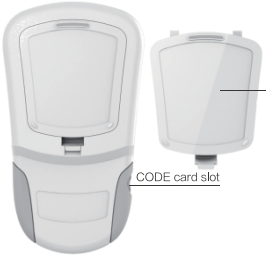

Figure 2 Product back diagram

Figure 3 Quality control card

3、Operation flowchart

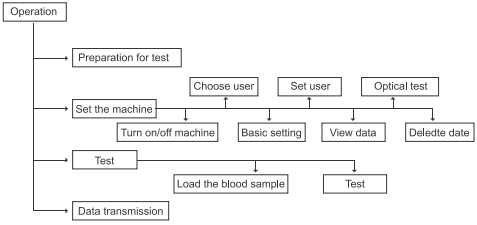

Figure 4 Operation flowchart

4、Preparations for the test

Before using the Cholesterol Analyzer, prepare the following items:

- Cholesterol Analyzer
- Quality control card
- Lipid Profile Test Strip
- Lancet
- Disposable trace blood collector
- Alcohol swab

5、Set the Instrument

5.1 Turn on/off the device

Place four AAA/1.5V batteries under the battery cover on the back of the device properly according to the markings "+" and "-". Press the " ⏻ " button and hold for 2s to turn on the device and enter the time setting interface. Set the year, month, day, hour, minute and second by referring to "5.3 Basic settings".

To perform a test immediately, insert the CODE card matching the Lipid Profile Test Strip into the CODE card slot of the Cholesterol Analyzer. If no CODE card is inserted, the screen will display a prompt "INSERT CODE card".

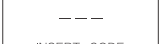

Figure 5 Insert a CODE card

If a CODE card has been inserted, the Cholesterol Analyzer will display the corresponding number of the CODE card, and enters the user selection interface after 1s. If the test is cancelled, press the “ ⏻ ” button and hold for 2s to turn off the device.

5.2 User selection

Before testing, a user's identity must be selected in the user selection interface.If there is no record of current user, select “+” to add user and enter the username setting interface.

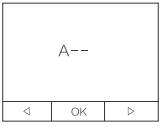

Figure 6 User selection

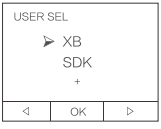

Figure 7 Username setting

In the username setting interface, use the left or right button to select an appropriate username consisting of 0–9 or A–Z. Be sure that username is not blank, otherwise, the system will display “Invalid username”. If the chosen username already exists, the system will display “Existing username” and the username needs to be changed. After clicking “OK”, the system will enter the test interface. Press the “ ⏻ ” button to enter the menu settings interface.

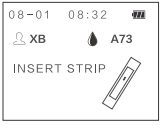

Figure 6 User selection

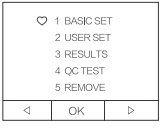

Figure 9 Menu settings

Note: The current battery level is displayed in the upper right corner of the test interface. If the battery level is low, the battery icon will blink constantly. When the battery level is seriously low, the instrument will prompt “E-4”.

5.3 Basic settings

In the basic settings interface, use the left or right button to select the unit, prompt tone and time, and then press the “ ⏻ ” button to confirm the settings. Select “BACK” and press the “ ⏻ ” button to return to the menu settings interface.

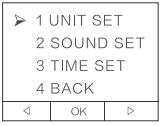

Figure 10 Basic settings

1、Unit settings

In the unit settings interface (Figure 11), press the left or right button to choose unit for results to be displayed. The available units are mmol/L and mg/dL. Press the " ⏻ " button to confirm selection, and then return to the basic settings interface.

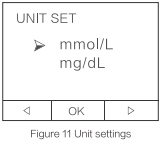

Figure 11 Unit settings

2、Sound setting

In the sound setting interface, press the left or right button to turn on or turn off a prompt tone. Press the "⏻" button to confirm, and

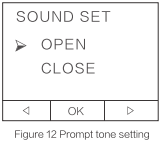

Figure 12 Prompt tone setting

3、Time setting

In the time setting interface, set year, month, day, hour, minute and second in sequence. The item to be set will blink. Press the left or right button to set the correct number, press the " ⏻ " button to confirm.

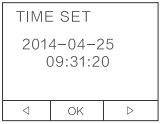

Figure 13 Time setting

5.4 User setting

Use the user setting interface to modify user selection settings. Select “BACK” and press the “ ⏻ ” button to return to the menu settings interface.

Figure 14 User setting

1、User edit

In the user edit interface, press the left or right button to select a user. After pressing “ ⏻ ” to confirm selection, you can choose to delete or modify the user. If the choice is to delete, user data will be deleted. If the choice is to modify, the user modification interface will start. See 5.2 for details of the setting method.

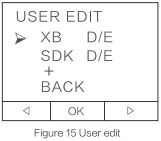

Figure 15 User edit

2、User selection

User selection can also be performed in the user setting directory. See 5.2 for the operation method.

5.5 Data viewing

In the data viewing interface, historical data is arranged in chronical order. Use the left or right button to select data to be viewed, and press the " ⏻ " button to confirm. In the data viewing interface, press the "⏻" button to return to the previous menu.

Figure 16 Data browsing

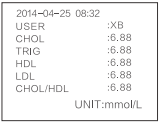

Figure 17 Data viewing

5.6 Optical check

A prompt "Insert QC" blinks in the lower right corner of the screen of the optical test interface, it indicates the need to perform an optical check on the device. Insert the corresponding quality control card, and the optical system check will start automatically. If "Pass" is displayed, the instrument is qualified. If "No pass" is displayed, the instrument is not qualified. After the quality control result is displayed, press the "⏻" button to return to the menu settings interface.

When entering the optical check interface, if no optical system check is required, press the "⏻" button to exit the optical check interface and return to the menu settings interface.

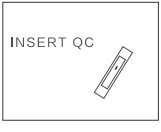

Figure 18 Instrument optical check

Note: If there is an unqualified result in the optical check, first check whether the quality control card is contaminated, bent or damaged. If any of the above are found, perform recheck with a new quality control card.

5.7 Data deletion

In the data deletion interface, press the left or right button to choose whether to delete data.If "YES", the system will perform data deletion. This operation will delete all data. At the same time, the interface will display a deletion progress bar. If "NO", system will return to the menu settings interface.

Figure 19 Data deletion

6、Test

6.1 Preparations

● If the product is used for the first time, place four AAA/1.5V batteries in the chamber, and close the battery cover. Pay attention to battery polarity during the installation.

● Insert the CODE card into the CODE card slot of the instrument. (A CODE card is provided with each box of test cards. Please be sure to use the CODE card matching the Lipid Profile Test Strip.

● Press the "⏻" button to turn on the device. After test interface appears, the code will be displayed at the top right of the display. Please check whether the code displayed on the LCD is consistent with that on the cartridge of Lipid Profile Test Strips (or single-person packing bag). If not, check whether the inserted CODE card and the Lipid Profile Test Strip are taken from the same box. If yes and the codes are still inconsistent, stop the test and unpack a new Lipid Profile Test Strip for testing.

● Perform an optical check on the instrument before the test, as described in 5.6.

● Take out a Lipid Profile Test Strip and insert the test card when the Lipid Profile Test Strip mark blinks on the screen. (Correct card insertion method: insert the test card into the instrument slot in the direction of the standard arrow on the test strip. The left and right indication arrows on the slot are aligned with the midline of the sample addition area. Push the test card gently forward until it can no longer be moved forward.)

Figure 20 Test card insertion

When the blood drop symbol blinks on the screen, the sample can be added.

Figure 21 Blood sample dripping prompt

Tip: if there is no operation within 3 minutes, the Cholesterol Analyzer will turn off automatically. Please complete the following steps for blood collection and blood addition as soon as possible. If the device turns off automatically, turn it on again and repeat the above operations.

6.2 Sample addition

6.2.1 Blood collection

A disposable lancet is used (need to buy separately).

Before blood collection, use alcohol or soapy water to disinfect the blood collection site. Blood can be collected only after site is dried or alcohol has evaporated. If necessary, wash your hands with hot water to increase blood circulation in your fingers. You can also promote blood circulation by squeezing from your wrist to your fingers.

Tip: Do not use an iodine-containing disinfectant when disinfecting the site.

Unscrew the tip of the lancet. Hold the end surface of the lancet firmly against the disinfected blood collection part. Press the start button to complete puncture accompanied by a sound of spring release. Discard the used lancet and slowly press forward from the root of the finger to obtain the blood sample to be tested. Discard the first drop of blood during blood collection.

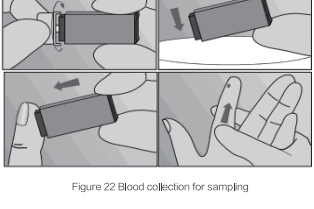

Figure 22 Blood collection for sampling

6.2.2 Sample addition

A. Sample addition at home

Quantitative blood collection with a disposable safe pipette (need to buy separately) or a quantitative capillary pipette can be used. If using capillary tube, place bulb before collecting sample.

Do not squeeze the bulb when collecting blood, and ensure that the opening of the bulb is not blocked. Gently hold the blood collection device to the surface of the drop. The angle between the blood collector and the blood sample should be about 15°. Stop blood collection when blood quantity reaches 35uL. When adding the sample to the test card, hold the pipette (glass capillary) vertically while gripping the bulb and press to add the sample at a uniform speed to the center of the sample addition area of the test card.

Figure 23 Sample addition

B. Sample addition in hospitals

Either the sample addition method described in A or a pipette can be used. After sample collection, mix the sample thoroughly and evenly. Choose a pipette with an appropriate measuring range. Draw a certain amount of the sample according to the requirements in Instructions for use of Lipid Profile Test Strip and drip it onto the center of the sample addition area of the test card. Be sure that the pipette tip does not touch the sample addition area.

Note:

1. Sample addition should be done only once.
2. Properly dispose the used blood collection device to avoid pollution.
3. Blood samples not containing anticoagulants should be tested as soon as possible after being collected. Blood samples containing anticoagulants should be used within 8 hours after being collected. Otherwise, unreliable results may be obtained.

6.3 Testing

1、After the sample is added, the device automatically starts testing. During this test, do not move the device or test strip and do not press the operation buttons on the panel.

Figure 24 Testing

2、Test values will be displayed within two minutes.

3、Press the left and right buttons to view the values of total cholesterol, high-density lipoprotein cholesterol, and triglyceride, the ratio of total cholesterol and high-density lipoprotein cholesterol, and the low-density lipoprotein cholesterol value calculated from these three measurements.

Figure 25 Test result browsing

4、After the test is completed, remove the test strip and press the “ ⏻ ” button to return to the test interface. Then the next test can now be performed.

Note: When the sample result exceeds the test range of the Cholesterol analysis system, the Cholesterol Analyzer will display “>” or “<”.

7、Main Technical Parameters and Performance Indicators

Parameters	Indicator
Test range	CHOL: 2.59–12.93mmol/L (100–500mg/dL) HDL: 0.39–2.59mmol/L (15–100mg/dL) TRIG: 0.51 –7.34mmol/L (45–650mg/dL)
Accuracy (relative deviation %)	CHOL：2.59–12.93mmol/L（100–500mg/dL）（≤15%） HDL：0.39–2.59mmol/L（15–100mg/dL）（≤15%） TRIG：0.51 –7.34mmol/L（45–650mg/dL）（≤15%）
Repeatability (CV%)	CHOL：5–7mmol/L（193–271mg/dL）（≤10%） HDL：0.8–1.5mmol/L（31–58mg/dL）（≤15%） TRIG：1.5–2.5mmol（133–221mg/dL）（≤10%）
Linear(r)	CHOL：2.59–12.93mmol/L（100–500mg/dL）（≥0.975） HDL：0.39–2.59mmol/L（15–100mg/dL）（≥0.975） TRIG：0.51 –7.34mmol/L（45–650mg/dL）（≥0.975）
Sample type	Whole blood (venous blood or capillary blood)
Sample addition quantity	35uL
Test time	≤120 s
Power supply	4 *1.5V AAA battery
Unit of measurement	mmol/L, mg/dL (mmol/L by default)
Storage	200 sets of data with the test date and time
Power-saving mode	The device will be turned off automatically if there is no operation within 3 minutes.
Device size	140mm × 82mm × 25mm
Weight	About 140g (excluding batteries)
Operating environment	10–30℃; humidity: ≤80%
Storage environment	0–50℃; humidity: ≤90%
USB port	For developer to debug

8、Prompts and Troubleshooting

The following table lists the problems that may be encountered during the use of the Cholesterol Analyzer and their solutions. If they cannot solve the problem, please contact the supplier or manufacturer.

Prompt	Meaning	Solution
E-1	The window surface under the test hole of the device is damaged.	Contact the supplier or manufacturer for repair
	The window surface under the test hole of the device is contaminated.	Clean the window surface with a clean soft cloth or swab
	A foreign object (such as a test strip, finger, etc.) is placed over the test hole	Remove the foreign object.
E-2	The test strip was removed while the device was performing an automatic test	Do not remove the test strip while the device is performing an automatic test
E-3	Too fast sample addition	Add the sample after the devcie shows the blood drop prompting sample addition
E-4	Low battery; a warning symbol appears on the screen	Replace the batteries
E-5	Insufficient sample addition	Be sure that the sample addition quantity is in accordance with the recommended quantity specified in the Instruction for use of Cholesterol Analyzer
E-6	Expiring test strip	1. Set the current date and time of the device correctly. 2. Use the test strip within its shelf life to perform test.
E-7	After the sample is added, the CODE card is pulled out while device was performing an automatic test.	Do not pull out the CODE card while the device is performing an automatic test
E-8	Wrong test card is used	Use a test strip corresponding to the code of the CODE card.
E-9	Abnormal test card	Replace the test card and perform retest
INSERT CODE	CODE card is not inserted	Insert the CODE card properly
HI.E	Test temperature too high	Recommended test temperature is not higher than 30°C
LI.E	Test temperature too low	Recommended test temperature is not lower than 10℃

9、Interpretation of Symbols

Symbol	Description
	Manufacturer
	Authorized representative in the European Community
	Date of manufacturer
	Use-by date
	Serial number
	Biological hazard
	In vitro diagnostic medical device
	Consult instructions for use
	Temperature limit
	Caution
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Direct(battery) current

10、Storage and Transportation Conditions

The Cholesterol Analyzer should be stored in a well-ventilated environment at a temperature of 0~50°C, with a relative humidity of no more than 90%, without corrosive gases.
Avoid moisture, crushing and severe jolting when transporting. Other considerations are the same as storage conditions.

11、Maintenance

1、The shell and LCD of the Cholesterol Analyzer can be wiped gently with a clean soft cloth or swab. If necessary, clean the device surface with a damp soft cloth and dry it with a clean soft cloth. It is strictly forbidden to use organic solvents such as gasoline, paint thinner, etc. to wipe the shell of the device.

2、 The holder of the test card can be removed for cleaning and then replaced after device is completely dried.

Figure 26 Removing the test card holder

3、The test window surface can be gently wiped with a clean soft cloth or swab. If necessary, gently wipe it with a damp soft cloth and wipe dry it with a clean soft cloth. Do not scratch the window surface.

Figure 27 Wiping the test window surface

12、Warranty

Lepu Medical Technology (Beijing) Co., Ltd. warranties for defects in materials and technologies within one year from the date of purchase. The only parts which the user can replace are the batteries and the back cover of the battery chamber. Tampering with other parts of the device, misuse of the device or not using the device in accordance with the instruction for use will invalidate the warranty.

Shelf life of the product: 3 years

Date of manufacturer: see the label.

13、Manufacturer and After-Sale Service

Manufacturer & After-sale service: Lepu Medical Technology (Beijing) Co., Ltd. (AKA "Lepu Medical")
Address: No. 37, Chaoqian Road, Changping District, Beijing, 102200, P.R.China
Tel.: 86 10-80120666
Fax: 86 10-80120600
Website: http://www.lepumedical.com

EC REP

Lepu Medical (Europe) Cooperatief U.A.
Address: Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Tel.: +31-515 573399
Fax: +31-515 760020

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