Cholesterol Meter

User Manual

HANGZHOU ALLTEST BIOTECH CO., LTD

Contents

Chapter 1 Introduction

1.1 Intended Use

The Cholesterol Meter is designed for the quantitative detection of the concentration of Total Cholesterol (CHOL), High-density Lipoprotein Cholesterol (HDL) and Triglyceride (TRIG) in human whole blood, serum and plasma based on the principle of light reflection with the use of the cholesterol test strips, as an aid to check the risk of heart disease and atherosclerosis (hardening, narrowing and blockage of blood vessels), and to predict the risk of cardiovascular disease.
For near-patient and laboratory professional *in vitro* diagnostic use only.
Please read this user manual carefully before operation.

1.2 Scope of Application

The Cholesterol Meter works with specific cholesterol test strips manufactured by **Hangzhou AllTest Biotech Co., Ltd.** for the quantitative detection of Total Cholesterol (CHOL), High-density Lipoprotein Cholesterol (HDL) and Triglyceride (TRIG) in human whole blood, serum and plasma. It's for near-patient and laboratory professional *in vitro* diagnostic use only. It can be used in emergency departments, clinical departments of medical or medical services (such as community health centers), etc.

1.3 Product Name and Model Type

Product Name: **Cholesterol Meter**
Model Type: **ACHR-100/100ST**

Chapter 2 Components and Specifications

2.1 Standard Equipment List

After unpacking, check whether components are missing or damaged according to the following packing list.

Packing List

No.	Description	Quantity	Remark
1	Cholesterol Meter	1	/
2	Control Strips	2	/
3	Lancing Device	1	/
4	AAA Batteries	4	/
5	Carrying Case	1	/
6	User Manual	1	/
7	Lancing Device Package Insert	1	/
8	Quick Reference Guide	1	/
9	Cholesterol Test Strips	8	Start Kit
10	Code Chip	1	Optional
11	Alcohol Pads	8	
12	Lancets	8	
13	Capillary Droppers	8	
14	Test Strip Package Insert	1	
15	Power Plug and USB Cable	1	Optional

Attention:

1) All accessories connected to the Meter through the USB port must meet the requirements of the IEC 60950.
2) Check the components according to above list. If any damage is found, please contact your local distributor.

2.2 Technical Specification

No.	Specification	Technical Parameters
1	Methodology	Reflectance Photometer
2	Test Time	≤ 120 s
3	Measurement Range	CHOL: 2.59-12.93 mmol/L(100-500 mg/dL) HDL: 0.39-2.59 mmol/L(15-100 mg/dL) TRIG: 0.51-7.34 mmol/L(45-650 mg/dL)

4	Specimen	Whole blood/Serum/Plasma
5	Specimen Volume	35 μL(3 in 1 test strip) 10 μL(Single test strip)
6	Power Source	4 AAA Batteries
7	Units of Measure	mg/dL or mmol/L
8	Units of Time	12 H or 24 H
9	Memory	999 results
10	Automatic Shut Off	5 minutes after the last action
11	Meter Dimension	135.3 mm*73.7 mm*27 mm
12	Display Size	50 mm*45 mm
13	Weight (without Batteries)	Approx. 122g
14	Meter connectors	USB Cable for Data Transfer or Power (optional)

2.3 Transportation and Storage Conditions

2.3.1 Transportation

- Temperature: -30 °C - 55 °C
- Relative humidity: ≤85%

Note: No toxic gases, flammable, explosive substances and corrosive gases are allowed. Attention should be paid to moisture proof, shock and severe vibration during transportation.

2.3.2 Storage

- Storage temperature: -10 °C - 50 °C
- Relative humidity: ≤85%
- Atmospheric pressure: 86 kPa-106 kPa, no corrosive gas.

2.4 Operating Conditions

- Power supply: 4 AAA batteries
- Environment temperature: 15-35 °C
- Relative humidity: ≤80%
- Atmospheric pressure: 86 kPa-106 kPa
- Do not perform under sunlight or extreme lighting conditions.

Chapter 3 Principle and Structure

3.1 Operating Principle

The Cholesterol Meter is designed to quantitatively detect the concentration of Total Cholesterol (CHOL), High-density Lipoprotein Cholesterol (HDL) and Triglyceride (TRIG) in human whole blood (venous blood and capillary blood), serum and plasma, and the CHOL/HDL and LDL values can also be calculated, which may help estimate patients with risk of Coronary Heart Disease.

When the specimen is added to the specimen application area of the cholesterol test strip, during the process of uniform and rapid infiltration, the blood cells are filtered out and the plasma spreads to the reaction layer, after the test reacts with enzymes and chemicals in the reaction layer, the reaction layer displays blue, which is proportional to the concentration of the analytes to be tested. If plasma and serum specimen are added to the test sample area, the sample directly spreads to the reaction layer to start the reaction, and without the process of filtering blood cells.

The Cholesterol Meter (Optical chemistry method) detects the colour strength of the reaction ending at 635 nm wavelength, and uses the reflex coefficient to calculate the concentration of Total Cholesterol (CHOL), High-density Lipoprotein Cholesterol (HDL), or Triglyceride (TRIG) in human whole blood, serum and plasma with the use of cholesterol test strip.

3.2 Meter Composition

1) Front View

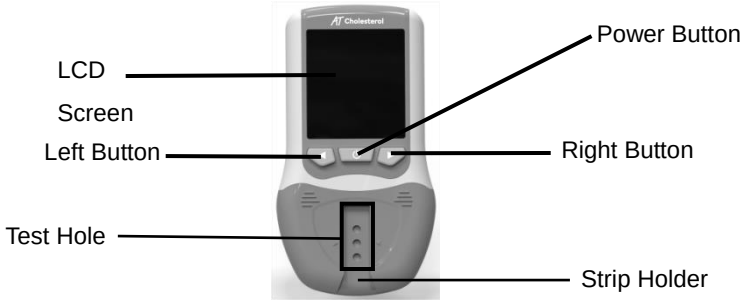


Fig 3.1

2) Rear View

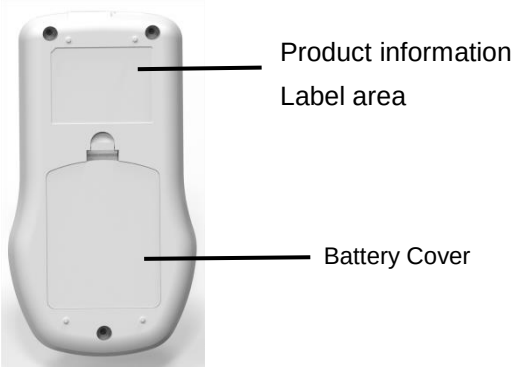


Fig 3.2

3) Top View

Fig 3.3

3.3 Packing Accessories

1) Lancing Device

Fig 3.4

2) Canister of Strips (Included in the start kit)

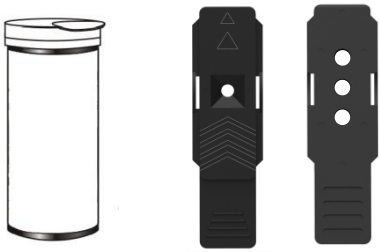


Fig 3.5

3) AAA Battery

Fig 3.6

4) Carrying Case

Fig 3.7

Chapter 4 Preparation before Use

4.1 Checklist upon Opening the Box

Before opening the box, check the packing is in good condition and box was not damaged during transportation.

Open the box carefully, and check the contents according to ***2.1 Standard Equipment List*** to ensure it is complete. If any missing or damaging is found, please contact the manufacture or your local agent.

Note:

Please keep the original box and packing materials for the future shipping/reference purpose.

4.2 Material Preparation

Prior to testing, read the user manual carefully and learn about all the components of the Cholesterol Meter. Depending on the package type you chose, some of the components may need to be purchased separately. The following items are needed to perform a test.

- **Meter**

Install the 4 AAA batteries into the meter correctly; replace the battery cover, place the meter on a level surface. Press right or left arrow buttons to change the year, date and time, press power button to confirm the changes. (Ref ***5.1 Initialization***) The meter will turn off after time setting.

Press power button to turn on the meter, check the displaying icons on the LCD screen as Fig 5.1.

Note:

This Meter is tested for immunity to electrostatic discharge and complies with the emission and immunity requirements described in IEC 61236-1 and IEC 61326-2-6. Use this meter in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results. Do not use this meter in close proximity to sources of strong electromagnetic radiation, as these may interface with proper operation of the meter.

- **Cholesterol Test Strip and Code Chip**

The Cholesterol Test Strip is composed of an upper baffle, a test strip and a bottom stent. Test method based on dry chemistry that works with the Cholesterol Meter to measure blood cholesterol concentration in whole blood, serum and plasma. Please refer to the package insert of the Cholesterol Test Strips for detailed information.

Each package of test strips is provided with a corresponding code chip, the curve of the test strips is stored in the code chip. The code number displayed on the meter screen shall be the same with that on the test strip outer package.

Note:

Only use the Cholesterol test strips manufactured by **Hangzhou AllTest Biotech Co., Ltd.** for proper function and accurate results. Remove the strips from the closed package, and use them as soon as possible. Do not touch the test area of the strip. Do not use after the expiration date.

- **Control Strip**

The Cholesterol Meter control strip is composed of an upper baffle, a standard mint green pad and a bottom stent which works with the Cholesterol Meter to ensure that the optical system is working properly.

Only use the Control Strips manufactured by **Hangzhou AllTest Biotech Co., Ltd.** for proper function and accurate results. Remove the control strip for immediate use. Put the control strip back immediately and close the canister tightly after use. Refer to Section ***5.5 Optical Check (Control Strip Testing)*** for details.

- **Lancing Device and Sterile Lancets**

The lancing device is used with sterile lancets to prick the finger for blood specimen collection. Please refer to the package insert of Lancing Device for detailed information.

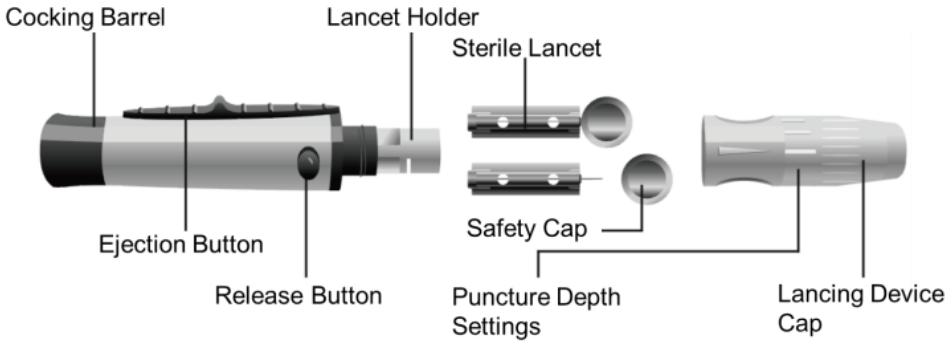


Fig 4.1 Lancing Device and Sterile Lancet

4.3 Environment Preparation

Prior to testing, bring the meter and cholesterol test strips to the environment according to ***2.4 Operating Conditions***.

4.4 Power Supply Preparation

- Power supply: 4 AAA batteries.
- In the use of dry batteries as power supply, please remove batteries if the meter remains unused for a few days or longer, to avoid damage caused by leakage of batteries to the meter.

Chapter 5 Instructions for Use

5.1 Initialization

- Open the battery compartment cover on the back of the meter.
- Install 4 AAA batteries according to the polarity mark in the battery compartment.
- Turn on the meter, all icons will be displayed for approx. 2 seconds (Ref Fig 5.1).

Fig 5.1

- Close the battery compartment cover.
- Place the meter on a level surface. Do not place the meter in such a way that it is difficult to operate the meter. Please use the meter under the proper conditions mentioned in ***2.4 Operating Conditions***.
- Press the right or left button to set the year, date and time, press power button to save.

Short press of the left button to decrease the value and the right button to increase the value. Long press the left or right button, the value will decrease or increase rapidly. Short press of the power button to save the changes and enter the next setting.

1) Press the right or left button to select the target year, short press of the power button to save the year setting and enter the month setting (Ref Fig 5.2).
2) Press the right or left button to select the target month, short press of the power button to save the month setting and enter the date setting (Ref Fig 5.3).

Fig 5.2

Fig 5.3

3) Press the right or left button to select the target date, short press of the power button to save the date setting and enter the hour setting (Ref Fig 5.4).
4) Press the right or left button to select the target hour, short press of the power button to save the hour setting and enter the minute setting (Ref Fig 5.5).

Fig 5.4

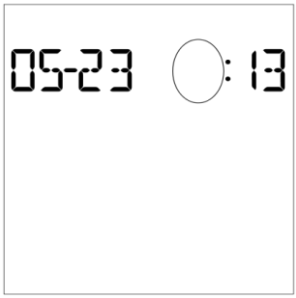


Fig 5.5

5) Press the right or left button to select the target minute, short press of the power button to save the minute setting and end the setting (Ref Fig 5.6).

Fig 5.6

After initial setting finished, the meter will turn off automatically.

5.2 Meter Switch on/off

- Turn on: After the battery is properly installed, press the power button to turn on

the Meter and enter the code chip interface. (Ref Fig 5.7).

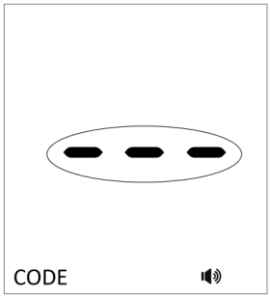


Fig 5.7

- Shutdown: Long press the power button for about 2 seconds to shut down the Meter.

5.3 Insert Code Chip

A new code chip is provided with each box of cholesterol test strips; insert the code chip into the meter code chip port when the corresponding strips are to be used.

- Take the code chip from the cholesterol test strips box. Insert the new code chip into the code chip slot of the meter. Compare the code number on the screen with the code number printed on the cholesterol test strips package. Results will be inaccurate if the two numbers are not identical.
- **The code chip should remain in the meter during testing**. The code number will appear on the initial Screen after start-up. (Ref Fig 5.8)

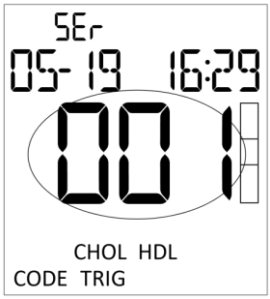


Fig 5.8

Note: If the code chip is not properly inserted into the code chip slot, or if it is missing, the meter will display three dashes “---” as Fig 5.7.

During the testing, the code chip should be kept in the Meter, and should not be pulled out halfway.

5.4 Settings

With the meter power off, press the power button about 2 seconds until "**SET**" appears on the LCD screen, release the button and the meter will enter the Setting mode. The test number setting screen is displayed. The relationship between setting models shown as Fig 5.9.

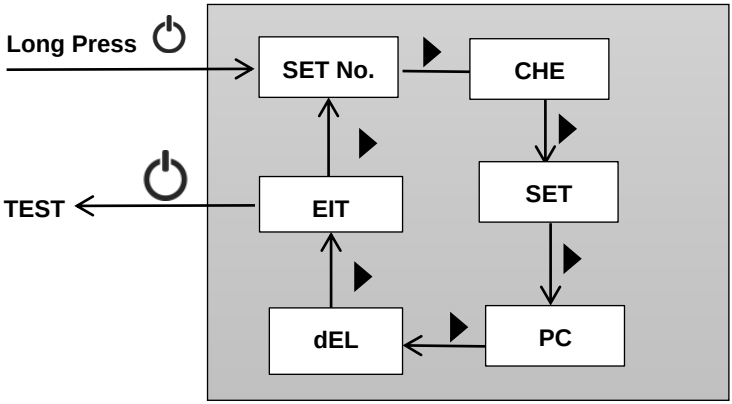


Fig 5.9

5.4.1 Test Number Set

The test number can be set according to this section (Ref Fig 5.10)

- In test number setting screen, press power button to enter test number setting.
- Press the right or left button to set the target test number, press and hold left or right arrow button to quickly cycle the target test number.
- Press power button to save the setting and turn to exit screen.

Note: Once the Meter reaches test number 999, the next test number will be 1.

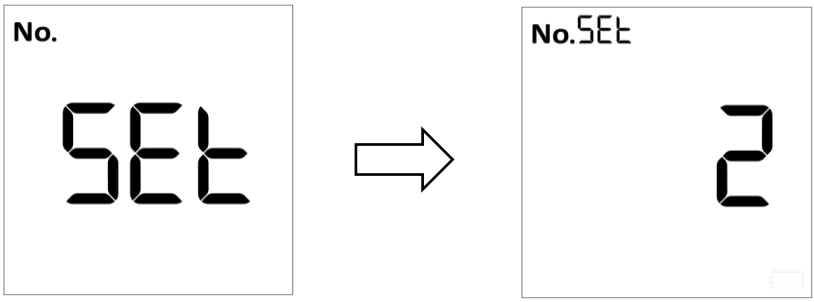


Fig 5.10

5.4.3 System Settings

Press the right or left button to enter the system setting mode as Fig 5.11, and press power button to enter this mode.

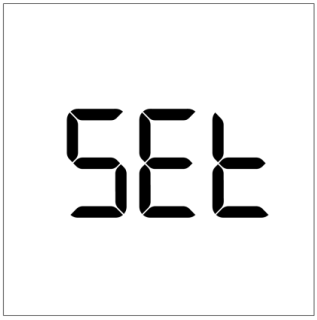


Fig 5.11

1) Time System

- Press the right or left button to select the Time System. The system can be set to "**12H**" or "**24H**" (Ref Fig 5.12).
- Press power button to save the time system and into Time Setting.

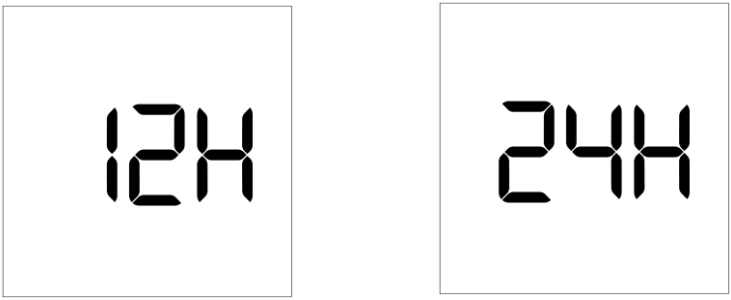


Fig 5.12

Note:

When set the time as 12-hour system, "**AM**" and "**PM**" will be displayed on the screen (Ref Fig 5.13).

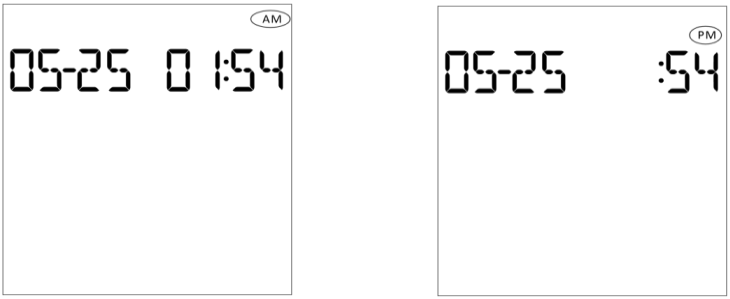


Fig 5.13

2) Time Setting

- After setting the time unit, user needs to reset the time, please refer to ***5.1 Initialization.***
- Press power button to save the time setting and enter into start test number set.

3) Set the start test number

- Press the right or left button to select "**On**" or "**OFF**" to set the start test number. (Ref Fig 5.14)

The start test number will reset to 1 for each day if "**On**" is; start test number will continue increase for each day if "**OFF**" is selected.

- Press power button to save the start test number and enter the Measurement unit.

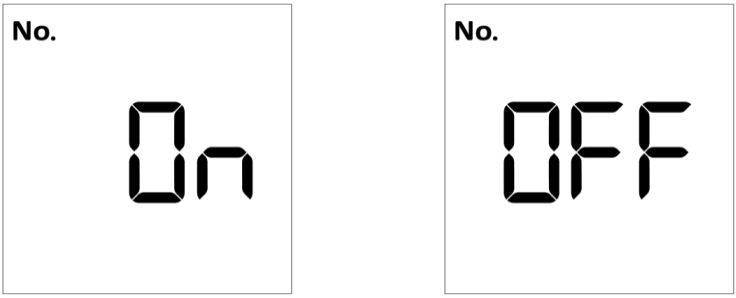


Fig 5.14

4) Measurement Unit

- Press the right or left button to select the Measurement Unit. The unit can be set to "**mg/dL**" or "**mmol/L**" (Ref Fig 5.15).

Fig 5.15

- Press power button to save the unit and enter the Sound setting.

Note:

Please check the test unit when view the test results.

5) Sound

- Press the right or left button to select "**On**" or "**OFF**" to set the sound. The sound will be turned on and sound symbol will appear on display if "**On**" is selected.(Ref Fig 5.16)

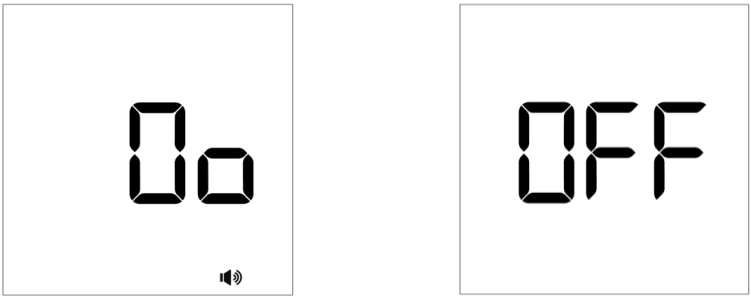


Fig 5.16

- Press power button to save the sound set and enter the Assessment of CHD.

Note：

If the prompt sound is turned on, the prompt sound will be issued when the meter is turned on, turned off and the test finished. With or without the sound turned off, the beep was sounded at the first and last query results, prompt the user that there is no next or previous record to view.

6) Assessment of CHD

- Press the right or left button to select "**On**" or "**OFF**" (Ref Fig 5.17).

Fig 5.17

- Press power button to save the Assessment of CHD set and exit the system settings (Ref Fig 5.18).

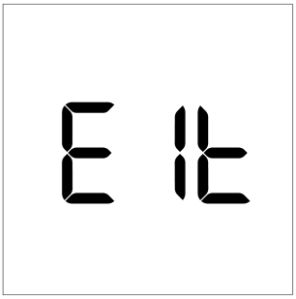


Fig 5.18

5.4.4 Report Transmit

- Press the right or left button to select the Report Transmit mode as Fig 5.19.
- Press power to enter the PC mode as Fig 5.20

Fig 5.19

Fig 5.20

- Connect meter to PC via USB cable (Optional).
- Press power button to start transmitting the test report.(Ref Fig 5.21)
- After the transmitting completed, the meter turns to exit.(Ref Fig 5.22)

Fig 5.21

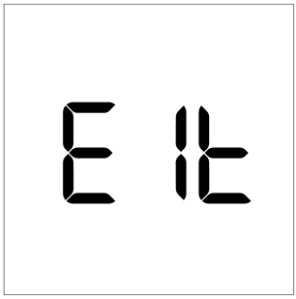


Fig 5.22

5.4.5 Delete Report

- Press the right or left button to select the Delete Report mode as Fig 5.23.

Fig 5.23

- Press power button to enter into this mode, and press the right or left button to select "**YES**" or "**NO**" (Ref Fig 5.24)

Press power button to select "**YES**" to delete all the reports in the meter and turn to exit screen. Press power button to select "**NO**" to give up, and turn to exit screen.

Fig 5.24

5.4.6 Exit Setting

- In the exit screen, press power button to enter into test mode screen.

5.5 Optical Check (Control Strip Testing)

5.5.1 Control Strip

The Cholesterol Meter control strip is composed of an upper baffle, a standard mint green pad and a bottom stent which works with the Cholesterol Meter to ensure that the optical system is working properly. It provides a standardized reflectance value as a reference for the optical system of the meter. After the control strip is inserted into the meter, the meter will compare the reflectance value to the pre-calibrated value stored in the meter software. The meter displays **YES** if the optical system is working properly or **NO** if the optical system is abnormal.

Storage and Stability

Store as a packaged in the closed canister at room temperature (2-30 °C). Keep out of direct sunlight, extreme temperature and humidity. Do not freeze or refrigerate. Remove the strip for immediate use and put it back into the canister after each use. Close the canister immediately.

Note: Once the canister has been opened, the remaining strips are stable for up to 2 years. Stability may be reduced in high humidity conditions.

Precautions

●The strip should remain in the closed canister until use. Do not use after the expiration date.

●Keep the control strip clean. Do not use a contaminated, discolored, bent or damaged control strip.

●Do not add any specimen to the sample hole or touch the sample hole.

●Do not disassemble or bend the control strip.

●Perform a Control Strip test in the following situations:

1) Every day of using the meter.

2) Anytime an unexpected test result is obtained.

3) After performing maintenance or service of the meter

5.5.2 Control Strip Testing

- Long press the power button to start the meter and enter the Setting mode.
- Press the right or left button to select the optical check mode as Fig 5.25
- Press power button to enter this mode and the cholesterol test strip mark on the

interface will flash. (Ref Fig 5.26)

Fig 5.25

Fig 5.26

- Insert the control strip provided with the meter into the strip holder in the same direction as the arrows indicated on the strip (Ref Fig 5.27).

Fig 5.27

- Press power button to start the optical check, if the meter displays "**Yes**", the meter is normal. If the meter displays "**No**", it means that the meter is not functioning properly. (Ref Fig 5.28)

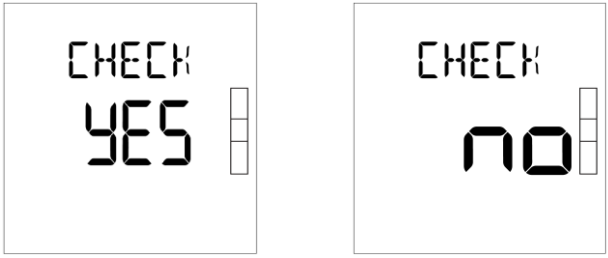


Fig 5.28

Note: If the meter displays "**No**", check the control strip for contamination or if it's

bent or damaged. If there are any visible signs of damage or contamination, discard the control strip and retest using a new control strip.

- Press the right or left button to turn to exit screen.

Note: The optical check should be performed under the normal lab lighting conditions. Do not perform under sunlight or extreme lighting conditions.

5.6 Testing

Before performing any test, the user should review the Cholesterol Meter's User Manual for detailed instructions. The following steps show how to use each component to measure the cholesterol concentration.

During operation, user will be exposed to a blood specimen. It is recommended to wear protective gloves to avoid direct contact with blood specimens especially in contact with infectious blood specimens.

5.6.1 Specimen Collection

The Cholesterol Meter requires a very small specimen which can be whole blood, serum or plasma. Whole blood can be obtained from the venous whole blood or fingertip whole blood, collect the whole blood as follows:

1. Use fresh capillary blood from the fingertip.
2. Use **heparinized or EDTA venous whole blood**, serum and **heparinized plasma** specimens.

Note: Before testing, choose a clean, dry work surface. Review the procedure and make sure all of the items needed to obtain a sufficient amount of blood are available.

- **Fingerstick Blood Collection**

The fingertip whole blood specimen can be obtained by using the lancing device provides with the meter and the lancet. Refer to the instructions for lancing device operation procedure.

Step 1: Unscrew the lancing device cover from the body of the lancing device. (Ref Fig 5.29)

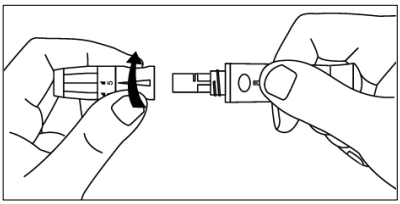


Fig 5.29

Step 2: Insert a sterile lancet into the lancet holder and push it until stop in the lancet holder (Ref Fig 5.30)

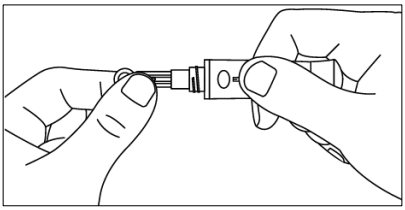


Fig 5.30

Step 3: Hold the lancet firmly in the lancet holder and twist the safety cap of the lancet, then pull the safety cap off. Save the safety tab for lancet disposal. (Ref Fig 5.31)

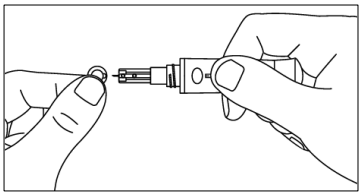


Fig 5.31

Step 4: Carefully screw the lancing device cover back to the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully seated on the lancing device. (Ref Fig 5.32)

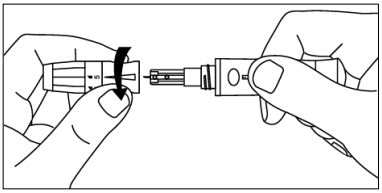


Fig 5.32

Step 5: Adjust the puncture depth by rotating the lancing device cover. There are a total of 6 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood. (Ref Fig 5.33)

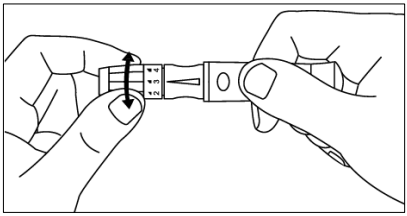


Fig 5.33

Step 6: Pull the cocking barrel back to set the lancing device. A click may be heard. The meter is now loaded and ready for obtaining a drop fingertip blood (Ref Fig 5.34).

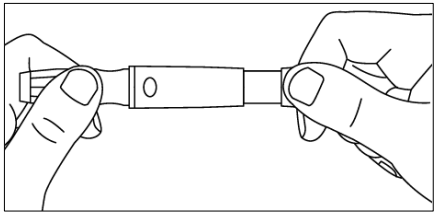


Fig 5.34

Step 7: Prior to collecting the capillary blood specimen, make sure the patient's hand is warm and relaxed. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow. Clean the puncture site with an alcohol swab and then dry the puncture site thoroughly.

Step 8: Hold the lancing device against the side of the finer to be pricked with the cover resting on the finger. Push the release button to prick the fingertip. A click should be heard as the lancing device actives. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. (Safety lancet can also be used to prick the finger) (Ref Fig 5.35).

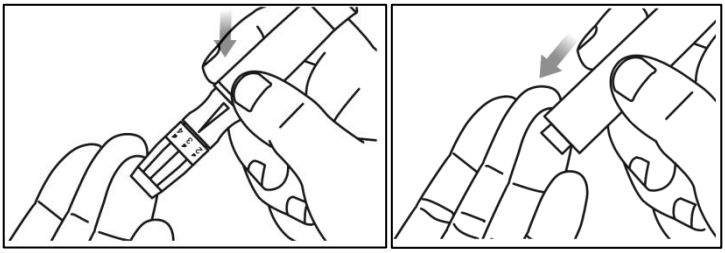


Fig 5.35

Step 9: Wipe away the first drop of blood. Apply light pressure to obtain the second drop of blood. Hold the dropper slightly downward and touch the tip of the capillary dropper to the blood drop. The dropper will automatically draw the

required specimen and then stop. (Ref Fig 5.36).

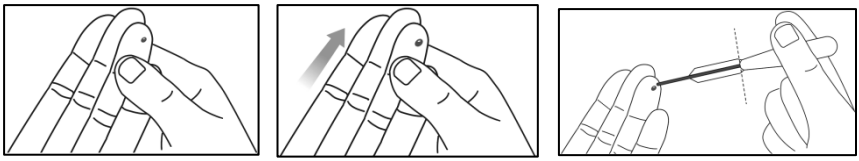


Fig 5.36

Note: Do not squeeze the bulb while sampling. Do not cover the air vents on the dropper bulb while sampling.

Step 10: Unscrew the lancing device cover. Place the safety cap of the lancet on a hard surface and carefully insert the lancet needle into the safety cap. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to eject the used lancet. Place the lancing device cover back on the lancing device (Ref Fig 5.37).

Note: Dispose of the used lancet according to local regulations.

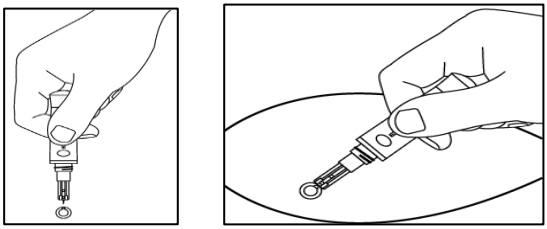


Fig 5.37

- **Venous Blood Collection**

For fresh venous whole blood specimens, collect the venous blood in a closed container with EDTA or heparin anticoagulants.

For heparinized or EDTA venous whole blood, serum and **heparinized plasma**, mix the specimen well, then collect specimen (35 µL for 3 in 1 test strip, 10 µL for single test strip,) into a capillary dropper or pipette. Apply it to the center region of the Specimen Application Area of the strip. Do not touch the test strip with the pipette or dropper.

- Specimen must be tested within 8 hours of collection.
- Mix the specimens well before testing in order to ensure the cellular components are evenly distributed.
- Allow the specimen to come to equilibrate to room temperature (15-30°C) if the specimen has been refrigerated.

• Anticoagulants other than EDTA and heparin are not recommended.

5.6.2 Test Processing

Ensure the meter is set up properly before the cholesterol test strip testing starts. Allow the materials to reach from temperature (15-30 °C) prior to testing.

- Press power button to turn on the meter.
- Insert the code chip provided with the strip. Make sure the code displayed on the LCD screen is the same with the number printed on the test strip package. The strip symbol will flash when the meter is ready for strip to be inserted.
- Press left button to enter the sample selection mode.
- Press the right or left button to select the sample, blood sample can be selected "**SEr**" (serum) or "**bLo**" (whole blood) or "**PLA**" (plasma) as Fig 5.38.

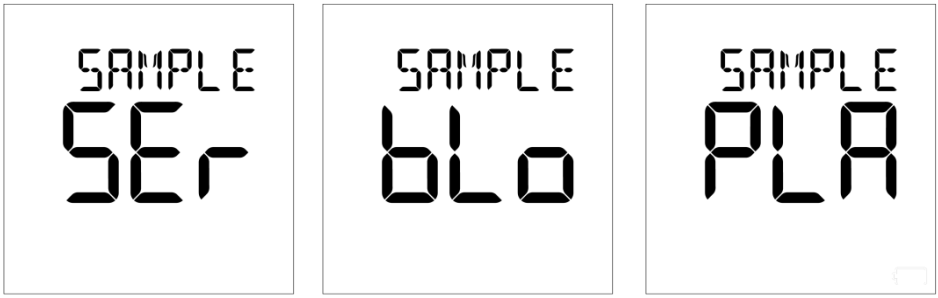


Fig 5.38

- Press power button to save the sample and enter the test interface.

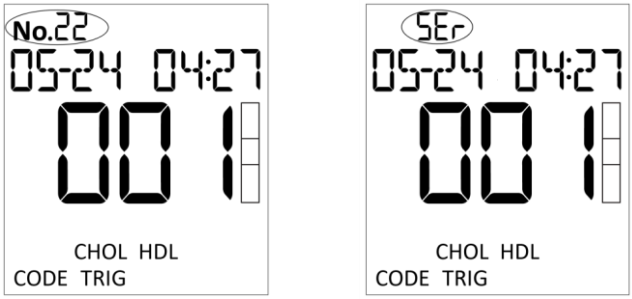


Fig 5.39

Note: In the test interface, the test "**No.**" and "**Sample type**" are alternately displayed in the upper left corner (Ref Fig 5.39).

- Insert a cholesterol test strip into the strip holder in the same direction as the arrows indicated on the strip. Ensure that the test strip is inserted to the end of the strip holder.

- The blood drop symbol will flash when the meter is ready for the specimen application area of the strip to apply the blood specimen (Ref Fig 5.40).

Fig 5.40

- Align the tip of the capillary dropper or pipette with the specimen application area of the strip to apply the blood specimen.

Note: Do not touch the strip with the capillary dropper or pipette. The capillary blood should be tested immediately after collected.

- The meter will begin testing automatically with three dashes in a line flashing on the LCD indicating the test is in progress. The test result will be displayed on the screen (Ref Fig 5.41).(Approx. 2 minutes)

Fig 5.41

- The results are displayed in order (Ref Fig 5.42):
  - CHOL: Cholesterol
  - HDL: High-density Lipoprotein
  - TRIG: Triglyceride

Fig 5.42

- CHOL/HDL: Rate of Cholesterol and high-density lipoprotein (Ref Fig 5.43)

Note：If CHOL and HDL are not in the measurement range, it will show "--", the meter cannot calculate the rate.

- LDL: Low-Density Lipoprotein

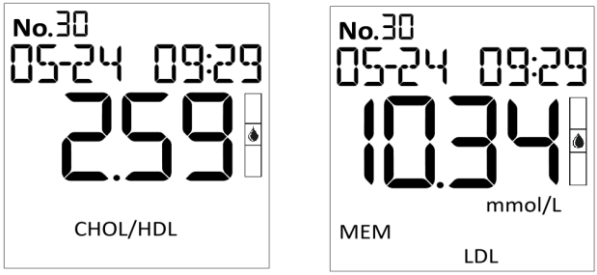


Fig 5.43

- Remove the used cholesterol test strip. The meter will return to the initial screen ready for another strip to be tested.

Note:

Discard all blood specimens, used cholesterol test strips and materials carefully. Treat all blood specimens as if they were infectious materials. Follow proper precautions and obey all local regulations when discarding blood specimens and materials.

The used cholesterol test strip may have biological risk or environment pollution problems, and should be received in the designated container.

5.7 Test Record Query

The meter can store 999 records of tests, which can automatically cover the earliest test data when it is full.

- In test mode screen, press right button to enter report query interface. Refer to

Fig 5.44, “36” indicates that the Meter has tested 36 records of tests.

- Press the right or left button to enter the data storage group selection. There are 4 kinds of test records.
- Press the right or left button to exit the test record query (Ref Fig 5.45).

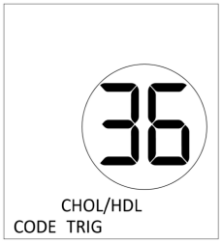


Fig 5.44

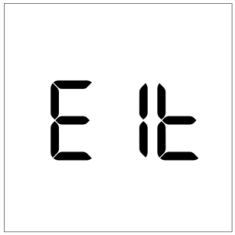


Fig 5.45

Note: If there is no record, the interface will show “0”.

1) Single measurement result query

- Press the right or left button to select the test report to query.

➢ Press power button to select the test results to view.

➢ CHOL value query interface (Ref Fig 5.46)

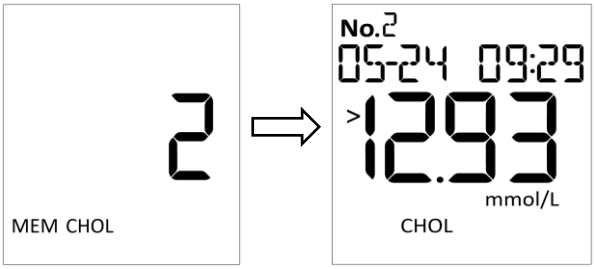


Fig 5.46

➢ HDL value query interface (Ref Fig 5.47)

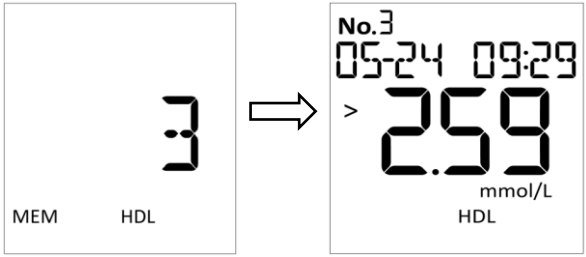


Fig 5.47

➢ TRIG value query interface (Ref Fig 5.48)

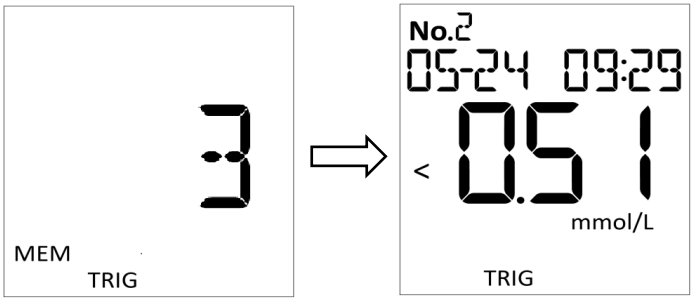


Fig 5.48

- Exit record inquiry: In any query interface, long press the power button to exit the query mode.

2) Cholesterol Query of measurement results

- Press power button to enter the report interface. (Ref Fig 5.49) The sample type, test time, test number and test result will be displayed on the interface.

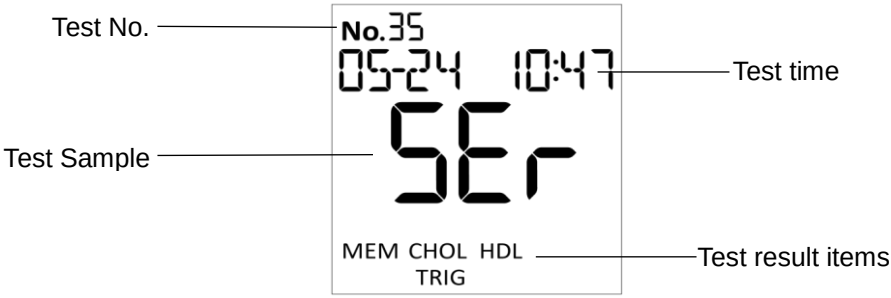


Fig 5.49

- Press power button to view the results, "**CHOL**" results displayed first, press the right button in sequence to query "**HDL**" "**TRIG**" "**CHO/HDL**" and "**LDL**" results (Ref Fig 5.42 and Fig 5.43).

3) Assessment of CHD

- In the LDL query results interface, press right button to enter the CHD assessment selection. There are two modes to choose: FRA or PRO. (Ref Fig 5.50)

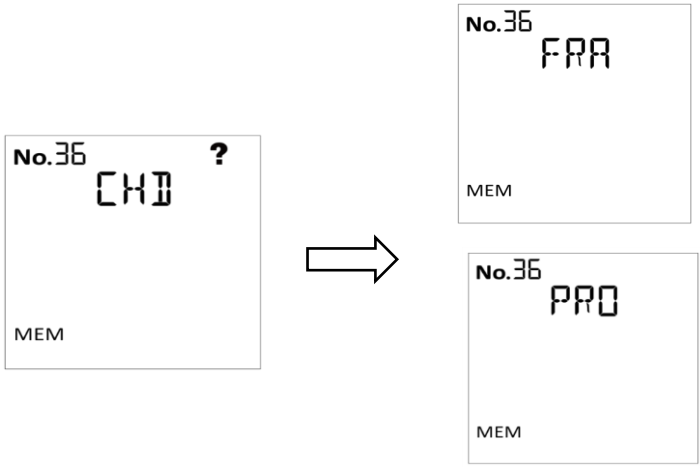


Fig 5.50

- FRA method: sex (Woman or Man), age, smoking status (✖or✔), systolic blood pressure and whether to treat hypertension (✖or✔) should be confirmed, after sequential selection, the assessment of CHD result is displayed (Ref Fig 5.51).

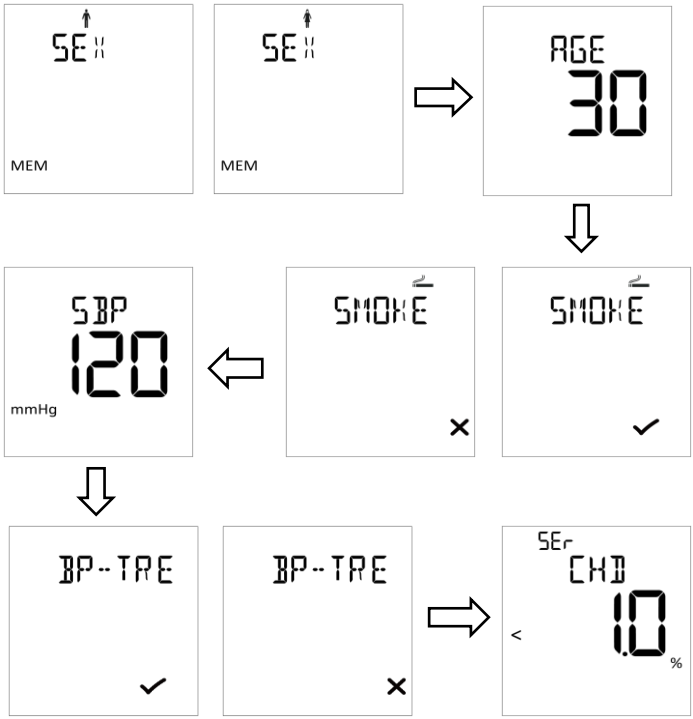


Fig 5.51

- PRO method: age, smoking status(✖or✔), history of diabetes(✖or✔), myocardial infarction(✖or✔), systolic blood pressure should be confirmed, after sequential selection, the assessment of CHD results are display.(Ref Fig 5.52)

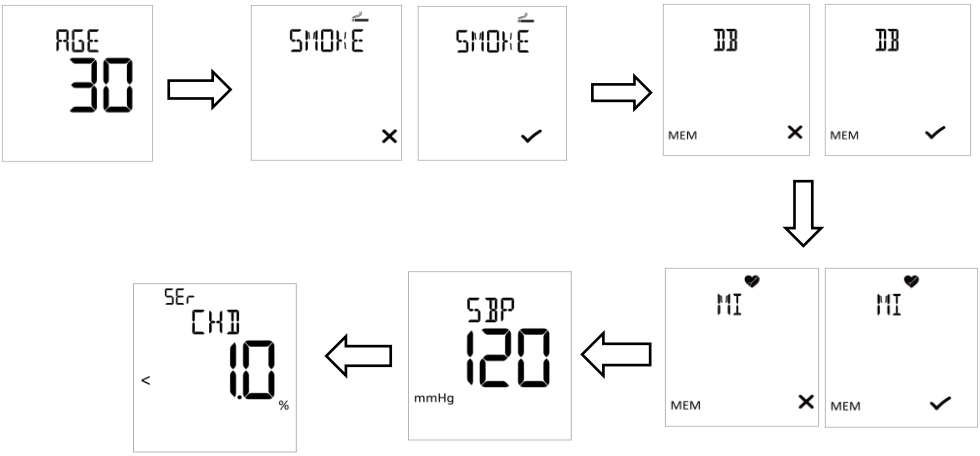


Fig 5.52

Note:

1) If the result of "**CHOL/HDL**" displayed "--", the PRO method cannot be used in the CHD risk assessment, and will show "---". Press the right or left button to select FRA method that not affected by the CHOL/HDL value.
2) CHD assessment results are for clinical reference only. Clinical diagnosis and treatment of patients should be comprehensively considered in conjunction with their symptoms/signs, medical history, other laboratory tests and treatment responses.

5.8 Power Saving Mode

The meter will be automatically turned off after 5 minutes of not working.

Chapter 6 Precautions and Maintenance

6.1 Precautions

Observe the precautions listed below to ensure accurate results and proper operation of the meter.

- To protection provided by the meter may be impaired if used in a manner not defined in this user guide.
- Make sure that the strips are within the expiry period, if not, inaccurate result may incur.
- During operation, you will likely be exposed to a blood specimen. It is recommended to wear protective gloves to avoid direct contact with blood specimens especially in contact with infectious blood specimens.
- When you touch components and parts labeled with biological symbols, please pay attention to protection, wearing protective gloves to avoid direct contact with the skin.
- Avoid storing or operating the meter in direct sunlight, excessive temperature, or high humidity.
- Keep the unit clean, especially the strip holder. Lightly wipe with a soft, clean, dry rag each day. Use water as needed.
- Discard all blood specimens, used cholesterol test strips and materials carefully. Treat all blood specimens as if they were infectious materials. Follow proper precautions and obey all local regulations when discarding blood specimens and materials.
- Operating the meter should be according to specifications of Lab Waste Disposal and meter maintenance.
- Do not get water of other liquids inside the meter. Keep the meter dry and avoid exposing it to extreme temperatures or humidity.
- Do not drop the meter or get it wet. If meter is dropped or has gotten wet, ensure the meter is working properly by running a calibration.
- Store control strips in the closed canister at room temperature with 2-30 °C (36-86 °F) and avoid exposing it to direct sunlight, extreme temperature of humidity. Control strips should be stored tightly capped in their protective canister to keep them in good working condition. Do not freeze or refrigerate. Keep the control strip clean and do not bend. Do not touch the test area of the strip.

- Any serious incident that has occurred in relation to device shall be reported to the manufacturer and the competent authority.
- The company will no longer be responsible for the safety, reliability and performance of the products in the following cases:

1) The Meter use date is not within the expiration date;
2) Without the authorization of the company, the Meter is disassembled, repaired;
3) The Meter is not used correctly in accordance with this User Manual.

- **Test sample requirement:**

1) Applicable specimen types including whole blood (venous and capillary blood), serum and plasma.
2) Blood specimens without anticoagulants should be tested as soon as possible after collection. Blood specimens containing anticoagulants should be used within 8 hours of collection.
3) Specimens in containers should be thoroughly mixed before testing.
4) Specimens can only be added at a time, not for multiple times.
5) The separated serum or plasma is added directly with a pipette gun.

- Test strips interference factors:

1) Ascorbate concentrations higher than 568 μmol/L(10 mg/dL), bilirubin concentrations higher than 240 μmol/L (10 mg/dL), and uric acid concentrations higher than 0.6 mmol/L (10 mg/dL) in the sample will result in low test results.
2) Skin care products containing glycerin can affect the test results.

6.2 Maintenance

A good operation specification needs to be established at the very beginning. A regular maintenance is necessary to extend the service lifetime and keep the output of the service correct.

For best results, the meter should be cleaned after each day of testing. A cotton cloth can be used to clean the surface of the meter. Gently push down the strip holder and use a damp cotton cloth if necessary (Ref Fig 6.1). A dry, soft cloth may be used to clean the LCD and the sensor area. After drying, loading the strip holder back.It is recommended that the meter be stored in the carrying case after each use. Take care to avoid getting liquids, residue or other things in the Meter Sensor Area with a cotton swab. Do not scratch the transparent window covering the sensor.

Fig 6.1

Note:

Do not use any type of solvent, oil, grease, silicone, spray, or lubrication on any part of the meter.

6.3 Replace the Batteries

- When the battery icon is flashing, the battery is running low and should be replaced as soon as possible. An “E6” error message will appear if the battery is too low to perform any tests. The meter will not run unless the battery is replaced.
- Make sure the meter is off before removing the batteries. Press the battery cover tab on the top and lift the cover to open it. Remove and discard the old batteries. Insert 4 new batteries in the battery compartment correctly.
- Close the battery cover and make sure that it snaps shut. Recheck and reset the time setting as necessary after battery replacement to ensure time is set correctly.

Note:

- When replacing the battery, 4 batteries should be replaced at the same time, and alkaline batteries required. Do not mix old and new batteries.
- When replacing the battery, please pay attention to the “+” and “-” poles of the battery.
- When replacing the battery, the time and history data will not be erased.
- In order to prolong the service life of the battery, the cholesterol test strip should be removed as soon as possible after the test result is displayed and the corresponding test should be withdrawn.
- Please do not use nickel-cadmium or rechargeable batteries.
- Waste batteries are easy to pollute the environment, do not discard at will; please follow the local regulations to deal with waste batteries.
- If User does not use this Meter for a long time, please remove the battery.

Chapter 7 Troubleshooting

The meter can work normally if all operations and maintenance are performed according to this user manual. When the meter encounters some abnormal situation, it will display an error message in order to alarm the operator. It is recommended to contact with the distributor or manufacturer for help. The following is a list of error messages.

Error Code	Error Message	Solutions
E1	When the Meter is turned on, it is found that the sensor area is dirty or blocked.	Ensure the sensor area is clean and that there are no objects covering the sensor area. Refer to ***Chapter 6 Precautions and Maintenance***. Restart the meter. Contact your local distributor if the sensor area window is broken.
E2	The CODE chip is expired.	Check the CODE chip information.
E3	Cholesterol test strip was removed during the test.	Retest, make sure the cholesterol test strip remains in right place before the test is complete.
E4	When the interface has not prompted the blood drop symbol, the specimen has been added.	Retest, ensure the drop blood marker is flashing before starting to add the sample.
E5	Insufficient specimen.	Please refer to the cholesterol test strips description for the specific specimen dosage.
E6	Batteries have discharged and meter will not allow more tests.	Replace the batteries. Please refer ***6.3 Replace the Batteries***.
E7	The ambient light tested by the Meter was above the normal range.	Please use this Meter within the scope of ***2.4 Operating Conditions*** requirements.
E8	The ambient temperature tested by the Meter was above or low the normal range.	Please use this Meter within the scope of ***2.4 Operating Conditions*** requirements.
E9	The wrong cholesterol test strip was used: The code for the three lipid tests, but the single cholesterol test strip was used. Use other brands of code and strips.	Replace the same cholesterol test strip as the code chip. The Meter can only use the code and cholesterol test strip produced by **Hangzhou AllTest Biotech Co., Ltd.**
- - -	No code chip in the meter. Code chip is damaged or inserted incorrectly.	Insert the code chip that accompanied the box of cholesterol test strips. If the code chip is damaged, use a new code chip with the correct code number. If the code chip is inserted incorrectly, remove the code chip and insert it into the code chip port.

Chapter 8 Service, Repair and Disposal

The Cholesterol Meter does not require special maintenance expect for keeping it clean. If service is required, please contact with the local distributor.

The Cholesterol Meter's internal parts, including the circuit boards, optical detection modules and display, can only be provided by manufacturer. Such items should not be sourced from any third-party, even if they claim to provide the same function. When issues related to the Meter, contact the local distributor. We provide technical support for users to perform troubleshooting. If the meter needs to be sent back to manufacturer, please contact local distributor and/ or **Hangzhou AllTest Biotech Co., Ltd.**, it normally takes about a week to fix problems. If it turns out not repairable within warranty period, we will replace it with a new one. If for any reasons the meter needs to be disposed of, please follow local regulations.

We provide technical support and software maintenance, including functional maintenance, corrective maintenance etc. We are only responsible and provide services when the Meter is properly used in compliance with the manufacturer's User Mannual, otherwise any damages incurred will not be covered.

This product is required to comply with the European Unions' Waste Electrical & Electronic Equipment (WEEE) Directive. If you wish to discard electrical and equipment (EEE), please contact your dealer or supplier for further information.

Chapter 9 Manufacturer Information

Name: Hangzhou AllTest Biotech Co., Ltd.

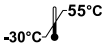
Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P. R. China.

Tel: +86-571-56267891

Wed: www.alltests.com.cn

Email: info@alltests.com.cn

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		*In vitro* diagnostic medical device
	Temperature limit		Catalogue number		Authorized representative in the European Community/ European Union
	Manufacturer		CE Mark		Keep dry
	Fragile, handle with care		Keep away from sunlight		Protect from heat and radioactive sources
	Caution		Biological risks		Unique device identifier
	Serial Number		Date of manufacture		Use-by date
	Dispose items according to local relevant laws regarding disposal and recycle				

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number H145023401

Revision date: 2024-01-29

STATEMENT: Information about manufacturer of lancet, alcohol pad and lancing device is placed on the packaging.

Appendix

A. Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within one year of purchase.
For your records, write the purchase date of your starter kit here:

_____

Note: This warranty applies only to the Meter in the original purchase.
It does not apply to the other materials include with the Meter.
Hangzhou AllTest Biotech Co., Ltd. warrants to the original purchaser that this Meter will be free from defects in materials and workmanship for a period of 2 years (24 months). The 2 years starts from the later of the date of original purchase or installation (except as noted below). During the stated one year period, **AllTest** shall replace the unit under warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. **AllTest** shall not be responsible for shipping charges incurred in the repair of such Meter.

This Warranty is subject to the following exceptions and limitations:
This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. **AllTest** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the Meter in accordance with the operations manual, or maintenance by anyone other than **AllTest**.
Furthermore, **AllTest** assumes no liability from malfunction or damage to Meter caused by the use of Meters other than Meters manufactured by **AllTest**. **AllTest** reserves the right to make changes in the design of this Meter without obligation to incorporate such changes into previously manufactured Meter.

Disclaimer of Warranties
This warranty is expressly made in lieu of any and all other warranties expressed or implied (either in fact or by operation of law) including the warranties of merchant ability and fitness for use, which are expressly excluded, and is the only warranty given by **AllTest**.

Limitations of liability
In no event shall AllTest be liable for indirect, special or consequential damages, even if AllTest has been advised of the possibility of such damages.
For warranty service, please contact your local distributor.

B. Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within one year of purchase.

Purchaser	
Model	
Serial Number	
Date of Purchase	
Address	
Telephone Number	
E-Mail Address	

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn