Hemoglobin Analysis Meter

BHM-101

User Manual

Hemoglobin Analysis Meter

Identification
Meter: BHM-101
Test strips:BHS-101

Important Safety Instructions

- Misuse of electrical meter can cause electrocution, burns, fire and other hazards.
- Do not place the meter in liquid, nor put it where it could fall into liquid. If the equipment becomes wet, unplug it before touching it.
- Use the meter only for the purpose described in the instructions for use.
- Failure to use the meter in the manner specified by the manufacturer may damage the protection provided by the equipment.
- Do not use accessories which are not supplied or recommended by the manufacturer.
- Please use the meter in a manner specified by the manufacturer, or protection may be impaired. Do not use the meter if it is not working properly or if it has suffered any damage.
- Do not let the meter come into contact with surfaces which are too hot to touch.
- Do not use the meter where aerosol sprays are being used or where oxygen is being administered.
- Do not use the meter out of doors.
- Control solution only purchased from local distributor or manufacturer
- Keep these instructions.

Table of Contents

Section 1 Introduction

Hemoglobin Analysis System is intended for the quantitative determination of Hemoglobin (Hb) and calculated Hematocrit (HCT) in capillary blood and venous whole blood as an aid in the diagnosis of anemia. It is not applicable to newborns. It is indicated for professional testing in clinical settings. It is intended for in vitro diagnostics use only.

To ensure accurate results:

- Read instructions carefully and complete any necessary training before use.
- Use the code chip that is included in each box of Test strips.
- Only use the Hemoglobin Test strips with the Hemoglobin Meter.
- For in vitro diagnostic use only. Your blood hemoglobin analysis system is only to be used outside the body for testing purposes.
- For professional use.
- Test only whole blood specimens. EDTA or heparin anticoagulants can be used.
- Keep out of reach of children.

Principle of measurement

The analyzer applies the principle of photochemistry and is used with Hemoglobin test strip(BHS-101). The whole blood sample to be tested is added into the sample area of the strip. In the process of rapid infiltration, blood cells are filtered out or

dissolved. The substrate react with enzymes and chemicals in the reaction layer and lead to the color change, then the color intensity is proportional to the concentration of the substance.

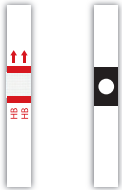
Section 2 Getting Started

Please check the following requirements when you first receive our products: unpack and make sure there is no lack of components or damage in the package. If you have any question, please contact the manufacturer.

Before testing, read the instructions carefully and learn about all the components of your hemoglobin analysis system. Depending on the product you purchased separately, please check the list of contents on the outer box for details of components.

Hemoglobin Analysis Meter

Front Back



Test Strip (Optional)
Optical Verify Strip has the same appearance.

Control Solution (optional)

Code Chip (Optional)

Capillary Transfer Tube (Optional)

Sterile Lancets (Optional)

USB Cable

Lancing Device (Optional)

Carrying Case

Component Descriptions

01. **Hemoglobin Meter:** Reads the test strips and displays the concentrations of Hemoglobin (HB) and calculated Hematocrit (HCT) values.
02. **Test strips(optional):** Part of the system, these are inserted into the meter to measure the concentrations of Hemoglobin (HB) and calculated Hematocrit (HCT) values.
03. **Optical Verify Strip:** Verifies the proper operation of the meter by checking that the meter can detect a pre-calibrated value.
04. **Code Chip(optional):** Automatically calibrates the meter with the code number when inserted into the meter.
05. **Capillary Transfer Tube (optional):** Collects 10μL of capillary blood from fingertip blood testing for accurate results.
06. **Sterile Lancets(optional):** Used with the lancing device to draw blood specimens for test. Sterile lancets are inserted into the lancing device for each blood draw and discarded after use.
07. **USB Cable:**Charge the meter.
08. **Lancing Device(optional):** Used with sterile lancets to prick the fingertip for blood specimen collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort. It can also eject the used lancets.
09. **Carrying Case:** Provides portability for testing.
10. **Instructions for use:** Provides detailed instructions on using the Hemoglobin Analysis Meter.
11. **Test strips Package Insert(optional):** Provides detailed instructions on using the Hemoglobin Test strips.
12. **Lancing Device Insert(optional):** Provides detailed instructions on how to use the lancing device.

13. **Control Solution(optional):** Verifies the proper operation of testing and validates the test strip and meter are working together properly.

⚠ Caution: Test strip, sterile lancets and Capillary Transfer Tube are disposable materials. Please use them before the expiration date. The table of quantity of components is as follow.

NO.	Component	Quantity
1	Meter	1
2	Canister of Test strips	Optional
3	Optical Verify Strips	2
4	Code Chip	Optional
5	Lancing Device	Optional
6	Sterile Lancets	Optional
7	Capillary Transfer Tube	Optional
8	USB cable	1
9	Carrying Case	1
10	Instructions for use	1
11	Test strips Package Insert	Optional
12	Lancing Device Package Insert	Optional
13	Control Solution	Optional

Section 3 Components

The Hemoglobin Meter reads the Test strips and displays the concentrations of Hemoglobin (HB) and calculated Hematocrit (HCT) value. Use this diagram to become familiar with all the parts of the meter.

Meter

1	USB Port	**2**	Liquid Crystal Display (LCD)
3	Right Arrow ► Button	**4**	On/Off ⏻ Button
5	Strip Channel	**6**	Test Strip Holder
7	Code Chip Slot	**8**	Left Arrow ◄ Button

Meter Use and Precautions

- Do not get water or other liquids on or inside the meter.
- Keep the Strip Channel clean.
- Keep the meter dry and avoid exposing it to extreme temperatures and humidity.
- Do not drop the meter or get it wet. If the meter is dropped or has gotten wet, ensure the meter is working

properly by running an Optical Check. Refer to Optical Verify Strip Test for details. Do not take the meter apart. Taking the meter apart will void the warranty.

- Refer to Maintenance for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter.

All Hemoglobin Analysis Meters Preventive Warnings with Regard to EMC

01. This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.
02. This instrument complies with the emission and immunity requirements described in EN 61326-1 and EN 61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the meter.
03. This instrument emission compliance is Class A. It is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
04. This instrument is designed for use in a professional healthcare facility environment. It is likely to perform incorrectly if used in home healthcare environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by

increasing the distance between the equipment and the source of the interference.

05. For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

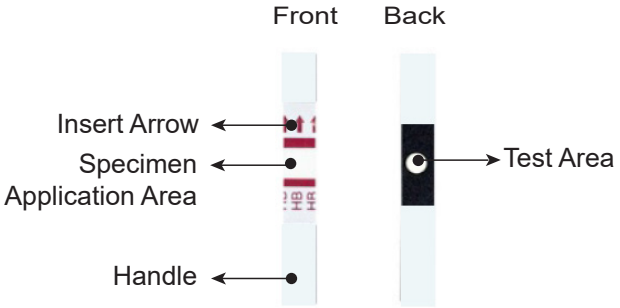
EMC requirements:

Phenomenon	Base Standard	Test Value
Conducted disturbances	CISPR 11 Class A Caution	CISPR 11 CLASS A Caution
Electromagnetic radiation disturbance	CISPR 11 Class A Caution	CISPR 11 CLASS A Caution
Electromagnetic discharge	±4 kV contact ±2kV, ±4kV, ±8kV air	±4 kV contact ±2kV, ±4kV, ±8kV air
Electromagnetic feld	3 V/m(80 MHz to 6 GHz)	3 V/m(80 MHz to 6 GHz)
Burst	± 1 kV(5 kHz or 100 kHz)	± 1 kV(5 kHz or 100 kHz)
Surge	± 0,5 kV line-to-line	± 0,5 kV line-to-line
Conducted RF	3 V(150 kHz to 80MHz)	3 V(150 kHz to 80MHz)
Power frequency magnetic feld	3 A/m(50Hz, 60Hz)	3 A/m(50Hz, 60Hz)
Voltage dips	0 % during 0,5 cycles 0 % during 1 cycle 70 % during 25/30 cycles	0 % during 0,5 cycles 0 % during 1 cycle 70 % during 25/30 cycles
Short interruptions	0 % during 250/300 cycles	0 % during 250/300 cycles

Test strips

The Hemoglobin Test strips are plastic devices that work with the Hemoglobin (Hb) Meter to measure the Hemoglobin (Hb) concentration in capillary and venous whole blood.

Test strip appears as shown below:



Insert Arrow: Located on the front of the test strip, the arrows indicate the direction in which the test strip should be inserted into the meter.
Specimen Application Area: After the strip is inserted into the Strip Channel, apply the correct specimen volume to the region in the center of the test strip.
Handle: Located on the end of the test strip, the handle is used to insert and remove the test strip from the meter.
Test Area: Located on the back of the test strip. The meter will detect and read this area to give results of HB levels.

Specimen Application

For best results, fill the Specimen Application Area with the correct specimen volume (10µL). Incorrect results may occur if the specimen is not applied correctly or if the Specimen Application Area is not filled with the correct amount.

After applying the specimen, ensure that the Specimen Application Area is completely covered. The Specimen Application Area should remain covered throughout the entire test. If the Specimen Application Area is not covered or if there is too much specimen covering the Specimen Application Area,

repeat the test with a new test strip.

Note: If the specimen applied to the Specimen Application Area is not enough, do not add more specimens to the Test strip. Instead, retest with a new strip.

Code Number

Printed on each package of test strips is a code number, lot number, unopened expiration date, and test quantity. Whenever a new package is opened, mark the date on the label. Calculate the expiration date for an opened vial by adding three months. Record this date on the label.

Test strip Precautions and Instructions for Use

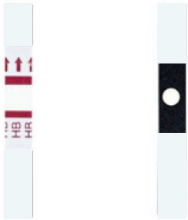
- Test strips should be stored in their tightly capped protective canister to keep them in working condition.
- Do not store test strips outside of their package. Test strips must be stored in the original package and sealed tightly.
- Do not transfer test strips to a new package or any other container.
- Replace the cap on the test strip canister immediately after removing a test strip.
- A new canister of test strips may be used for 3 months after first being opened. The opened expiration date is 3 months after the date the canister was first opened. Write the opened expiration date on the canister label after opening. Discard the canister 3 months after it is first opened. Usage after this period may result in inaccurate readings.
- For in vitro diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in

anyway.
- Do not reuse test strips.
- Before performing a test, make sure that the code number on the meter display matches the number shown on the test strip canister pouch and on the ink-jet printing on the code chip.
- Refer to the test strip package insert for more details.

Optical verify strip

The Hemoglobin optical verify strips work with Hemoglobin Meter to ensure the optical part is working properly. After the optical verify strip is inserted into the meter, the meter's optical part detects the color intensity of the optical verify strip. The meter displays ***yES*** or ***no*** to indicate whether the meter is functioning properly.

The optical verify strip appears as shown below:



Precautions

- Store in the closed canister at room temperature or in the refrigerator within 2-30°C. Avoid exposure to direct sunlight, extreme temperatures, and humidity.
- Optical verify strip should be stored in their tightly capped canister to keep them in working condition.
- Keep the optical verify strip clean. Do not touch the test

area of the strip.

- Take the optical verify strip out of the canister. Put the optical verify strip back and close the canister tightly immediately after use. Do not use contaminated, discolored, or damaged optical verify strip.
- Do not use it after the expiration date.
- For in vitro diagnostic use only.

Storage and Handling

- Store optical verify strips in a cool, dry place. Store away from heat and direct sunlight.
- Transport and store in its closed canister within 2-30°C with less than 90% humidity.
- Replace the cap on the strip canister immediately after removing a strip. Expired strip may produce incorrect test results.

Section 4 Initial Setup

Before testing, ensure the following procedures are followed.

Turn on Meter

Press ⏻ to turn the meter on.
The meter will automatically turn off after 5 minutes of inactivity.

Coding the Meter

Each time a new canister of test strips is used, the new code chip included in the box must be inserted into the meter. Compare the code number on the code chip from the box with the code number printed on the test strip canister. Results may be inaccurate if the two numbers are not identical. Insert the new code chip into the code chip slot of the meter. It should easily snap into place. The code chip should remain in the meter. Do not take it out until a new box of test strips is needed. The code number will appear on the Initial Screen after startup. If the code chip is not properly inserted into the code chip slot or if it is missing, the meter will display ***no CODE***.

Section 5 Meter Setup and Options

With the meter turned off, press ⏻ and hold for 2 seconds to enter the Main Menu mode. Press ◄ or ► to display several setup sub-modes.

No. SEt

Press ⏻ to enter the ***No.SEt*** item.The test number can be set to any number from 0-999, please press ◄ or ► to switch. Press ⏻ to save.

SEt

Press ⏻ to enter the ***SEt*** item.Please press ◄ or ► to switch between ***12*** or ***24*** hour mode. Press ⏻ to save.

Year Setup

As the year is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Month Setup

As the month is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Day Setup

As the day is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Hour Setup

As the hour is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Minute Setup

As the minute is displayed, please press ◄ or ► to switch. Press ⏻ to save.

Test Number Reset Setup

Press ◄ or ► to turn the test number reset ***On*** or ***OFF.*** The test number will reset to 1 for each new day of testing when the test number reset is turned on. Press ⏻ to save.

Sound Setup

As the sound 🔊 is displayed, press ◄ or ► to switch between ***On*** and ***OFF***. Press ⏻ to save.

PC

Press ⏻ to enter the ***PC*** item and ***MEM*** icon is displayed. Press ⏻ and the memory is transferred to the computer until the ***MEM*** icon disappears.

dEL

Press ⏻ to enter the ***dEL*** item and ***MEM*** icon is displayed. Press ⏻ and all memories are deleted until the ***MEM*** icon disappears.

Press ◄ or ► until ***Elt*** is dispalyed and press ⏻ to exit setup. The screen will briefly go blank and display the Initial Screen.

Note: The units are fixed as ***g/dL*** , ***mmol/L*** or ***g/L***.

Section 6 Testing

Before performing any test, the user should review Hb Hemoglobin Analysis Meter's instructions for use. The following steps show how to use each component to measure the Hemoglobin concentration.

Specimen Collection

01. Use fresh capillary blood from the fingertip.
02. Use fresh, heparinized or EDTA anticoagulated venous whole blood. Please refer to Professional Testing below.

⚠ **Caution: Before testing, choose a clean, dry work surface. Review the procedure and make sure all of the items needed to obtain a drop of blood are available.**

Testing with heparinized or EDTA venous whole blood

For heparinized or EDTA venous whole blood, mix the specimen well, then collect specimen (10 µL) into a Capillary Transfer Tube. Apply it to the center region of the Specimen Application Area of the strip. Do not touch the test strips with the Capillary Transfer Tube.

- Specimen must be tested within 8 hours after collection.
- Mix the specimens well before testing in order to ensure the cellular components are evenly distributed.
- Allow the specimen to come to operating temperature (10-40°C) for approximately 15 minutes if the specimen has been refrigerated.
- Anticoagulants other than EDTA and heparin are not recommended.

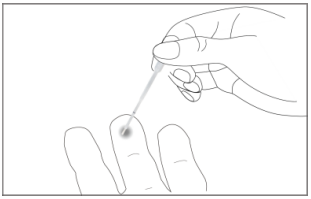
Note: Refer to CLSI Documents GP41, Diagnostic Venous Blood Sample Collection.

Testing with fingertip blood

Wipe away the first drop of blood. Apply light pressure to obtain a second drop of blood. Use a Capillary Transfer Tube to collect 10 µL capillary blood.

Note: Refer to CLSI Documents GP42 , Procedures And Devices For The Collection Of Diagnostic Capillary Blood Specimens.

For use with the Capillary Transfer Tube, hold the tube slightly downward and touch the tip of the Capillary Transfer Tube to the blood specimen. Capillary action will automatically draw the specimen to the fill line and stop.



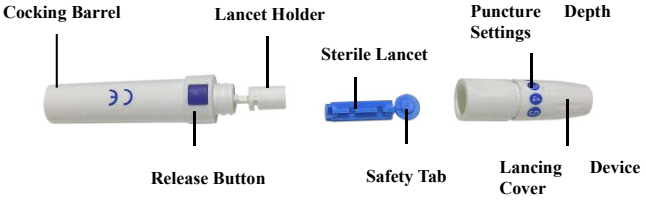
Note: The Capillary Transfer Tube will fill automatically. Make sure the blood covers the air vent of the tube, or it will be difficult to squeeze the blood out. Never squeeze the Capillary Transfer Tube while sampling.

Align the tip of the Capillary Transfer Tube with the center hole of the Specimen Application Area of the test strips to apply the second drop of blood (10µL).

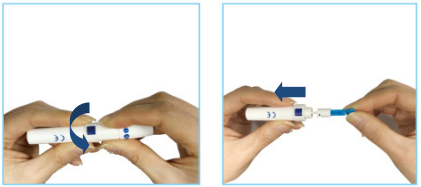
Note: Do not touch the test strip with the Capillary Transfer Tube. The capillary blood should be tested immediately after collected. Use of a Capillary Transfer Tube is recommended for accurate results. Do not reuse the Capillary Transfer Tube.

Lancing Device

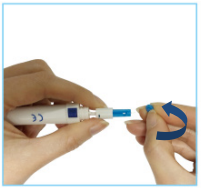
For obtaining a drop of blood from the fingertip, adjust the penetration depth on the lancing device to reduce discomfort.



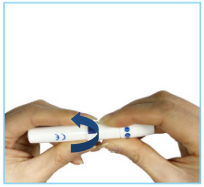
Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.



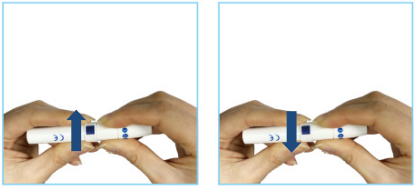
Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens. Then pull the safety tab off of the lancet. Save the safety tab for lancet disposal.



Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully seated on the lancing device.

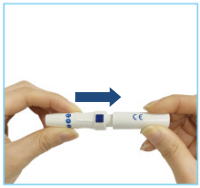


Adjust the puncture depth by rotating the lancing device cover. There are a total of 5 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.
Use settings 1 and 2 for delicate skin, 3 and 4 for normal skin, or 5 for calloused or thick skin.



Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

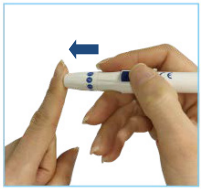
Pull the cocking barrel back to set the lancing device. A click may be heard. The device is now loaded and ready to obtain a drop of blood.

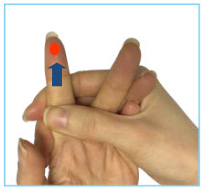


Prior to testing, make sure the patient's hand is warm and relaxed before collecting the capillary blood specimen. Use warm water to increase blood flow if necessary.Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

Clean the testing site with an alcohol swab or by washing the hands with warm soapy water and then dry the testing site thoroughly.

Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick the fingertip. A click should be heard as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood. For the greatest reduction in pain, lance the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make the fingers sore and callused.





Note: Make sure the hand is warm and relaxed before collecting a capillary blood specimen. Use warm water to increase blood flow if necessary. Don't use an infection swab containing iodine. This can give inaccurate results.

Disposal of the Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface. Carefully insert the lancet needle into the safety tab.

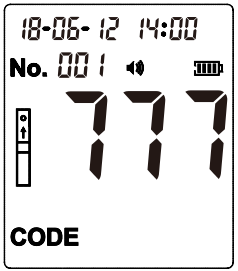
Pull the used lancet off. Place the lancing device cover back on the lancing device.

Note: For professional use, please refer to CLSI Documents GP42 , Procedures And Devices For The Collection Of Diagnostic Capillary Blood Specimens.

Test Processing

Ensure the meter is set up properly, as described in previous

sections. Turn the meter on. Ensure the code chip is inserted. Compare the number showed in the display with the code number printed on the canister label. The test strip icon flashes to indicate that it is ready for the strip to be inserted.

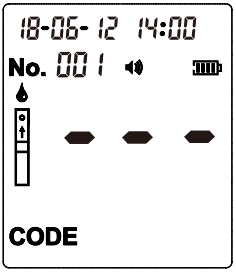


Testing

For use with a test strip, insert a strip into the Strip Channel in the same direction as the arrows indicate on the strip. Ensure that the test strip is inserted all the way to the end of the Strip Channel.

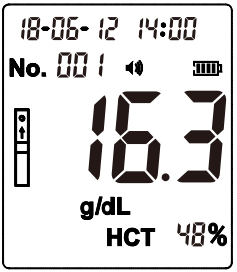
Note: For testing capillary blood, use the second drop of blood for accurate results.

The ***blood drop symbol*** will flash when the meter is ready for the specimen to be applied. Apply the blood specimen (10 µL) to the center region of the Specimen Application Area of the test strip.



The meter will begin testing automatically with ***three dashes*** in a line flashing on the display indicating the test is in progress.

Hb results will be displayed within 5 seconds, with HCT value displayed on the screen.



Note: The date in the display will be shown according to the mode you previously selected.

Remove the used test strip. The meter will return to the Initial Screen and is ready for another test strip to be inserted and to perform a new test.

Note: Discard all blood specimens, used Test strips,

and materials carefully. Treat all blood specimens as if they were infectious material. Follow proper precautions and obey all local regulations when discarding blood specimens and materials.

Perform daily cleaning when testing is completed for the day. Refer to the Maintenance section.

The meter will automatically turn off after 5 minutes of inactivity or when ⏻ is pressed.

Section 7 Memory/Communication

Memory/Database

Press ◄ to enter the ***MEM*** mode. Press ◄ or ► to display the latest 1000 test records.

If no data is stored the meter will display ***no*** and ***MEM***.

Communication

Press ⏻ to enter ***PC***. When pressing ⏻, the meter will send all records via USB.

Section 8 Optical Verify Strip Test

After entering the ***CHE*** Mode, press ⏻ and then the test strip icon flashes. Follow the direction of the arrows indicated on the strip. Ensure that the optical verify strip is inserted all the way.

01. Press ⏻ . If the meter displays ***yES***, the meter is normal. If the meter displays ***no***, the meter is not functioning properly.

Note:

- The optical verify strip is intended to check the optical system.
- Allow the optical verify strips and the meter to reach operating temperature (10-40°C) prior to testing.
- The optical check should be performed under normal lab lighting conditions. Do not perform under sunlight or extreme lighting conditions.

If the meter displays ***no***, check the optical verify strip for contamination or to check if it is damaged. If there are any visible signs of damage or contamination, discard the optical verify strip and retest using new optical verify strip.

Remove the optical verify strip. The meter will return to the Initial Screen.

Section 9 Maintenance

Proper maintenance is recommended for best results.

General Cleaning

For best results, the meter should be cleaned after each day of testing.

Meter Surface

A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary.
A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use.
Avoid getting liquids or residue entering the meter through the Strip Channel or Code Chip Slot.

Test strip Holder

Remove the Test strip Holder by pressing in on the middle of the Test strip Holder and sliding it out from the meter. Wipe it down with a damp cloth or a mild detergent. Dry it with a dry, soft cloth. Slide the Test strip Holder back into the meter by laying it flat on the meter. Firmly press down on the two sides of the Test strip Holder with your thumb and push it in until it clicks into place.

Note: Do not use organic solvents, such as gasoline or paint thinner. This will cause damage to the meter.

Meter Sensor Area

Remove the Test strip Holder as described in the previous section. Wipe down the Meter Sensor Area with a cotton swab. Do not scratch the transparent window covering the sensors.

Note: Do not use bleach or alcohol to clean the Meter Sensor Area. This will cause damage to the meter.

Cleaning Process

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. Use a damp cotton cloth if necessary.

A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use.

Take care to avoid getting liquids, residue, or control solutions in the meter through the Test Strip Holder, Code Chip Slot or USB Port.

After cleaning, visually inspect the surface of the meter, the test strip holder and the sensor area for visible contaminants such as liquids or residues, if still present re-cleaning is required.

Charging step

The meter is powered by lithium battery and can be charged by USB port. Connecting the Micro USB port to the meter, connecting the other end to the PC's USB port or adapter (output:5V ⎓ 0.5A), can charge the meter. The meter can not be tested when it is charging. Equipment with overcharge and over discharge protection device.

⚠ **Caution:The adapter or computer should meet the requirements of current edition of the IEC60950-1. Lithium batteries meet the standard requirements of the IEC 62133-2.**

Battery Maintenance

Lithium batteries are built-in and cannot be disassembled.

- Meters should be stored in a cool, dry and safe environment.
- Avoid approaching the meter to heat source, open fire, flammable and explosive gas and liquid, otherwise it will

lead to battery leakage, heating, smoking, ignition and explosion.

- If not used for a long time (more than a month), it is recommended to charge 40% - 60% of the battery.

Section 10 Precautions

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

- The protection provided by the meter may be impaired if used in a manner not defined in this instruction manual.
- Wear gloves to avoid contact with potentially hazardous biological specimens during testing.
- Avoid storing or operating the meter in direct sunlight, excessive temperatures, or high humidity. Refer to Appendix 1 Meter Specifications for operating condition requirements.
- Keep the meter clean. Wipe it frequently with a soft, clean, and dry cloth. Use a damp cloth when needed.
- Do not clean the meter with substances, such as gasoline, paint thinner or other organic solvents to avoid any damage to the meter.
- Do not clean the LCD or sensor area with water. Lightly wipe with a soft, clean, dry cloth.
- The test strip holder must be kept clean. Lightly wipe with a soft, clean, dry cloth before use. Use a damp cloth as needed. Refer to the Maintenance section.
- Follow all local regulations when discarding the meter or its accessories.
- Do not use the meter or the strip outside of the operating temperature ranges: 10-40°C; ≤ 90% RH.

Section 11 Troubleshooting

Display	Causes	Solution
E-1	The sensor area is damaged, dirty, or blocked at turn-on, such as a used test strip left in the meter.	Ensure the sensor area is clean and that there are no objects covering the sensor area. Refer to Maintenance. Restart the meter. Contact your local distributor if the sensor area window is broken.
E-2	Test strip was removed during the test.	Repeat the test and ensure the test strip remains in place.
E-3	Adding samples too early.	Add samples after the blood drop symbol flashes.
E-4	Battery power is low. The meter can not be tested until it is charged.	Charging post-test.
E-6	Code chip is removed during testing or test strip is expired.	Insert proper code chip. Confirm the code chip matches the test strip code and repeat the test. Insert the correct test strip.
E-7	The environment temperature is higher than 40°C or lower than 10°C.	Get the meter in a proper environment where the temperature is between 10-40°C.
no code	The CODE is not inserted.	Inserted the CODE.
HI	The result is higher than the limited.	Retest with a new strip and contact your doctor.
Lo	The result is lower than the limited.	

Section 12 Limitation

The following substances do not interfere with test results:

Substance	Amount	Substance	Amount
Acetaminophen	200mg/L	Cholesterol	13 mmol/L(5g/L)
Ascorbic Acid	60mg/L	Tetracycline	15mg/L
Creatinine	442 μmol/L (5mg/dL)	Urea	42.9 mmol/L (2.574g/L)
Ibuprofen	500mg/L	Uric Acid	1.4 mmol/L (235mg/L)
Dopamine	0.9mg/L	Methyldopa	15mg/L

High concentrations of triglycerides and salicylic acid can lead to low Hb measurements. High concentration of billrubin can lead to high Hb measurement. Anticoagulants,such as heparin and EDTA, are recommended for use with venous whole blood. Do not use anticoagulants such as iodoacetate, sodium citrate or those containing fluoride.Do not use plasma or serum with the Hemoglobin Analysis System.

Section 13 Meter Performance

The Accuracy

Item	Range of sample	Bias
HB	4.5g/dL-10.0g/dL	≤±1g/dL
	10.1g/dL-25.6g/dL	≤±10%

The Precision

Item	Range of sample	SD/CV
HB	4.5g/dL-10.0g/dL	SD≤0.8g/dL
	10.1g/dL-25.6g/dL	CV≤8%

Appendix 1 Meter Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Test Time	5 seconds
Measurement Range	4.5g/dL-25.6 g/dL 45g/L-256 g/L 2.8mmol/L-15.9 mmol/L
Specimen	Whole blood(capillary blood and venous whole blood)
Specimen Volume	10 µL
Power Source	Charging battery; Note: during charging, the meter is not operatable
Units of Measurement	g/dL, g/L, mmol/L
Memory	1000 records
Automatic Shut Off	After 5 minutes of inactivity
Meter Size	135 mm × 66mm × 19 mm
Weight	90g
Meter storage and transportation conditions	0°C - 55°C; ≤ 90% RH
System Operating Conditions	10°C - 40°C; ≤ 90% RH; indoor only
pollution degree of the intended environment	2
System operating altitude	Max. 2000 m
Test strip storage and transportation conditions	2°C - 30°C; ≤ 90% RH
Control strip storage and transportation conditions	2°C - 30°C; ≤ 90% RH
Meter Software Version Number	1.0

Appendix 2 Labelling And Information


Do not re-use


Use-by date


Keep dry


Manufacturer


Biological risks

LOT Batch code


Humidity limitation

REF Catalogue number


Temperature limit

SN Serial number


Date of manufacture

CE CE marking

EC REP Authorised representative in the European Community / European Union


Contains sufficient for <n> tests


Consult instructions for use

IVD In vitro diagnostic medical device


Caution, the user must be consulted in all cases where this symbol is marked


Symbol for the marking of electrical and electronics devices according to Directive 2012/19/EU.The device accessories and the packaging have to be disposed of waste correctly at the end of the usage. Pleases follow Local Ordinances of Regulations for disposal

Appendix 3 Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within 30 days of purchase.

Note: This warranty applies only to the meter in the original purchase. It does not apply to the other materials included with the meter.

Hangzhou Lysun Biotechnology Co., Ltd. warrants to the original purchaser that this meter will be free from defects in materials and workmanship for a period of two years (24 months) since the latest date of original purchase or installation, except as noted below. Within the prescribed two years, Lysun Biotechnology Co., Ltd. shall replace the meter under warranty with a reconditioned meter, at its option, repair at no charge if a meter that is found to be defective. Lysun Biotechnology Co., Ltd. shall not be responsible for shipping charges incurred in the repair of a 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. Lysun Biotechnology Co., Ltd. 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 user's manual, or maintenance by anyone other than Lysun Biotechnology Co., Ltd. Furthermore, Lysun Biotechnology Co., Ltd. assumes no liability from malfunction or damage to meters caused by the use of devices other than devices manufactured by Lysun Biotechnology

Co., Ltd. Lysun Biotechnology Co., Ltd. reserves the right to make changes in the design of this meter without obligation to incorporate such changes into previously manufactured meters.

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 merchantability and fitness for use, which are expressly excluded, and is the only warranty given by Lysun Biotechnology Co., Ltd.

Limitations of Liability

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

Hangzhou Lysun Biotechnology Co., Ltd.
6th Floor, 6th Building, No.95 Binwen Road,
Xixing Street, Binjiang District, Hangzhou,
Zhejiang, P.R. China

Tel: 0086-571-86716518

Printed in China. Effective date: 2024-07

Warranty Card

If the product you buy is abnormal, please call our service hotline +86-571-86716518 for consultation from 8:30-17:30 on working days.
Send warranty card back to our company with the product in order to get the warranty service provided by our company.

Product Name			Purchase Date		
Product SN Number			Purchase Address		
Product problem Description					
Name		Tel		Email	
Address					

Recipient: Hangzhou Lysun Biotechnology Co., Ltd.
After-sales service group
Address:6th Floor, 6th Building, No.95 Binwen Road, Xixing Street,Binjiang District, Hangzhou,Zhejiang,P.R. China
Postcode: 310051 Tel: +86-571-86716518
Email:info@lysunbio.com

Note: The above warranty only includes the product host itself, excluding other accessories in the package bag, such as lancing device, battery, etc.