



HB-101 Hb Hemoglobin Testing System

Owner's Booklet



Reliable Hemoglobin Testing System

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**Thank you for choosing Sejoy HB-101 Hemoglobin Testing System.
Before you start testing, carefully read this Owner's Booklet.**

Intended Use

The Sejoy HB-101 hemoglobin Meters are used with the Sejoy HS-101 Test Strips to quantitative measuring hemoglobin content with fresh capillary wholeblood from the finger or venous blood. The hemoglobin Meters can be used for self-testing at home or for professional use. The product is for in vitro diagnostic use only. It can not be used as the only basis for the diagnosis of anemia.

Test Principle

The system consists of a portable meter that analyzes the intensity and color of light reflected from the reagent area of a test strip, ensuring quick and accurate results.

The Sejoy® Hb Hemoglobin Testing System provides results in less than 10 seconds and requires only a single drop of whole blood. The meter can store up to 1000 results. The meter can be operated by 3 AAA (1.5V) batteries.

To ensure accurate results:

- Read instructions and complete any necessary training before use.

Use the code chip that accompanies each box of test strips.

Use only Sejoy® Hb Hemoglobin Test Strips with the Sejoy® Hb Hemoglobin Meter.

For in vitro diagnostic use only.

Test only whole blood specimens. EDTA or heparin sodium anticoagulants can be used.

Keep out of reach of children.

Important Safety information

Warning

- Venous whole samples collection and preparation should be obtained by healthcare professionals.
- During normal testing, any Hb Hemoglobin Meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfecting.
- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from blood borne pathogens.
- Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, blood borne pathogens.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- Disinfect the meter and lancing device before allowing anyone else to handle them. Do not allow anyone else to test with the meter or lancing device.
- It is important to keep the meter and lancing device clean and disinfected. Clean and disinfect the lancing device once per week to remove visible dirt or other material for safe handling and/or prior to disinfecting.
For instructions on how to clean and disinfect the meter and lancing device, see Chapter Caring for your Meter.
- Wash hands thoroughly before and after handling the meter, lancing device, or test strips.
- Choking hazard. Small parts. Keep away from children.
- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use this meter close to sources of strong electromagnetic radiation.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.
- The matching USB data cable is our company's dedicated data line for hemoglobin analyzer online. Please do not use the USB data cable not provided by our company to connect with the computer, So as to avoid damaging the hemoglobin meter.

Important Health-Related information

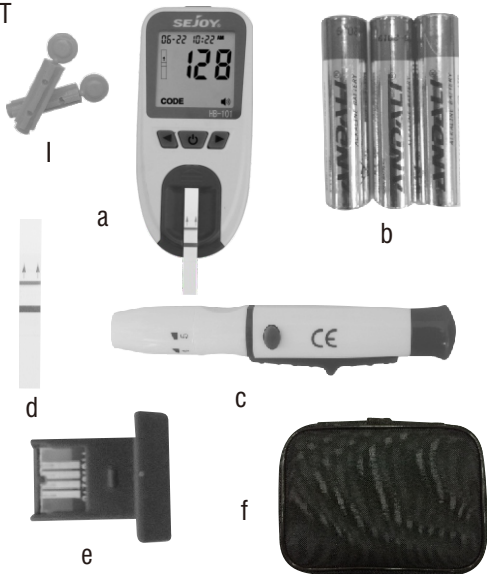
- Run a control test when you open a new box of test strips or if you think that your test result is incorrect. Running a Optical check mode you know that the meter is working properly.
- **DO NOT CHANGE YOUR TREATMENT BASED ON A SINGLE RESULT THAT DOES NOT MATCH HOW YOU FEEL OR IF YOU BELIEVE THAT YOUR TEST RESULT COULD BE INCORRECT.** If your hemoglobin content result doesn't match how you feel and you have followed the instructions in this manual, follow your doctor's instructions, or call your doctor.
- Children should be taught how to use the meter and any other medical products appropriately.
- If you have followed all the instructions in this booklet and still have symptoms that don't seem to match your test results – or if you have questions – talk to your doctor.
- The sejoy hemoglobin monitoring system HB-101 is designed for using with fresh capillary whole blood from the finger or venous samples.

Environmental conditions for normal use of the instrument

- indoor use.
- Altitude :Up to 10,000 feet (3,048meters) above sea level.
- Operating temperature: 10°C~40°C.
- Operating relative humidity: < 90%RH.
- Over voltage category : Not applicable.
- Pollution degree of the intended environment:2.
- Resettable fuses :UL type fuse ,Voltage rating DC 6V ,hold current 350mA.

INCLUDED WITH YOUR KIT

- a. Hb Meter
- b. AAA Batteries
- c. Lancing Device
- d. Quality control Strips
- e. Code Chip
- f. Carrying Case
- g. Usb data cable
- h. test Strips
- I. Sterile Lancet



Manufacturer of Lancing Device and Sterile Lancet



Shandong Lianfa Medical Plastic Products Co., Ltd.No.1
Shuangshan Sanjian Road, 250200, Zhangqiu City, Jinan, Shandong, PEOPLE'S
REPUBLIC OF CHINA



Shanghai International Holding Corp. GmbH (Europe)
Eiffelstrasse 80, 20537 Hamburg Germany

CE for lancing device; CE0123 for sterile lancet



Beijing Ruicheng Medical Supplies Co., Ltd.
No. 558 Zhangzikou, Yangsong Town, Huairou District, 101400 Beijing, China



Lotus NL B.V.
Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.

CE for lancing device; CE0197 for sterile lancet

Hb Meter: Reads the test strips and displays the hemoglobin (Hb) concentration and calculated hematocrit (Hct) value.

Test Strips: Part of the system and used with the meter to measure Hb concentration and calculated Hct in blood.

Code Chip: Automatically calibrates the meter with the code number when inserted into the meter.

AAA Batteries: Provides power for the meter.

Carrying Case: Provides portability for testing.

User's Manual: Provides detailed instructions on using the Hb Hemoglobin Testing System.

Mini USB COM: Use Special USB data cable to connect computer (meet the requirement of IEC 60950 and IEC 62368), input rated voltage is 5V DC (no external power supply).

Quality control Strips: In Optical Check mode, check whether the Optical system works normally.

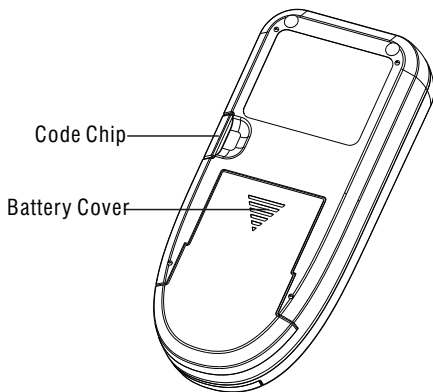
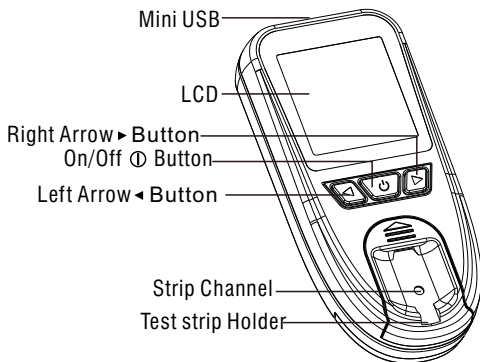
Test Strip Package Insert: Provides detailed instructions on using the Hb Hemoglobin Test Strips.

Lancing Device: 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.

Lancing Device Package Insert: Provides detailed instructions on using the Lancing Device.

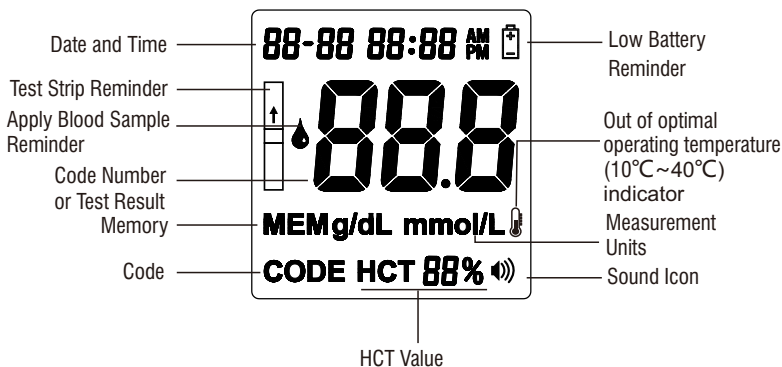
Sterile Lancets: Used with lancing device to draw blood specimens. Sterile lancets are inserted into the lancing device with each blood draw and discarded after use.

a. Meter



WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery cover, batteries and test strips, are choking hazards.

b. Meter Display



Sound Icon: Appears when the sound is turned on.

Low Battery Reminder: Appears when the battery should be replaced.

Code Number or Test Result: Indicates code number or test result.

Memory: Indicates a test result is being recalled from memory.

Code: Indicates the code number of the test strips.

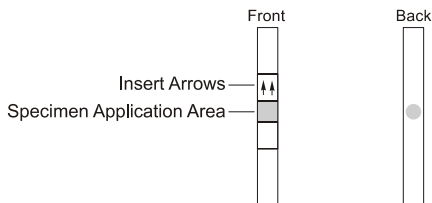
Measurement Units: Indicates the units for the test result.

HCT Value: Shows calculated HCT value.

Test Strip Reminder: Indicates when to insert test strip.

Apply Blood Sample Reminder: Indicates when to apply Blood Sample.

c. Test Strips



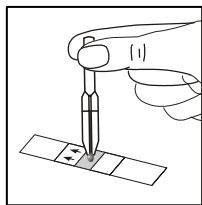
Specimen Application Area - After strip is inserted into the Strip Channel, apply a blood drop to the center of test strip. The Specimen Application Area is visible from the front and the back of the Test Strip.

Insert Arrows - Located on the front of the test strip, the arrows show the direction in which the test strip should be inserted.

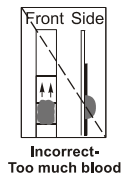
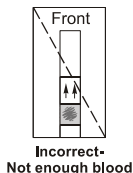
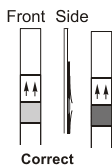
Important: the meter should only be used with HS-101 test strips. Using other test strips with this meter can produce inaccurate results.

Specimen Application

For best results, fill the Specimen Application Area with approximately 10 μ L of blood specimen. Incorrect results may occur if the specimen is not applied correctly, or if the Specimen Application Area is not filled.

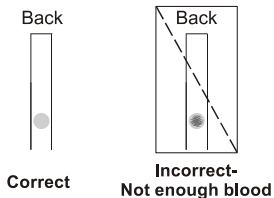


Before Testing




After applying the specimen, ensure 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.

After Testing



Code Number

Each package of test strips is printed with a code number **CODE** , lot number **LOT** and expiration date  . Whenever a new vial is opened, mark the date on the label. Calculate the expiration date by adding three months. Record this expiration date on the label.

Important test strip information for use

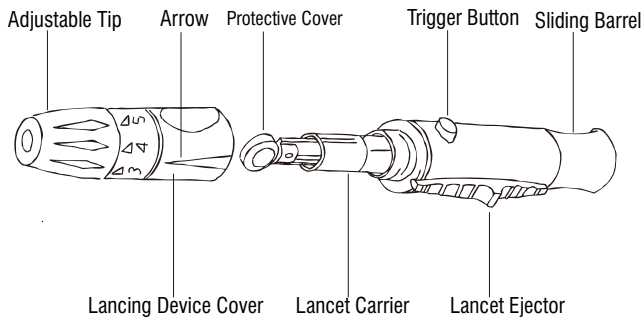
- The system has operating range of $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$ ($50^{\circ}\text{F} \sim 105^{\circ}\text{F}$) . For the most accurate results, try to test as close to room temperature $15^{\circ}\text{C} \sim 30^{\circ}\text{C}$ ($59^{\circ}\text{F} \sim 86^{\circ}\text{F}$) as you can.
- Store the test strip package in a cool, dry place between $2^{\circ}\text{C} \sim 30^{\circ}\text{C}$ ($35.6^{\circ}\text{F} \sim 86^{\circ}\text{F}$) .
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight or heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.

- After removing a test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.
- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter test strips.
- Write the first open date and expiration date on the vial label when you first open it. Discard the vial 3 months after first open date. 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 any way. Do not reuse test strips.
- Before performing a hemoglobin test, make sure that the code number on the meter display matches the number shown on the test strip vial and on the code chip ink-jet printed.

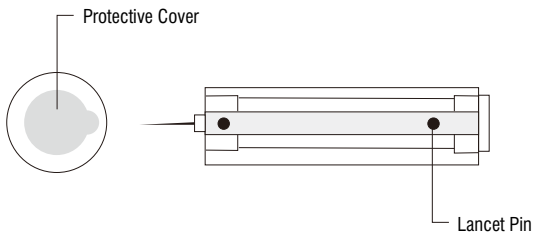


Warning: The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

c. Lancing Device



d. Lancet



a. Initial Setup


The meter will turn on automatically after the batteries are inserted. The meter will display the full screen. Please follow below procedures to set the parameters of the meter.

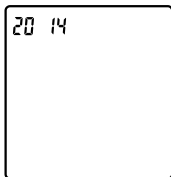
b. Meter Setup

When use the meter not for the first time and need to set up the meter, with the meter turned off, press and hold for 2 seconds to enter **Meter Setup** mode shown below.



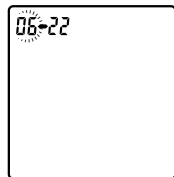
Press ◀ or ▶ to display several setup sub modes:

<i>Set</i>	System setup, including date, time, units and sound.
<i>CHE</i>	Optical Check mode. Use Quality control strips.
<i>dEL</i>	Memory Delete mode.
<i>EIt</i>	Exit setup modes and save changes when  is pressed. The meter will automatically turn off.



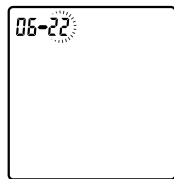
① Set the year

The year will appear at the top of the display. Press ◀ or ▶ until the correct year is displayed. Press button ⏻ to save and the Month and Date figure is flashing automatically.



② Set the month

The month and date will appear at the top of the display separated by a single dash (-), with flashing month. Press ◀ or ▶ until the correct month is displayed. Press button ⏻ to save and the Date figure is flashing automatically.

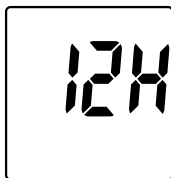


③ Set the date

The month and date will appear at the top of the display separated by a single dash (-), with flashing date. Press ◀ or ▶ until the correct date is displayed. Press button ⏻ to save and the 24 hour figure is flashing automatically.



OR



④ Set the time format

The meter can display the time in either an AM/PM(12-hour) or a 24:00(24-hour) format. Press ◀ or ▶ to switch between the two settings. Press button ⏻ to save and Time figure is flashing automatically.



⑤ Set the time

The hour and minutes will appear at the top of the display separated by a colon, with flashing hour. Press ◀ or ▶ until the correct hour is displayed. Press ⏻ to save and proceed to **HOUR**.

Note: The meter will display **AM** or **PM** if the 12H time setting is chosen.

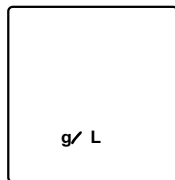
Minutes will flash. Press ◀ or ▶ until the correct **minutes** are displayed. Press ⏻ to save and proceed to **Minutes**.



OR

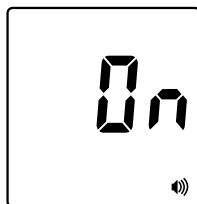


OR

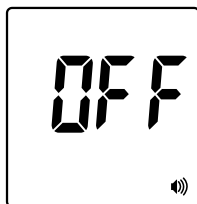


⑥ Set the measuring unit

The meter can display test results in either grams per decilitre(g/dL) or millimoles per litre(mmol/L) or grams per litre(g/L). Press ◀ or ▶ to select g/dL, g/L or mmol/L. Press ⏻ to save and proceed to Measuring unit setup



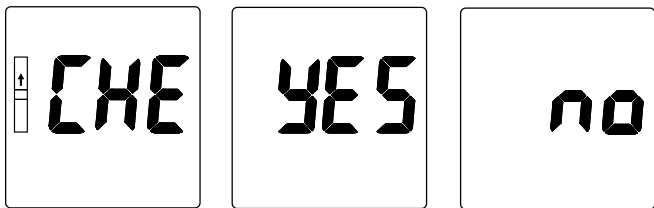
OR



⑦ Set the sound

Press ◀ or ▶ to select sound either ON or OFF. The Sound Symbol will appear on the display when the sound is turned on. Press ⏻ to save and proceed to Sound setup.

c.Optical Check



with the meter turned off, press and hold for 2 seconds to enter **Meter Setup** mode. Press ◀ or ▶ until PC is display. Press ⏻ to enter optical check mode, insert the quality control strips, and then press ⏻ to start the optical system inspection. If “YES” is displayed, the Meter is normal; If “NO” is displayed, the Meter is abnormal.



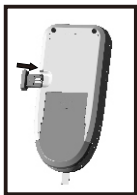
Note: if the optical system is abnormal, please check the quality control strips for contamination, bending or damage. If the above phenomenon is found, please check again with a new quality control strip. If there is still problem in the reinspection, please contact the local dealer or manufacturer.

Coding your meter



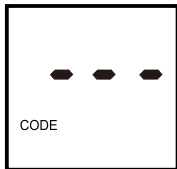
① Check the code on the test strip vial before inserting the test strip

Code numbers are used to calibrate your meter with the test strips you are using



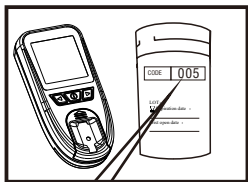
② Put the code chip from strip package into the chip port of meter.

Each strip package contains one chip code. Replace the existed code chip when you start using a new vial of strips



Note: If there's no chip on the meter, the LCD will display — — —

Follow step 2 to install the code chip.



005
(Example)

④ **Match the code on the meter with the code on the test strip vial**

- If the code on the meter match the code on the test strip vial, the meter is now ready to perform a hemoglobin test.
- If the code on the meter does not match the code on the test strip vial, please discard this vial test strips and contact vendors.



CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check it to make sure the code numbers match.

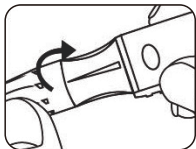
Preparing the lancing device



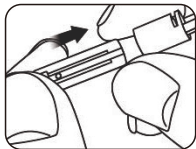
Warning

- During normal testing, any Hb Hemoglobin meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.
- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from bloodborne pathogens.
- Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, bloodborne pathogens.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- Disinfect the meter and lancing device before allowing anyone else to handle them. Do not allow anyone else to test with the meter or lancing device.
- It is important to keep the meter and lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see Chapter Maintenance.
- Wash hands thoroughly before and after handling the meter, lancing device, or test strips.
- You must not insert the lancet cap into the lancing device and simultaneously press the release button or hold the lancing device with the release button resting on a surface such as a table top. This could release a lancet and inadvertently cause injury.

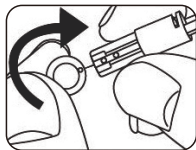
Preparing the lancing device



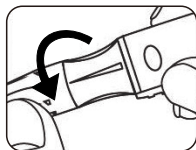
- ① Twist off the lancing device cover.



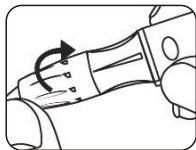
- ② Insert a new lancet into the lancet carrier firmly.



- ③ Hold the lancet needle cover and gently twist it until it separates from the lancet.



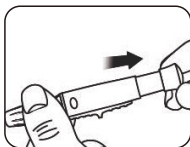
- ④ Replace the lancing device cap.
Avoid touching the lancet pin.



- ⑤ Adjust the depth setting
The adjustable tip offers 5 levels of skin penetration. Twist the lancing device cap until the desired setting appears.

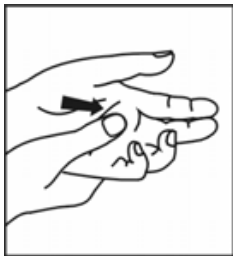
Note: A shallower puncture may be less painful. Try a shallower setting first and increase the depth until you find the one deep enough to get a sufficient blood drop for testing.

Preparing the lancing device



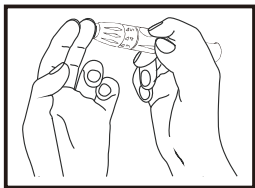
- ⑥ Cock the lancing device
Slide the ejection spring controller back until it clicks. The lancing device is ready to use.
If it does not click, that's okay. It may have been cocked when you inserted the lancet.

Fingertip Blood Sampling



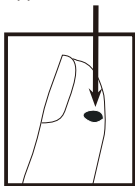
- ① Prior to testing, make sure the hand is warm and relaxed before collecting the capillary blood specimen. Use warm water to increase blood flow if necessary. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

Clean the testing site with an alcohol swab and then dry the testing site thoroughly.



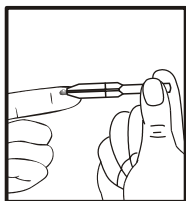
- ② Place the lancing device firmly against the side of your fingertip. Press the Release Button.

Approximate size



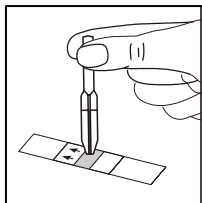
- ③ Gently squeeze your finger until you get a round drop of blood. Discard the first drop. If the blood smears or runs, Do Not use that sample. Wipe the area and gently squeeze another drop of blood or puncture a new site.

Fingertip Blood Sampling



- ④ For use with the Capillary Transfer Tube, hold the tube horizontally and touch the tip of the Capillary Transfer Tube to the blood sample. Capillary action will automatically draw the sample to the fill line and stop.

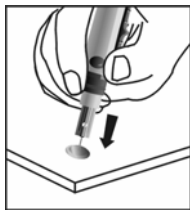
Note: The Capillary Transfer Tube will fill automatically. Never squeeze the Capillary Transfer Tube while sampling.



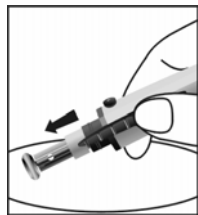
Align the tip of the Capillary Transfer Tube with the Specimen Application Area of the strip to apply the second drop of blood (approximately 10 μ L).

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

Disposal of the Lancet



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



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.

Venous Blood Sampling

For fresh whole blood venous specimens, collect the venous blood in a closed container with EDTA or heparin sodium anticoagulants. Mix the specimen well, then collect approximately 10 μL into a plastic syringe or pipette. Apply it to the center of the Specimen Application Area of the strip. Do not touch the strip with the pipette.

Whole Blood 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 room temperature (15-30°C or 59-86°F) for approximately 15 minutes if the specimen has been refrigerated.

Anticoagulants other than EDTA are not recommended for use.

Note: Refer to NCCLS Documents H3-A6, Collection of Diagnostic Blood Specimens by Venipuncture.

Blood Sampling

IMPORTANT:

- Use only Test Strips HS-101.
- Make sure your meter and test strips are about the same temperature before you test.
- Testing must be done within the operating temperature range $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$ ($41^{\circ}\text{F} \sim 104^{\circ}\text{F}$).


For the most accurate results, try to test as close to room temperature $15^{\circ}\text{C} \sim 30^{\circ}\text{C}$ ($59^{\circ}\text{F} \sim 86^{\circ}\text{F}$) as you can.

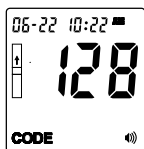
- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- Do Not open the test strip vial until you are ready to remove a test strip and perform a test. Use the test strip immediately after removing it from the vial.
- Do Not return the used test strip to the vial after performing a test.
- Do Not re-use a test strip that had blood or control solution applied to it. Test strips are for single use only.
- Write the first open date on the vial label when you first open it. Discard the vial 3 months after first open date.

Testing



- ① Turn the meter on. The screen will briefly display all of the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on, and there are no missing icons or elements.

Note: If  appears, it indicates the battery is almost out of power. Replace the battery now.



- ② After startup, the Initial Screen will be displayed. Ensure the code chip is inserted, and compare the number showed in the display with the code number printed on the test strip canister label. Refer to Section 3 Coding the Meter.

The **strip symbol** will flash when the meter is ready for the strip to be inserted.



- ③ Insert a test strip into the strip channel in the same direction as the arrows indicated on the strip. Ensure that the test strip is inserted all the way to the end of the strip channel.



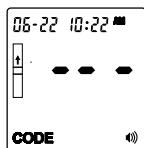
- ④ The **blood drop symbol** will flash when the meter is ready for the specimen to be applied.

Testing

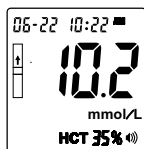


- ⑤ Apply approximately 10 μL of blood to the middle of the Specimen Application Area of the test strip.

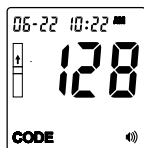
Note: For testing capillary blood, use the second drop of blood for accurate results. Refer to Section 6 Fingertip Testing for details.



- ⑥ The meter will begin testing automatically with **three dashes** in a line flashing on the display indicating the test is in progress.



- ⑦ **Hb** results will be displayed within 10 seconds, with **Hct** value displayed at the bottom of the screen.



- ⑧ Remove the used test strip and press \odot button, the meter will return to the initial screen ready for another strip to be inserted and a test performed.

Note: Discard all blood specimens, used 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.

Deleting Data

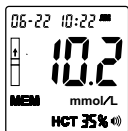
To delete all data from the meter database, enter the Setup Menu (refer to Section 4 Meter Setup). Press ◀ or ▶ until dEL is displayed. Press ⏻ to delete all data. After flashing, all data will be cleared and dEL will be displayed again.

Memory

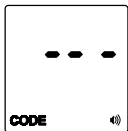
The meter automatically stores up to 1000 test results with the time and date of the test and any test markers. Results can be reviewed at any time. Test results are stored from the newest to the oldest, so set the time and date correctly in the meter.



① Press ⏻ to turn on the meter.




② From the Initial Screen, press ◀ or ▶ to review each record. Press ⏻ to return to the initial screen.



③ If no data is stored the meter will display three dash(-) and MEM.

Replacing the battery

If your battery runs low, the battery symbol “ ” appears on every display screen until you change the battery. An **E-4** error message will appear if the battery is too low to perform any more tests. The meter will not function until the battery is replaced.



- ① With the meter off, turn the meter over to locate the battery cover. Press the battery cover tab on the top and lift the cover to open it.



- ② Remove and discard the old batteries. Insert three AAA batteries on top of the plastic tape. Make sure the two outside batteries are aligned with the plus (+) side down, towards the bottom of the meter, with the middle battery aligned with the plus (+) side facing up, towards the top of the meter.



- ③ Put the battery cover back into position until it locks into place.



Note: Batteries need to be properly disposed of. Contact your local government for disposal or recycling practices in your area.

Caring for your system

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip port.

Important: Never immerse the meter in water or any other liquid. This may cause inaccurate reading or meter malfunction.

Storing your system

Store your meter, test strips and other items in your carrying case after each use. Store each item in a cool, dry place. Test strips should be stored between $2^{\circ}\text{C} \sim 30^{\circ}\text{C}$ ($35.6^{\circ}\text{F} \sim 86^{\circ}\text{F}$). Meter and other items should be stored between $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$ ($-4^{\circ}\text{F} \sim 131^{\circ}\text{F}$).

Do Not refrigerate. Keep all items away from direct sunlight and heat. Tightly close the cap on the test strip vial immediately after use to avoid contamination or damage. Store test strips only in their original vial.

Checking for expiration or damages to test strips and control strip

Expiration dates for test strips are printed on their vial labels.

When you first open a new vial of test strips, record the discard date on the label. Refer to the test strip vial for instructions on determining vial for instructions on determining the discard date.

Cleaning your meter

To clean your meter, wipe the outside with a soft cloth dampened with water and mild detergent. Do Not use alcohol or another solvent to clean your meter.

Do Not get any liquids, dirt, dust, blood inside the meter through the test port.

Test Strip Holder

Remove the **Test Strip Holder** by pressing in on middle of the **Test Strip Holder** and sliding it out from the meter. Wipe it with a damp cloth or a mild detergent and 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 center 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 to scratch the transparent window covering the sensor.




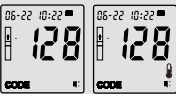


Note: Do not use bleach or alcohol to clean the **Meter Sensor Area**. This will cause damage to the meter.

Cleaning your lancing device

- To clean, wipe them with a soft cloth dampened with water and mild detergent. Do Not immerse the lancing device in any liquid.
- To disinfect, prepare a solution of one part household bleach to ten parts water. Wipe the lancing device with a soft cloth dampened with this solution. Immerse the caps only in this solution for 30 minutes. After disinfecting, rinse briefly with water and allow both to air dry.

Message	Possible Cause	What to do
 CODE 	No code chip or the chip is not well installed.	Insert the code chip to the meter correctly.
	Test strip was removed during the test.	Repeat the test and ensure the test strip remains in place.
	Specimen was applied to the test strip too soon.	Repeat the test and apply specimen after blood drop symbol appears.
	Used or dirty test strip	Ensure the test strips are with the expiration date printed on the canister label.
	Low battery	Replace the batteries, then repeat the test.

	No test record.	Check the memory when test results are stored.
	The test result is lower than 4.5 g/dL .	If the specimen was taken from a specimen container, ensure the specimen is mixed well and repeat test.
	Insufficient specimen less than 1 μ L	Repeat test and apply enough specimen. Use at least 10 μ L of whole blood.
	The test result is higher than 25.6g/dL.	If the specimen was taken from a specimen container, ensure the specimen is mixed well and repeat test.
	Temperature prompt flashing, Operation the working temperature is not in the range of 10°C ~ 40°C (50°F ~ 104°F)	It is suggested to use it in the temperature range of 15°C ~ 30°C (59°F ~ 86°F) to obtain more accurate test data

Meter does not enter the test mode after inserting a test strip.

Probable Cause	What to Do
The battery power is low.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Contact the vendor.
Blood or foreign objects put into the test strip port.	Contact the vendor.

Test does not start after applying the blood sample.

Probable Cause	What to Do
Blood sample too small.	Repeat the test with a new test strips and a larger blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after meter times out and turns off.	Repeat the test using a new test strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Contact the vendor.

Specifications

Meter Type	HB-101
Blood Sample	Capillary and Venous whole blood
Blood Volume	10uL
Test Strip Type	HS-101
Measuring Range	4.5-25.6g/dL, 45-256g/L, 2.8-15.9mmol/L
Measuring Time	< 10seconds
Power	3*AAA Battery or MiniUSB DC5V
Battery Life	Approximately more than 2000 tests
Memory Capacity	1000 test results
Operation Environment	10°C ~ 40°C (50°F ~ 104 °F) <90%RH (non-condensing)
Meter storage environment	-20°C ~ 55°C (-4°F ~ 131°F) <90%RH (non-condensing)
Strip storage environment	2°C ~ 30°C (35.6°F ~ 86 °F)
Dimensions	126*57*24 mm
Weight	185g(with battery)
Expected service life	Ten years

Specifications

Automatic power off	Approx.3 minutes after last user action
Unit of measure	g/dL,g/L or mmol/L
Repeatability	4.5-10.0g/dL, Standard Deviation (SD) ≤ 0.8 g/dL. 10.1-25.6g/dL, Coefficient of Variation (CV) $\leq 3\%$.
Accuracy	4.5-10.0g/dL, absolute deviation ≤ 1 g/dL. 10.1-25.6g/dL, relative deviation $\leq 4\%$.

Warning

- Any product coming in contact with blood is considered contaminated (potentially infectious).
- During normal testing, any Hemoglobin meter may come in contact with blood.
- Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.

Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used batteries.

Please consider the following points when disposing of used testing materials:











- Consider recycling of the meters and batteries at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be disposed of accordingly.
- Disinfect the meter before recycling or disposing.








* 29 CFR 1910.1030 – Bloodborne pathogens

* Directive 2012/19/EU– Directive on waste electrical and electronic equipment (WEEE)

Limited 2-Year Warranty

The meter is guaranteed for 2-year from the date of purchase. If the meter does not function properly due to defective components or poor workmanship, we will repair or replace it freely. This warranty does not cover damage due to improper handling in any way. Battery does not included in the warranty.

	Consult instructions for use
	In vitro diagnostic medical device
	Serial number
	Caution
	Batch code
	Manufacturer
	Storage temperature limitation
	Storage humidity limitation
	Do not reuse
	Use by

	The product conforms to the requirements of the CE mark in vitro diagnostic medical devices
	
	Biological risks
	Keep dry
	This symbol indicates that you should not discard waste electrical or electronic equipment (WEEE) in the trash. For proper disposal, contact your local retailer where product was purchased
	Direct Current
	European Authorized Representative

Document No.: DHB-0104-002

Version:B

Date of Issue: 2021.5

Distributed By:



Hangzhou Sejoy Electronics & Instruments Co., Ltd.

Area C, Building 2, No.365, Wuzhou Road, Yuhang
Economic Development Zone, Hangzhou City
311100 Zhejiang China.



The product is in compliance with the
requirements of IVD 98/79/EEC, "0123" is the
identification number of notify body



Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany