SENSA CORE®

5 YEARS WARRANTY
Hemoglobin Meter

Hemo Spark

Hemoglobin Measuring System

For testing hemoglobin & hematocrit in whole blood

n   1
MEM
15.2
HCT 45 % g/dL
19-09-03 09:00

Hemo Spark

S

USER MANUAL

SCHS-0120A

Table of Contents

Section 1   Introduction

Intended Use

The Hemo Spark Hemoglobin (Hb) Testing System is for the quantitative determination of hemoglobin in capillary whole blood or arterial or venous whole blood. The testing system is designed for *in vitro* diagnostic use only (external use only), and is suitable for self-testing. The system is for health care professionals and persons with anemia to measure hemoglobin. Simply add a drop of blood to the test strip, and the result is displayed on the screen in 15 seconds. This device has not been evaluated for pediatric subjects.

Principle of Operation for the Methodology

The Hemoglobin Test strip includes a mesh covered sample reaction zone. Sample is applied to the center of the sample reaction zone. The mesh functions to separate the sample evenly on the entire reaction layer. The reagents on the reagent layer function to hemolyze and release the hemoglobin. The hemoglobin is converted to methemoglobin to cause a color change on the cartridge/strip.

The meter reads the reflection of the strip at every second until the end point of the reaction is detected. The reflection at the end point is directly proportional to the hemoglobin concentration. The end point is defined as following:

The reflection changes between ±1% in three continuous second. Then the reflection at the last second will be read as the end point.

The Hemo Spark Hemoglobin (Hb) Testing System provides results in less than 15 seconds. The test only requires a single 10 µL drop of whole blood. The meter can store up to 1,000 results and can be powered by 3 AAA (1.5V) batteries or an optional AC adapter.

To ensure accurate results:

* Read instructions carefully. Complete any necessary training before use.

* Use the Code Chip included in each box of test strips.

* Only use Hemo Spark Hemoglobin (Hb) Test Strips with the Hemo Spark Hemoglobin (Hb) Meter.

* For *in vitro* diagnostic use only.

* For professional use only.

* Test only whole blood specimens. Blood samples with EDTA or heparin anticoagulants can be used.

* This device has not been evaluated for pediatric subjects.

* Keep out of reach of children.

* For help with any additional questions or issues, please contact Customer Support at 1800 212 2880

Section 2   Contents in Hemo Spark Kit

Inspect the kit box, meter, and accessories for any visible damage, contact Customer Support at 1800 212 2880.

Before testing, read the instructions carefully and learn about all the components of the Hemo Spark Hemoglobin (Hb) Testing System.

The following items are needed to perform a test:

Items in the Package

1. Hemo Spark Hb Meter
2. Hemo Spark Hemoglobin User Manual
3. Hemo Spark Hemoglobin Control Strips
4. Hemoglobin Control Strips Insert Sheet
5. Carrying Case

Hemo Spark Hemoglobin (Hb) Meter: Reads the Test Strips. Displays the hemoglobin (Hb) concentration and the estimated hematocrit (Hct) value.

User's Manual: Provides detailed instructions on how to use the Hemoglobin (Hb) Testing System.

Control Strip or Control Device: Verifies the proper operation of the meter by checking that the meter can detect a pre-calibrated value.

Control Strip Package Insert: Provides detailed instructions on using the Hb Hemoglobin Control Strips or Control Devices.

Carrying Case: Provides portability for testing wherever you go.

Section 3   Components

The Hemo Spark (Hb) Hemoglobin Meter reads the test strips and displays the hemoglobin (Hb) concentration and hematocrit (Hct) value. Below diagram describes the parts of your meter.
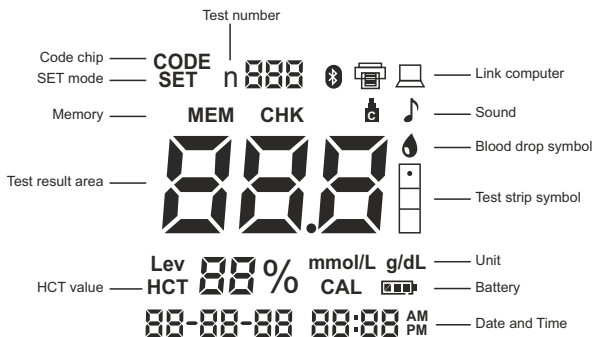
Meter
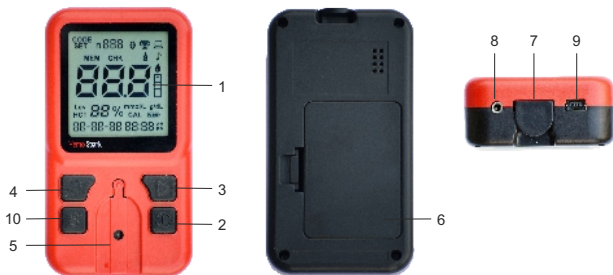
1. LCD (Liquid Crystal Display)
2. On/Off ⏻ Button
3. Right Arrow ▶ Button
4. Left Arrow ◀ Button
5. Strip Channel

6. Battery Cover
7. Code Chip Slot
8. Printer Interface
9. USB interface
10. Setup Button

Meter Display

During testing, the Hemo Spark (Hb) Hemoglobin Meter will display icons showing the status, options available and prompts for testing:

Sound Icon: Appears when the sound is turned on.

Battery: Appears when the battery should be replaced.

Test Number: Indicates assigned test number.

Test Result Area: Indicates test result or displays menu options.

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

Code: Indicates the code number of the test strip or devices.

Measurement Units: Indicates the units for the test result.

Hct Value: Shows calculated Hct value.

Test Strip and Blood Drop Symbols:

Indicates when to insert test strip/device or apply sample/specimen.

Meter Use and Precautions

  * Do not get water or other liquids on or inside the meter.
  * Keep the test strip channel clean.
  * Keep the meter dry. Avoid exposure to extreme temperatures or humidity.
  * Do not drop the meter or get it wet. If either has occurred, ensure the meter is working properly by running an Optical Check. Refer to **Section 8 Optical System Check** for details.
  * Do not take the meter apart. This will void the warranty.
  * Refer to **Section 10 Maintenance** for details on how to clean 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 and used batteries.

All Hb Systems Preventive Warnings with Regard to EMC

1. 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 can cause erroneous results.

2. This instrument complies with the emission and immunity requirements described in IEC 61000-4-8 and IEC 61000-4-3. Do not use this instrument in close proximity to strong sources of electromagnetic radiation. These may interfere with proper operation of the meter.

3. For professional use, the electromagnetic environment should be evaluated prior to operation of the system.

Test Strips

The Hemo Spark Hemoglobin (Hb) Test strips are made out of plastic. A reagent layer within the test strip contains a chemical reagent system that works with the Hemo Spark Hemoglobin (Hb) Meter to measure the hemoglobin (Hb) concentration in capillary and venous whole blood or arterial whole blood.

Each Test strip appears as shown:

Front   Back
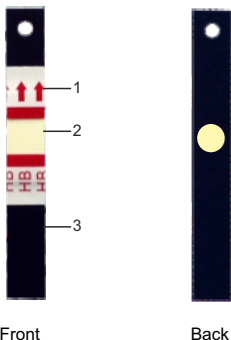
1. Insert Arrows:
Located on the front of the test strip. These arrows indicate the direction in which the test strip should be inserted.
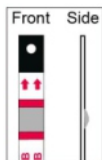
2. Sample Application Area:
After the test strip is inserted into the strip Channel, apply 10 µL of blood to the hole in the center of the test strip.
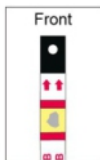
3. Handle:
Located on the end of the test strip. This handle is used to insert and remove the test strip from the meter.
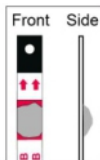
Sample Application

For best results, fill the sample application area with approximately 10 µL of blood. Incorrect results may occur if the sample is not applied correctly or if the sample application area is not filled.

| Correct | Incorrect- Not enough blood | Incorrect- Too much Blood |

After applying the sample, ensure the sample application area is completely covered as shown in the above picture. This area should remain covered throughout the entire test. If it is not covered, or if there is too much specimen covering the area, repeat the test with a new test strip.

Correct   **Incorrect- Not enough blood**

Note:

Do not add more blood to the test strip if the sample applied to the sample application area. When a "**Lo**" or "**E-5**" appears on the display, check the back side of the sample application area to confirm whether or not enough blood has been applied as in the above picture. Discard the used strip and retest with a new strip.

Code Number

Each package of test strips is printed with a code number (Code), lot number (Lot), unopened expiration date (Exp), and test quantity (Quantity) in a vial. Whenever a new vial is opened, mark the date on the label. Calculate the opened expiration date by adding three months. Record this date on the label.

Test Strips Storage and Handling

* Store test strips in a cool, dry place. Store away from heat and direct sunlight.
* Store as packaged in the closed vial at room temperature (2-40°C)
* Do not freeze or refrigerate.
* Replace the cap on the test strip vial immediately after removing it from container.
* Do not use your test strips past the unopened expiration date printed on the label. Using the test strips past the unopened expiration date may produce incorrect test results.

Test Strips Precautions and Instructions for Use

* Test strips must be stored in the original vial with the cap tightly closed.
* Replace the cap on the test strip vial immediately after removing a test strip.
* A new vial of test strips may be used for 3 months after first being opened. The opened expiration date is 3 months after the date the vial was first opened. Write this date on the vial label after opening. Discard the vial 3 months after it was first opened. Usage after this period may result in inaccurate readings.
* For *in vitro* diagnostic use. Test vials are only to be used outside the body for testing purposes.
* Do not use test strips that are damaged in any way. Do not reuse test strips.
* Before testing, make sure that the code number on the meter display matches the number shown on the test strip vial label and the ink-jet printing on the code chip. Refer to the test strip package insert for more details.

Control Strips

The Hemo Spark (Hb) Hemoglobin Control Strips are plastic strips containing a brown reference pad which works with the Hemo Spark (Hb) Hemoglobin Meter to ensure the optical system is working properly. After the control strip is inserted into the meter, the optical system of meter detects the color intensity of the control strip or device. The meter displays **YES** or **no** to show whether the meter is functioning properly. Refer to *Section 8 Optical Check* for details. The control strip/device appears as shown below:

Front

Back

Reference Pad

Precautions

* Store in the closed vial at room temperature within 2-40°C (36 - 104°F) and avoid exposing it to direct sunlight, extreme temperature or humidity. Control strips or control devices should be stored tightly capped in their protective vial to keep them in good working condition.
* Do not freeze or refrigerate.
* Keep the control strips or control devices clean and do not bend. Do not touch the test area of the strip or device.
* Remove the control strip or control device for immediate use. Put the control strip or control device back and close the vial tightly immediately after use. Do not use contaminated, discolored, bent or damaged control strips or control devices.
* Do not use after the expiration date.
* For *in vitro* diagnostic use only.

Storage and Handling

* Store control strips in a cool, dry place. Store away from heat and direct sunlight.
* Transport and store in its closed vial within 2-40°C (36 - 104°F), less than 95% humidity.
* Do not freeze or refrigerate.
* Replace the cap on the control strips vial immediately after removing it from container.
* A new vial of control strips may be used for 2 years after first being opened. The opened expiration date is 2 years after the date the vial was first opened. Write the opened expiration date on the vial label after opening. Discard the vial 2 years after it is first opened. Usage after this period may result in inaccurate readings.

Section 4   Initial Setup

Before testing, ensure the following procedures are followed.

Turn on Meter

The meter can be operated using the certified AC Adapter or 3 AAA batteries (1.5V). To use the meter with batteries, insert 3 AAA batteries (1.5V) into the battery compartment located on the back of the meter.

To use the meter with the power adapter, connect the Mini USB port of the power adaptor to the USB port located on the top of the meter with a USB cable, and plug the adaptor into a 100-240V ac, 50-60 Hz primary power outlet. The meter can also be powered from the USB port of a personal computer, connected by a USB cable. OR The meter will turn on automatically after the batteries are inserted. The meter will display the date and time setup screen. Refer to *Section 5 Meter Setup* for details. After the date and time have been set, the meter will automatically turn off.

Press ⏻ button to 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. After startup, observe there are no permanently turned on segments or icons.

The meter will turn off automatically after 5 minutes of inactivity.

Coding the Meter

Each time a new box of test strips are used, the code chip packaged with the new box of test strips must be inserted into the meter. Take the code chip from the test strips or test devices box. Compare the code number on the code chip with the code number printed on the vial label. Results may be inaccurate if the two numbers are not identical. If the code number on the code chip does not match the number on the vial label with which it was packaged contact customer support or local distributor immediately.

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 or test devices is needed. The code number will appear on the Initial Screen after startup.

Please contact your local distributor immediately. If the code number on the code chip does not match the number that is displayed on the screen.

If the code chip is not properly inserted into the code chip slot, or if it is missing, the meter will display three dashes.
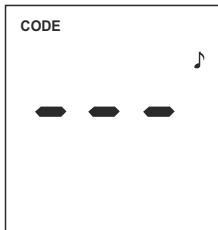
Section 5   Meter Setup and Options

With the meter turned on, press setup button and hold for 4 seconds to enter Meter Setup mode shown below.

n

SEt

Press ⏻ button to display several setup sub-modes. Press ◀ or ▶ to select and press ⏻ button to enter following setup sub-modes:

No. SEt	Test number setup. The test number can be from 1 to 999. Refer to P15
CHE	Optical Check mode. Refer to Section 8
SYS	System Setup mode. Refer to P16
PC	Data transfer mode. Refer to Section 7
dEL	Deleting Data mode. Refer to Section 7
Elt	Exit setup mode. Confirm exit by ⏻ button

Test Number Setup

From the *No. SEt* screen, press ⏻ button to enter **Test Number Setup** mode.

```
      n
     SEt
```
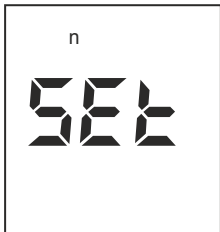
The test number can be set to any number from 1 - 999.

```
      n
     123
```

Press ◄ or ► until the correct test number is displayed. To quickly cycle to the desired test number, press and hold ◄ or ►

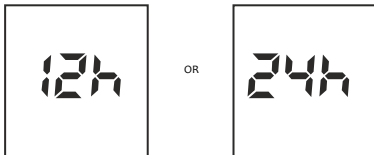Press ⏻ to save and return to **No. SEt** screen.

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

Meter Setup

From the **SEt** screen, press ⏻ to enter **Meter Setup mode**

Hour Setup

The first option sets the clock to either 12 or 24 hour mode. Press ◄ or ► to switch between the two settings.

$$12h \quad \text{OR} \quad 24h$$

Press ⏻ to save and advance to setting the year.

Year Setup

The year, month & date will appear at the bottom of the display. They will be separated by a single dash(-) with year flashing and **y** displayed on test result area.

Press ◄ or ► until the correct year is displayed

Press ⏻ button to save and start setting month and date.

$$\text{y} \\ 19\text{-}09\text{-}03$$

Month and Date Setup

Next, with **m** displayed on test result area with month flashing at the bottom of the screen.
Press ◄ or ► until the correct month is displayed.
Press ⏻ button to save.
The day will flash with **d** displayed on the screen. Press ◄ or ► until the correct day is displayed.
Then press ⏻ button to save and proceed to setup time.

Time Setup

The hour and minutes will appear at the top of the display. They will be separated by a colon, with flashing hour.

Press ◄ or ► until the correct hour is displayed. Press to save and proceed to setup minute.

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 ⏻ button to save and proceed to Test Number Reset Setup.

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 and proceed to setup unit.

"**OFF**" means test number will continue the last number when meter turns off at last time.
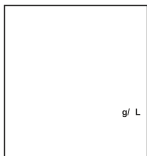"**On**" means test number will start from No. 1 and do not continue the last number.

Press ⏻ button to save.

Units Setup

Press ◄ or ► to select either *g/dL*, *g/L*, or *mmol/L*.

|		
g/dL	g/ L	mmol/L

OR ... OR

Press ⏻ button to save.

Sound Set Up

Press ◄ or ► to turn the sound **ON** or **OFF**. The Sound Symbol will appear on the display when the sound is turned on. Press ⏻ button to save and return to the setup screen.

Press ◄ or ► until **Elt** is displayed and press ⏻ button to exit setup. The screen will briefly go blank and display the initial screen.

Section 6   Testing

Before performing any test, review the Hemo Spark Hemoglobin (Hb) meter User's manual. Review **Section 9** Quality Control for detailed instructions on running quality control tests to ensure that results are within range prior to reporting test results. The following steps show how to use each component to measure the hemoglobin (Hb) concentration.

Sample Collection
The Hemo Spark Hemoglobin (Hb) Meter requires a very small specimen. This may be obtained from fresh capillary whole blood. EDTA venous whole blood may be used as well. Before testing, choose a clean, dry work surface. Review the procedure. Make sure all of the items needed to obtain a drop of blood are available.

Venous Blood & Arterial Blood Testing
For fresh whole venous blood specimens, collect the venous blood in a closed container with EDTA-K2, EDTA-K3, and EDTA-Na2 anticoagulants. Mix the specimen well. Then collect approximately 10 μL into a capillary transfer tube. Apply it to the center hole of the sample application area of the strip. Do not touch the test strip with the tube.

- Whole Blood must be tested within 8 hours of collection.
- Mix the sample well before testing. This is to ensure the cellular components are evenly distributed.
- Allow the sample to reach a temperature between 2-40°C (36 - 104°F), approximately 15 minutes if the sample has been refrigerated.
- Anticoagulants other than EDTA-K2, EDTA-K3, EDTA-Na2 are not recommended for use.

Note:
Refer to the Clinical and Laboratory Standards Institute (CLSI) Documents H3-A6, Collection of Diagnostic Blood Specimens by Venipuncture

Fingertip Blood Testing
Here is an example of how to use a Lancing device with sterile Lancets for fingertip blood sampling. If you use a different single-use auto-disabling safety lancet, please follow the manufacturer's instructions.

Instructions for use of Lancing Device

Intended Use

The lancing device is intended for the collection of capillary whole blood sample for testing purpose from the fingertip and from other sites, such as palm, upper arm, and forearm, which is referred to as alternate site testing. The lancing device is only for single patient use.
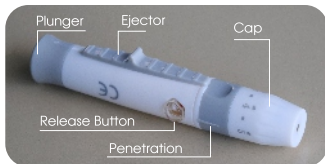
Below are the steps which have to be followed to ensure proper and safe usage of the Lancets and Lancing Device:

Inserting a Lancet

Step 1: Remove the cap from the lancing device.

Step 2: Insert a new lancet firmly into the lancet holder as far as it will go.

Step 3: Twist the protective cap to remove from the lancet. (Don't bend the protective cap)

Step 4: Place the cap back on to the device. The cap must audibly click into place.

To Obtain a Blood Sample

Step 5:

Select the desired penetration depth then pull the plunger (on the end of the device) all the way down & you hear a click sound. Then the device is ready.

Step 6:

Wash your hands & dry them thoroughly. Hold the lancing device against your finger tip, then press the release button. The lancet is released and it penetrates the skin.

Note :

1. The amount of blood that emerges depends on the penetration depth and the pressure used to hold the lancing device against the skin.

2. If not enough blood emerges, apply more pressure on the lancing device when you next obtain blood. If that is not sufficient, increase the penetration depth progressively in addition.

3. If too much blood emerges, decrease the penetration depth.

4. Test your blood Hemoglobin immediately after you obtained blood, according to the instructions for use for your blood Hemoglobin meter.

Penetration Depth

You can set the penetration depths between (1 to 5). The larger the number provides the greater penetration depth. Penetration depth depends on the skin thickness, If you have sensitive skin set a low penetration depth below 3. Rotate the lancing device dial until the desired penetration depth is set.

Ejecting the used lancet

1. Remove the cap from lancing device.
2. Push the lancet needle into the protective cap and discard the lancet from the lancing device.
3. Place the cap back on to the device.

Note :

It is Important to use a new lancet each time you obtain a blood sample. This will help to prevent from infections. Discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used lancets maybe considered biohazardous waste in your area. Be sure to follow your healthcare professionals recommendations or local regulations for proper disposal.

Strip Test Processing

Ensure the meter is set up properly as described in previous sections. 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. The meter will briefly show a blank display. Observe there are no segments or icons permanently turned on.


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 vial label. Refer to *Section 4 Coding the Meter*. The strip symbol will flash when the meter is ready for the device to be inserted.

Strip Testing

Insert a test strip into the Strip/Device 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/Device Channel, until the white edge of the test strip above the black line is no longer visible.


The blood drop symbol will flash when the meter is ready for the sample to be applied. Apply approximately 10 μL of venous blood or a drop of finger blood to the center hole of the sample application area of the test strip.
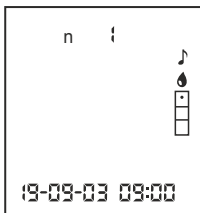
Note:
For testing capillary blood, use the second drop of blood for accurate results.
Refer to *Section 6 for Fingertip Testing* details.

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 15 seconds, with Hct value displayed at the bottom of the screen
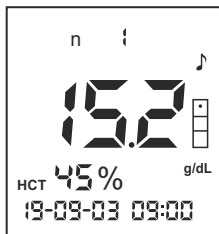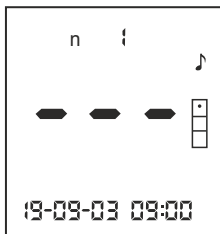
If the insufficient sample, meter display **LO**. The meter will display **Hi** if the concentration is more than 25.6 g/dL (256 g/L or 15.9 mmol/L).

Remove the used test strip or test device. The meter will return to the initial screen ready for another test strip or test device to be inserted and a test performed.

Note:
Dispose all blood samples, 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.

Perform daily cleaning when testing is completed for the day. Refer to *Section 10 Maintenance.* The meter will automatically turn off after 5 minutes of inactivity, or when ⏻ button is pressed. If the meter is powered with an AC adaptor, turn off the meter before removing it from the power outlet. Remove the batteries if the meter will not be used for an extended period of time.

Section 7   Data/Communication

Data Transfer/Transmission

Plug the USB cable into the USB port located on the top of the meter and connect the other end of the USB cable to a suitable PC.

Note: The PC must have suitable software installed to receive and process the data being transmitted from the meter.

From the Setup screen (refer to *Section 5 Meter Setup*), press ◄ or ► until PC is displayed. Press ⏻ button to enable the Data Communication mode, **MEM** will be displayed.

Press ⏻ button to transmit data to an external certified PC.

After data transmission is complete, the meter will return to the Setup Menu.

Note: Up to 1000 test records are automatically stored in memory. After 1000 test records are stored, the oldest test record will be replaced by a new record. For example, if 1000 records are stored in memory, the next test result (1,000) will replace the first result stored in memory.

Deleting Data

To delete all data from the meter database, enter the Setup Menu (refer to *Section 5 Meter Setup*). Press ◄ or ► until **dEL** is displayed.
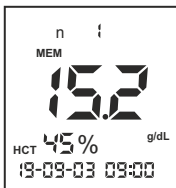
Press ⏻ button to enable data deletion, **MEM** will be displayed.

```
    MEM
   dEL
```

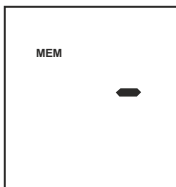Press and hold ⏻ button until the meter returns to the Setup Menu.

Memory/Database

From the Initial Screen (refer to *Section 5 Meter Setup*), press ◄ or ► to show the first record.

```
      n    1
    MEM
   15.2
HCT 45%    g/dL
  19-09-03 09:00
```

Press ◄ or ► to view each record in date/time sequence.   Press and hold ⏻ button to return to the Initial Screen.

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

```
  MEM

        ➖
```

Section 8   Optical System Check

Press Set up button and ▶ to find Check Control Solution mode.

```
CHE
```

Note: * The control strip or control device is intended for checking the optical system.
         Refer to *Section 9 Quality Control Test* for using control solutions.

       * Allow the control strips or control devices and the meter to reach room
         temperature 2-40℃ (36 - 104°F) prior to testing.

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

Press ⏻ button to enter this mode. The meter will flash the strip symbol as shown below.

```
CHE
```

Insert a control strip or control device into the Strip/Device Channel in the same direction as
the arrows indicate on the strip or device. Ensure that the control strip or control device is
inserted all the way.

Press ⏻ button to start the optical check. If the meter displays **YES**, the meter is normal. If the meter displays **no**, the meter is not functioning properly.

YE5 OR no
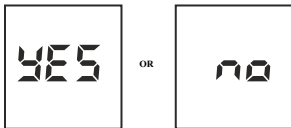
If the meter displays **no**, check the control strip for contamination or if it is bent or damaged. If there are any visible signs of damage or contamination, discard the control strip or control device and retest using a new strip or device.

Press ⏻ button to return to the Setup Screen.

Section 9   Quality Control

Each lab should use its own standards and procedures for performance. Test known specimens/controls at each of the following events in accordance with local, state, and/or federal regulations or accreditation requirements.

* Each new day of testing.

* A new strip of test strips or test devices is opened

* A new operator uses the meter

* Test results seem inaccurate

* After performing maintenance or service on the meter

If QC tests do not provide expected results, perform the following checks:

* Ensure the test strips or test devices used are not past their expiration date.

* Ensure test strips or test devices are fresh from a new vial.

* Ensure the controls are not past their expiration date.

* Repeat the test to ensure no errors were made during the test.

Section 10   Maintenance

Proper maintenance is recommended for best results.

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

Replacing the Batteries
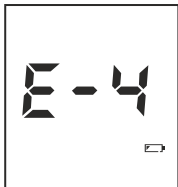
When the battery icon ▱ is flashing, the battery is running low and should be replaced as soon as possible. An **E-4** error message will appear if the battery is too low to perform any more tests. The meter will not function until the battery is replaced.

Make sure the meter is off before removing the battery. Turn the meter over to locate the battery cover. Press the battery cover tab on the top and lift the cover to open it. Remove and discard the old batteries. Insert 3 AAA batteries on top of the plastic tape. Make sure the batteries are aligned with the plus (+) side facing up, towards the top of the meter.

Close the battery cover and make sure that it snaps shut. Recheck and reset the clock setting as necessary after battery replacement to ensure time is set correctly. Refer to *Section 4 Initial Setup.*

> **Note:** Do not discard batteries along with household waste. Follow local regulations for disposal.

Section 11   Precautions

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

* The protection provided by the equipment 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 temperature, or high humidity. Refer to *Appendix 1 Meter Specifications* for operating condition requirements.

* Keep the unit clean. Wipe it frequently with a soft, clean and dry cloth. Use fresh water when needed.

* Do not clean the unit 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 rag.

* The Strip Channel must be kept clean. Lightly wipe with a soft, clean, dry rag each day. Use water as needed. Refer to *Section 10 Maintenance.*

* Follow all local regulations when discarding the unit or its accessories.

* Do not use the unit or the devices outside of the operating temperature ranges listed below.

Meter:	0-50 °C (32-122 °F)
Strips:	2-40°C (36 - 104°F)

Section 12   Troubleshooting

Display	Causes	Solution
E-1	The sensor area is damaged, dirty, or blocked at turn-on, such as a used test strip/device left in the meter.	Ensure the sensor area is clean and that there are no objects covering the sensor area. Refer to *Section 10 Cleaning*. Restart the meter. Contact your local distributor if the sensor area window is broken.
E-2	Test strip/device was removed during the test.	Repeat the test and ensure the test strip/device remains in place.
E-3	Sample was applied to the test strip/device too soon.	Repeat the test and apply sample after blood drop symbol appears.
▀▄	Batteries are discharged but have enough power to run 20 more tests.	Test results will still be accurate, but replace the batteries as soon as possible.
E-4	Batteries have discharged and meter will not allow more tests until discharged batteries are replaced.	Replace the batteries, or connect the meter to the AC Adapter, then repeat the test.
E-5	Insufficient sample.	Repeat test and apply enough sample. Use around 10μL of whole blood
E-6	Expired test strips/device	Ensure the test strips/devices are within the expiration date printed on the vial label.
E-7	Code chip was removed during testing.	Insert proper code chip. Confirm the code chip matches the test strips/device code and repeat the test.

Lo	Insufficient sample	Repeat test and apply enough sample. Use around 10μL of whole blood.
HI	The test result is higher than 25.6 g/dL (256 g/L or 15.9 mmol/L)	If the sample was taken from a sample container, ensure the sample is mixed well and repeat test
code **- - -**	No code chip in the meter; Code chip is damaged or inserted incorrectly.	Inser t the code chip that accompanied the box of test strips/devices. 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 slot.

Appendix 1   Meter Specifications

Feature	Specifications
Methodology	Reflectance Photometry
Test Time	Less Than 15 seconds
Measurement Range	0-25.6 g/dL, 0-256 g/L, 0-15.9 mmol/L
Sample	Whole blood (Capillary, Venous, Arterial)
Sample Volume	10 µL
Power Source	3 AAA batteries (1.5V)
	AC Adapter (Mini USB, 5V DC)
Battery Life	100 hours or 1000 tests
Units of Measure	g/dL, g/L, mmol/L
Memory	1,000 records with date and time
Automatic Shut off	5 minutes after last use
Meter Size	100 mm x 54.5 mm x 25.5 mm
Display Size	38.5 mm × 37.5 mm
Weight	72 g (without batteries)
Meter Storage conditions	0 - 50 °C (32 -122 °F)
Operating Conditions	2 - 40 °C (35.6 -104 °F)
Working Humidity	5 - 95%
Analyzer Port	USB cable for Data Transfer or Power (optional)
Capabilities	USB Data Transfer to PC and Printer
Strips (Working Environment)	Disposable (working temperature 2 - 40ºC, Working Humidity 5-95%)
Strip (Storage Environment)	Stable at 2 - 40ºc and Humidity 5-95% shelf life of the strip 24 months
Auto Calibration	Auto/Self Calibrations
Sensitivity	More than 80%
Specificity	More than 80%
Bias (Limits of Agreement)	0.5 g/dL (±1gm/dL)
Accuracy	98%
Reproducibility	CV : < 3%

Appendix 2   Index of Symbols

📖	Attention, see instructions for use	⧗	Use by
🏭	Manufacturer	CODE	Code Number
IVD	For *In vitro diagnostic* use only	☂	Keep Dry
LOT	Lot Number	🌡 **50℃** / **0℃**	Meter Store between 0-50 ℃
∇Σ	Tests per Kit	SN	Serial Number
♻	Do not discard along with household waste	⟵•←+ USB	USB Port
☀	Keep away from sunlight and heat	②	Do not reuse
⚠	Caution	🚫	Do Not Use if package is Damaged

Appendix 3   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 included with the meter. Sensa Core Medical Instrumentation Pvt. Ltd. warrants to the original purchaser that this meter will be free from defects in materials and workmanship for a period of three years (36 months). The three years starts from the later of the date of original purchase or installation (except as noted below). During the stated three years period, Sensa Core shall replace the meter under warranty with a reconditioned meter or, at its option, repair at no charge a meter that is found to be defective. Sensa Core 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. Sensa Core 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 Sensa Core. Furthermore, Sensa Core assumes no liability from malfunction or damage to meters caused by the use of strips other than strips manufactured by Sensa Core. Sensa Core 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 express 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 Sensa Core.

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