

Mission[®] Plus

Hb Hemoglobin Testing System

User's Manual



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IVD



CE

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Section 1 Introduction

The *Mission® Plus* Hb Hemoglobin Testing System is intended for the quantitative determination of hemoglobin (Hb) and calculated hematocrit (Hct) in capillary and venous human whole blood. The easy to operate system consists of a portable meter that analyzes the intensity and color of light reflected from the reagent area of a test strip or device, ensuring quick and accurate results.

The *Mission® Plus* Hb Hemoglobin Testing System provides results in less than 15 seconds and requires only a single drop of whole blood. The meter can store up to 1,000 results and records can be transferred to a computer for further analysis using the USB port. The meter can be operated by 4 AAA (1.5V) batteries or an optional AC adapter.

To ensure accurate results:

- **For professional use only.**
- Read instructions and complete any necessary training before use.
- Use the code chip that accompanies each box of test strips or devices.
- Use only *Mission® Plus* Hb Hemoglobin Test Strips or *Mission® Plus* Hb Hemoglobin Test Devices with the *Mission® Plus* Hb Hemoglobin Meter.
- For *in vitro* diagnostic use only.
- Test only whole blood specimens. EDTA or heparin anticoagulants can be used.
- Keep out of reach of children.

Note: Throughout this user guide, meter parts or functions will appear in **bold**. Items appearing on displays are identified in ***bold italics***.

Section 2 Getting Started

Inspect the kit box, meter and accessories for any visible damage. If any visible damage exists, please contact your local distributor. Remove the meter and other packaging contents from the kit box. The starter kit consists of the following:

For use with test strips:



Hb Meter



Canister of Test Strips



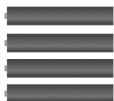
Code Chip



Control Strip



Capillary Transfer Tube/Dropper



AAA Batteries



Carrying Case



Lancing Device



Sterile Lancets

For use with test devices:



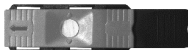
Hb Meter



Canister of Test Devices



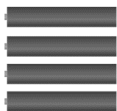
Code Chip



Control Device



Capillary Transfer Tube/Dropper



AAA Batteries



Carrying Case



Lancing Device



Sterile Lancets

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

Test Strips or Test Devices: 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.

Capillary Transfer Tubes or Droppers: Collects 10 μ L of capillary blood for

fingertip blood testing and accurate results.

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.

Quick Reference Guide: Provides a brief overview of the Hb Hemoglobin Testing System and testing procedures.

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

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.

Note: For increased blood flow, or for calloused fingers, a larger gauge such as 21G can also be used.

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.

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

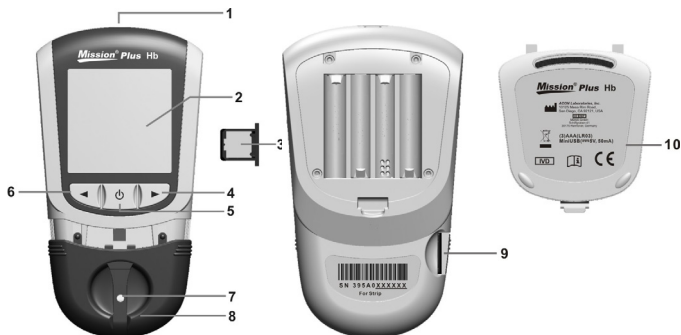
Warranty Card: Should be completed and returned to the distributor to qualify for the 2-year meter warranty.

Section 3 Components

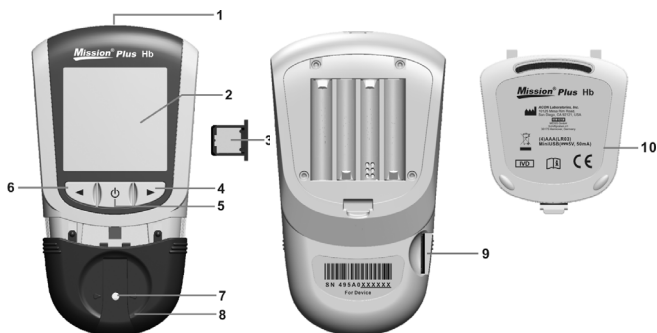
The *Mission® Plus* Hb Hemoglobin Meter reads the test strips and displays the hemoglobin (Hb) concentration and hematocrit (Hct) value. Use this diagram to become familiar with all the parts of your meter.

Meter

For use with test strips:



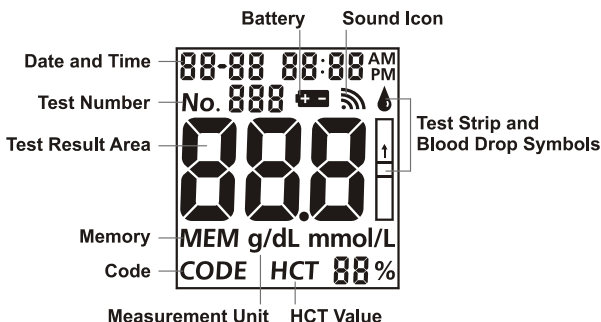
For use with test devices:



- | | | | |
|---|------------------------------|----|----------------------|
| 1 | USB Port | 6 | Left Arrow ◀ Button |
| 2 | Liquid Crystal Display (LCD) | 7 | Strip/Device Channel |
| 3 | Code Chip | 8 | Strip/Device Holder |
| 4 | Right Arrow ▶ Button | 9 | Code Chip Slot |
| 5 | On/Off ⏻ Button | 10 | Battery Cover |

Meter Display

During testing, the *Mission® Plus* 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 specimen.

Meter Use and Precautions

- Do not get water or other liquids inside the meter.
- Keep the Strip/Device Channel clean.
- Keep the meter dry and avoid exposing it to extreme temperatures or humidity.
- Do not drop the meter or get it wet. If meter is dropped or has gotten wet, ensure the meter is working properly by running an Optical Check. Refer to Optical System Check in Section 8 for details.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to Section 10 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 and used batteries.

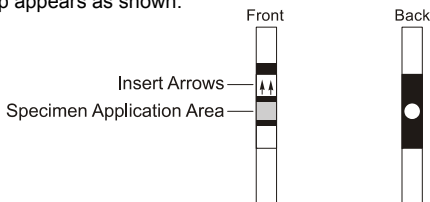
All Hb systems preventive warnings with regard to EMC

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 may cause erroneous results.
2. 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.
3. For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

Test Strips

The *Mission® Plus* Hb Hemoglobin Test Strips are thin plastic strips which contain a chemical reagent system which works with the *Mission® Plus* Hb Hemoglobin Meter to measure the hemoglobin (Hb) concentration in capillary and venous whole blood.

Each test strip appears as shown:



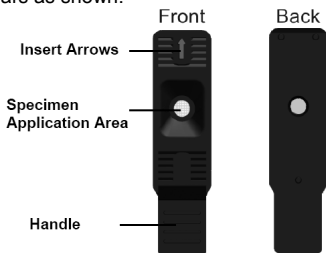
Specimen Application Area - After strip is inserted into the Strip Channel, apply 10 μ L of blood to the center of the test strip. The Specimen Application Area is visible from the front and the back of the test strip.

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

Test Devices

The *Mission® Plus* Hb Hemoglobin Test Devices are plastic devices, in which a reagent layer containing a chemical reagent system works with the *Mission® Plus* Hb Hemoglobin Meter to measure the hemoglobin (Hb) concentration in capillary and venous whole blood.

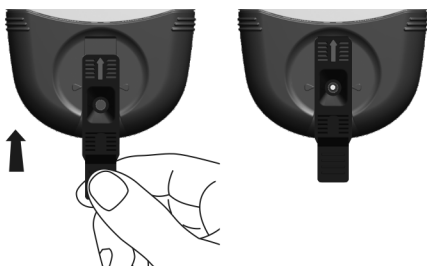
Each test device appears as shown:



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

Specimen Application Area - After device is inserted into the Device Channel, apply 10 μ l of blood to the hole in the center of the test device.

Handle - Located on the end of the test device, the handle is used to insert and remove the test device from the meter.



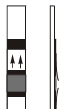
Specimen Application

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

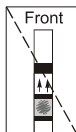


Before Testing

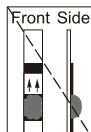
Front Side



Correct



Incorrect-
Not enough blood



Incorrect-
Too much blood

OR



Before Testing

Front Side



Correct



Incorrect-
Not enough blood



Incorrect-
Too much blood

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 or device.

After Testing

Back



Correct



Incorrect-
Not enough blood

OR

After Testing

Back



Correct

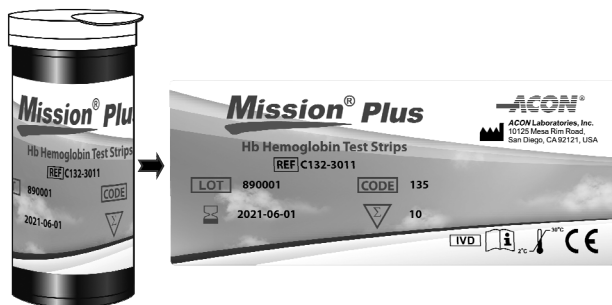


Incorrect-
Not enough blood

Note: Do not add more blood to the test strip or test device if the specimen applied to the Specimen Application Area is too little. Error **E-5** or a low result may appear on the display. Discard the used strip/device and retest.

Code Number

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



Test Strips or Test Devices Precautions and Instructions for Use

- Test Strips or Test Devices should be stored tightly capped in their protective canister to keep them in good working condition.
- Do not store test strips or test devices outside their protective canister. Test strips or test devices must be stored in the original canister with the cap tightly closed.

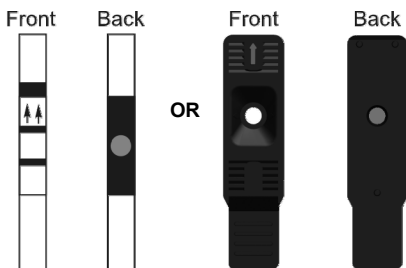
- Do not transfer test strips or test devices to a new canister or any other container.
- Replace the cap on the test strips or test devices canister immediately after removing a test strip or test device.
- A new canister of test strips or test devices may be used for 3 months after first being opened. 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 or test devices are to be used only outside the body for testing purposes.
- Do not use test strips or test devices that are torn, bent, or damaged in any way. Do not reuse test strips or test devices.
- Before performing a hemoglobin test, make sure that the code number on the meter display matches the number shown on the test strip canister and on the code chip ink-jet printed.

Refer to the test strips or test devices package insert for more details.

Control Strips or Control Devices

The *Mission® Plus* Hb Hemoglobin Control Strips or Control Devices are plastic strips or devices containing a brown reference pad which works with the *Mission® Plus* Hb Hemoglobin Meter to ensure the optical system is working properly. After the control strip or device 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:



Precautions

- Store in the closed canister at room temperature within 2-30°C (36 - 86°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 canister 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 canister 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 or control devices in a cool, dry place. Store away from heat and direct sunlight.
- Transport and store in its closed canister within 2-30 °C (36-86 °F), less than 85% humidity.
- Do not freeze or refrigerate.
- Replace the cap on the control strips or control devices canister immediately after removing it from container.
- A new canister of control strips or control devices may be used for 1 year after first being opened. The opened expiration date is 1 year after the date the canister was first opened. Write the opened expiration date on the canister label after opening. Discard the canister 1 year after it is first opened. Usage after this period may result in inaccurate readings.

Note: The expiration date is printed in a Year-Month-Date format.

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 4 AAA batteries (1.5V).

To use the meter with batteries, insert 4 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.

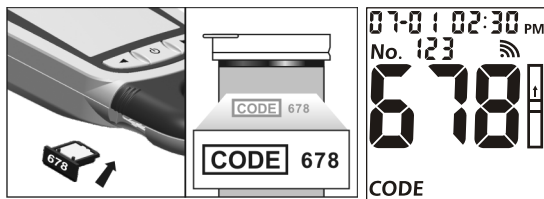
Press  to turn the meter on. The screen will briefly display all of the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on, and there are no missing icons or elements. After startup, observe there are no permanently turned on segments or icons. After the power-on diagnostic check, the Initial Screen will be displayed.

The meter will turn off automatically after 8 minutes of inactivity.

Coding the Meter

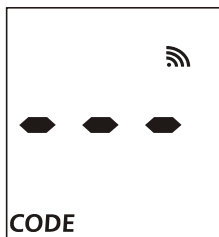
Each time a new box of test strips or test devices is used, the **code chip** packaged with the new box of test strips or test devices must be inserted into the meter. Take the **code chip** from the test strips or test devices box. Compare the code number on the **code chip** with the code number printed on the canister 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 canister label with which it was packaged, contact your 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.



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

If the **code chip** is not properly inserted into the **code chip slot**, or if it is missing, the meter will display **three dashes** as shown below.



Section 5 Meter Setup and Options

With the meter turned off, press and hold  for 4 seconds to enter **Meter Setup** mode shown below.



Press  or  to display several setup submodes:

No. SET	Test number setup. The test number can be set from 1 to 999.
SET	System setup, including date, time, test number reset, units and sound.
CHE	Optical Check mode. Refer to Section 8.
PC	Data Transfer mode. Refer to Section 7.
dEL	Memory Delete mode. Refer to Section 7.
ElT	Exit setup modes and save changes when  is pressed. The meter will automatically return to the Initial Screen.

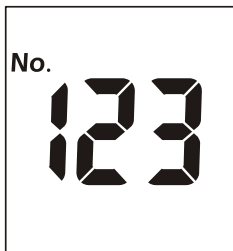
Press  to enter the mode when the desired submode is displayed.

Test Number Setup

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



The test number can be set to any number from 1 – 999.



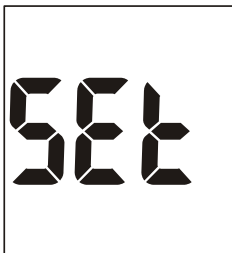
Press ◀ or ▶ until the correct test number is displayed. To quickly cycle to the desired test number, press and hold ◀ or ▶.

Press  to save and return to the **Meter Setup** screen.

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

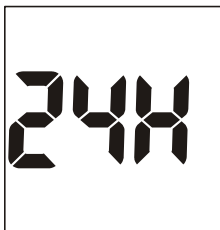
System Setup

From the **SEt** screen, press  to enter **System Setup**.

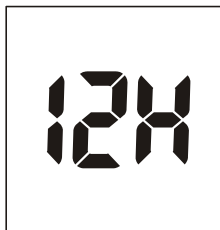


Hour Setup

The first option sets the clock to either **12** or **24 hour** mode. Press ◀ or ▶ to switch between the two settings.



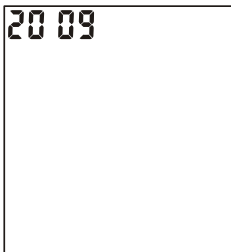
OR



Press  to save and advance to **Year Setup**.

Year Setup

The year will appear at the top of the display. Press ◀ or ▶ until the correct year is displayed.



Press  to save and enter **Month and Date Setup**.

Month and Date Setup

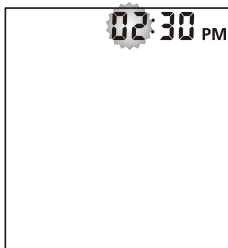
The month and date will appear at the top of the display separated by a single dash (-), with flashing month. Press ◀ or ▶ until the correct month is displayed.



Press  to save. The day will flash. Press ◀ or ▶ until the correct day is displayed, then press  to save and proceed to **Time Setup**.

Time Setup

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



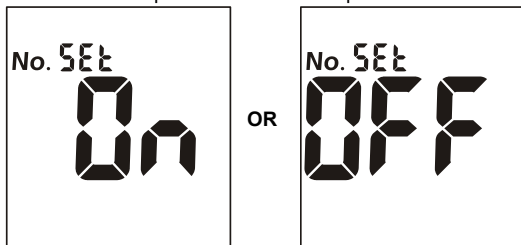
Press ◀ or ▶ until the correct hour is displayed. Press  to save and proceed to **Minutes**.

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 Test Number Reset Setup.

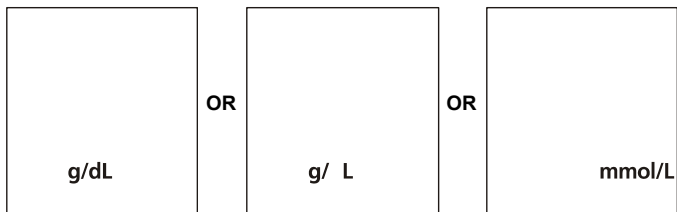
Test Number Reset Setup

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 Units Setup.



Units Setup

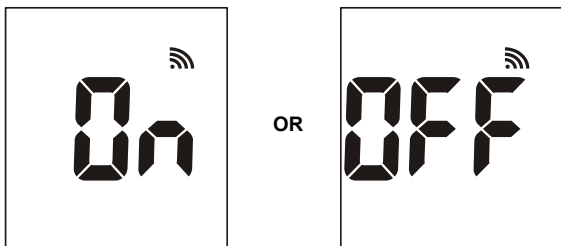
Press ◀ or ▶ to select either **g/dL**, **g/L** or **mmol/L**.



Press  to save and proceed to **Sound Setup**.

Sound Setup

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 return to the setup screen.



Press ◀ or ▶ until **Elit** is displayed and press  to exit setup. The screen will briefly go blank and display the Initial Screen.

Section 6 Testing

Before performing any test, the user should review the *Mission® Plus* Hb Hemoglobin meter manual for detailed instructions. The following steps show how to use each component to measure the hemoglobin concentration.

Specimen Collection

The *Mission® Plus* Hb Hemoglobin Meter requires a very small specimen which may be obtained from the whole blood. Fresh or EDTA or heparin-anticoagulated capillary or venous whole blood may be used. 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.

Venous Blood Testing

For fresh whole blood venous specimens, collect the venous blood in a closed container with EDTA or heparin anticoagulants. Mix the specimen well, then collect approximately 10 µL into a plastic syringe or pipette. Apply it to the center hole of the Specimen Application Area of the strip/device. Do not touch the test strips or test devices 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 and heparin are not recommended for use.

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

Fingertip Blood Testing

For best results, the blood drop should be collected in one take, and without milking the finger.

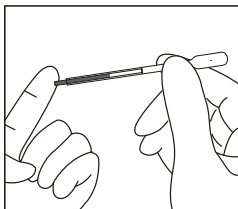
Note: For increased blood flow, or for calloused fingers, a larger gauge such as 21G can also be used.

Wipe away the first drop of blood. Apply light pressure to obtain a second drop of blood. Collect 10 μL of capillary blood using a Capillary Transfer Tube or pipette.

Note: To mitigate the drop to drop variation in fingerprick blood, venous blood can be used.

Note: Refer to NCCLS Documents H04-A6, Collection of Diagnostic Blood Specimens by Skin Puncture.

When drawing the blood sample into the capillary tube, it is important not to squeeze the bulb and/or cover the air vent. Holding the tube at a slightly downward angle, touch the tip of the capillary tube to the blood drop. The blood will automatically be drawn into the black fill line and stop. Make sure that blood reaches the black line, or it will be difficult to squeeze the blood out of the tube.



Note: Never squeeze the Capillary Transfer Tube and/or cover the air vent while collecting the blood sample.

Align the tip of the Capillary Transfer Tube with the Specimen Application Area on the test strip. Squeeze the bulb and cover the air vent to apply the blood sample to the application area.



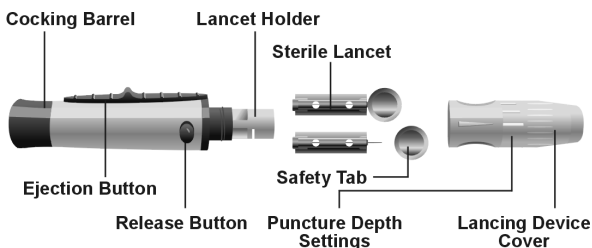
OR



Note: Do not touch the test strips or test devices with the Capillary Transfer Tube or pipette. The air vent should be covered while expelling the blood sample. The capillary blood should be tested immediately after collected. Use of a Capillary Transfer Tube or pipette is recommended for accurate results. Do not reuse the capillary transfer tube.

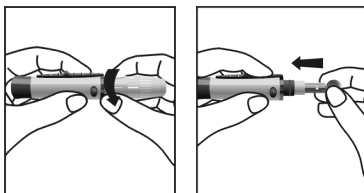
For REF C112-3021 / C112-3031:

Blood specimens can also be obtained by using a lancing device. Refer to the instructions below for details.

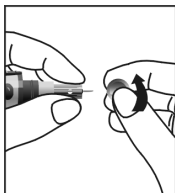


For obtaining a drop of blood from the fingertip, adjust the penetration depth on the lancing device to reduce discomfort.

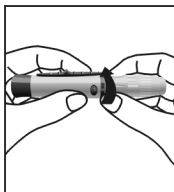
Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.



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 the lancet. Save the safety tab for lancet disposal.

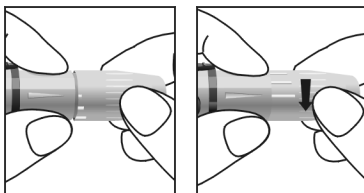


Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully seated on the lancing device.



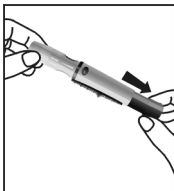
Adjust the puncture depth by rotating the lancing device cover. There are a total of 6 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.

Use settings 1 and 2 for delicate skin, 3 and 4 for normal skin, and 5 and 6 for calloused or thick skin.



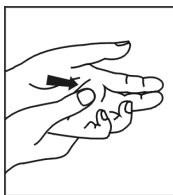
Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

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

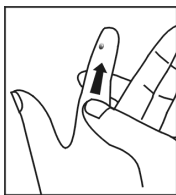
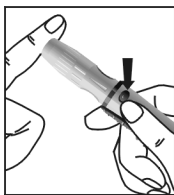


Prior to testing, make sure the patient's hand is warm and relaxed before collecting the capillary blood specimen. Use warm water to increase blood flow if necessary. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

Clean the testing site with an alcohol swab 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 on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make the fingers sore and callused.



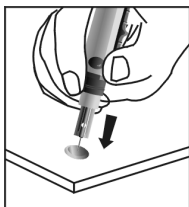
Note:

- Make sure the patient's hand is warm and relaxed before collecting a capillary blood specimen. Use warm water to increase blood flow if necessary.
- For best results, the blood drop should be collected in one take, and without milking the finger.

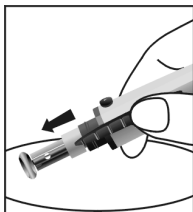
- For increased blood flow, or for calloused fingers, a larger gauge such as 21G can also be used.
- To mitigate the drop to drop variation in fingerstick blood, venous blood can be used.

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.

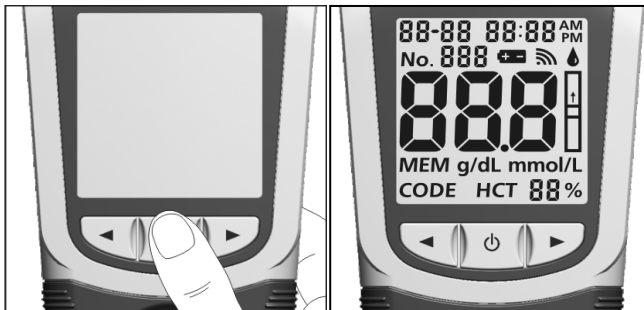


Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to eject the used lancet. Place the lancing device cover back on the lancing device.



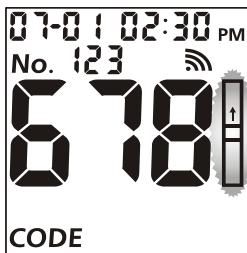
Test Processing

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 canister label. Refer to Section 4 Coding the Meter.

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



Testing

For use with a test strip, 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.



For use with a test device, insert a test device into the Strip/Device Channel in the same direction as the arrows indicate on the device. Ensure that the test device is inserted all the way to the end of the Strip/Device Channel, until the Insert Arrows are parallel with the two arrows on the Device Holder.



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



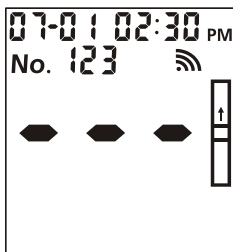
OR



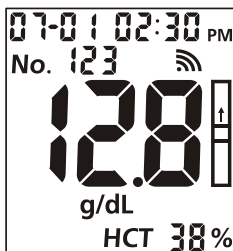
Note:

- For testing capillary blood, use the second drop of blood for accurate results. Refer to Section 6 Fingertip Testing for details.
- For best results, the blood drop should be collected in one take, and without milking the finger.
- For increased blood flow, or for calloused fingers, a larger gauge such as 21G can also be used.
- To mitigate the drop to drop variation in fingerstick blood, venous blood can be used.

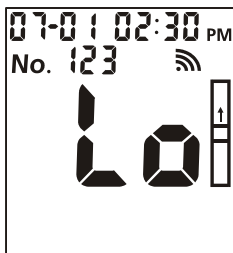
The meter will begin testing automatically with **three dashes** in a line flashing on the display indicating the test is in progress.



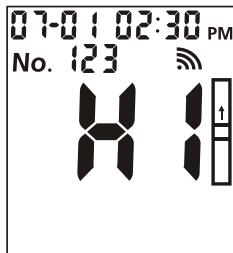
Hb results will be displayed within 15 seconds, with **Hct** value displayed at the bottom of the screen.



If the concentration of hemoglobin is less than 4.5 g/dL (45 g/L or 2.8 mmol/L), the meter will 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).



OR



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: Discard all blood specimens, used test strip or test device 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 8 minutes of inactivity, or when  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.

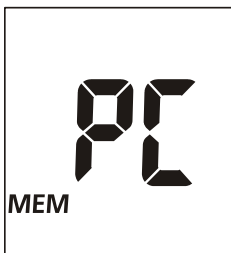
Section 7 Data/Communication

Data 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  to enable the Data Communication mode, **MEM** will be displayed.



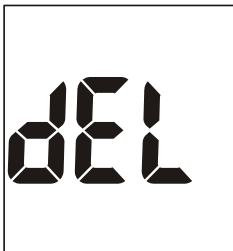
Press  to transmit data to an external certified PC.

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

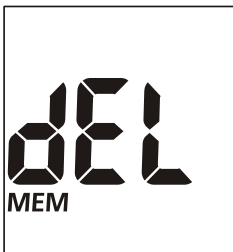
Note: Up to 999 test records are automatically stored in memory. After 999 test records are stored, the oldest test record will be replaced by a new record. For example, if 999 records are stored in memory, the next test result (1,000) will replace the first result stored in memory.

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.



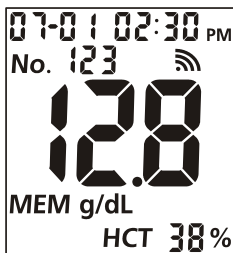
Press  to enable data deletion, **MEM** will be displayed.



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

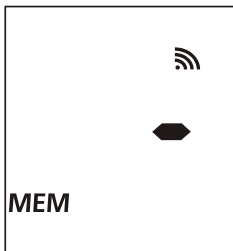
Memory/Database

From the Initial Screen (refer to Section 5 Meter Setup), press ◀ or ▶ to show the first record.



Press ◀ or ▶ to view each record in date/time sequence. Press and hold  to return to the Initial Screen.

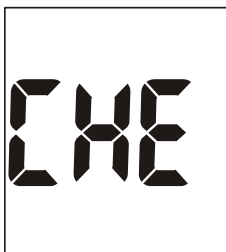
If no data is stored the meter will display **one dash (-)** and **MEM**.



Section 8 Optical System Check

Optical Check

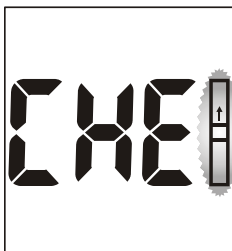
Press ◀ or ▶ from the Setup Screen to select the Optical Check mode as shown.



Note:

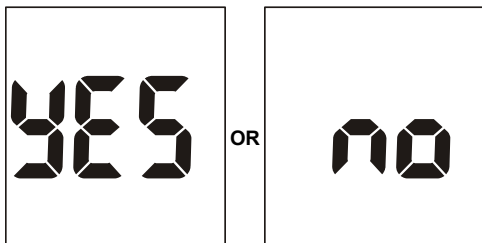
- The control strip or control device is intended for checking the optical system. Refer to Section 9 Quality Control Test for using control solutions.
- Allow the control strips or control devices and the meter to reach room temperature (15-30°C or 59-86°F) prior to testing.
- The optical check should be performed under normal lab lighting conditions. Do not perform under sunlight or extreme lighting conditions.

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



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  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.



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.

Note: Please contact your local distributor to double check if any Problem with system.

Press  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 canister of test strips or test devices is opened
- A new operator uses the analyzer
- Test results seem inaccurate
- After performing maintenance or service on the analyzer

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 canister.
- Ensure the controls are not past their expiration date.
- Repeat the test to ensure no errors were made during the test.

For US customers, call customer service toll free at 1-(800)-838-9502 for additional information. For customers outside the US, contact your local distributor.

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

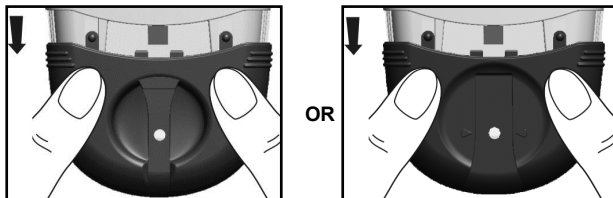
A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary.

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**.

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 two side 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 sensor.



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

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 four 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.



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 analyzer.

- 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.

Analyzer: 10-40 °C (50-104 °F) ; ≤90% RH

Strips: 15-30 °C (59-86 °F) ; ≤85% RH

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	Specimen was applied to the test strip/device too soon.	Repeat the test and apply specimen 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 specimen.	Repeat test and apply enough specimen. Use around 10 µL of whole blood.
E-6	Expired test strips/device.	Ensure the test strips/devices are within the expiration date printed on the canister 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	The test result is lower than 4.5 g/dL (45 g/L or 2.8mmol/L).	If the specimen was taken from a specimen container, ensure the specimen is mixed well and repeat test.
	Insufficient specimen less than 1µL	Repeat test and apply enough specimen. Use around 10 µL of whole blood.
Hi	The test result is higher than 25.6 g/dL (256 g/L or 15.9 mmol/L).	If the specimen was taken from a specimen container, ensure the specimen is mixed well and repeat test.
	No code chip in the meter; Code chip is damaged or inserted incorrectly.	Insert 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.

For US customers, call customer service toll free at 1-(800)-838-9502 for details. For customers outside the US, contact your local distributor.

Appendix 1 Meter Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Test Time	<15 seconds
Measurement Range	4.5-25.6 g/dL, 45-256 g/L, 2.8-15.9 mmol/L
Specimen	Whole blood
Specimen Volume	10 µL
Power Source	4 AAA batteries (1.5V)
	AC Adapter (Mini USB, 5V dc, 50 mA)
Battery Life	360 hours or 2,700 tests
Units of Measure	g/dL, g/L, mmol/L
Memory	1,000 records
Automatic Shut Off	8 minutes after last use
Meter Size	137 mm × 79 mm × 26 mm (5.4" × 3.11" × 1.02")
Display Size	50 mm × 50 mm (1.97" × 1.97")
Weight	145g (without batteries)
Meter Storage Conditions	0 - 50 °C (32 -122 °F); ≤90% RH
Operating Conditions	10 - 40 °C (50 -104 °F); ≤90% RH
Meter Connectors	USB cable for Data Transfer or Power (optional)

Appendix 2 Index of Symbols

	Consult instructions for use		<i>In vitro</i> diagnostic medical device
	Catalogue number	SN	Serial Number
	Manufacturer		Authorized representative in the European Community
	Lot Number		Use by
	Contains sufficient for <n> tests		Temperature limit
	Sterilized using irradiation		Code Number
	Do not discard along with household waste		USB Port
	Fragile, handle with care		This Side Up
	Keep away from sunlight and heat		Keep Dry
	Do not reuse		

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.

ACON Laboratories, Inc. 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). The two years starts from the later of the date of original purchase or installation (except as noted below). During the stated two years period, **ACON** 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. **ACON** 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. **ACON** 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 **ACON**. Furthermore, **ACON** assumes no liability from malfunction or damage to meters caused by the use of strips other than strips manufactured by **ACON**. **ACON** 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 **ACON**.

Limitations of Liability

In no event shall **ACON** be liable for indirect, special or consequential damages, even if **ACON** has been advised of the possibility of such damages.

For warranty service, please contact your local distributor.

