ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District
Hangzhou, P.R.China, 310030
www.aconbio.com

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

Number: 1151566301
Effective date: 2024-12-02

Mission® HemoPro

Hemoglobin Meter

User's Manual

IVD

CE

Attention: By approving the enclosed design draft, you (ACON's Customer) accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, you (ACON's Customer) are responsible for the cost of any inventory which is deemed unsuitable for sale and/or not compliant with local regulations .

☐ US ■ OUS ☐ DOMESTIC ☐ OTHER

Description	Mission HemoPro CE Hb User's manual (En) Bio		Part Number	1151566301	Size 110x165mm
Printing Contents			L Number		Size
Designer	rene	Design Date/Version	Oct 26, 2023 / A		
Artwork checked by		Material	封面200g双铜纸+水性上光，内页80g双胶纸		Checked by
Approved by Customer		Approved by Marketing/Sales			
Approved by P.M.T.		Approved by QA			Effective Date

Table of Contents

Section 1 Introduction

Intended Use

The *Mission® HemoPro* Hemoglobin Meter, used together with *Mission® HemoPro* Hemoglobin Microcuvette, is based on Spectrophotometry technology, and is intended for the quantitative determination of Hemoglobin (Hb) and for calculating Hematocrit (HCT) in human capillary and venous whole blood. The *Mission® HemoPro* Hemoglobin Meter is designed for professional *In Vitro Diagnostic* use only.

The microcuvette is designed for single use only, and it serves as both a pipette and a measuring cuvette. A blood specimen or control solution of approximately 10 µL is drawn into the cavity by capillary action. Measurement of the whole blood absorbance at the Hb/HbO_2 isobestic point is carried out on the meter. It is factory calibrated by an international reference method and no further calibration is needed.

The *Mission® HemoPro* Hemoglobin Meter provides results in less than 2 seconds. The meter can store up to 1,000 results and records can be transferred to a computer for further analysis by using the USB port. The meter can be operated with 4 AAA (1.5V) batteries or a USB adapter.

To ensure accurate results

- Read instructions and complete all necessary training before use.
- Only the *Mission® HemoPro* Hemoglobin Microcuvette can be used with the *Mission® HemoPro* Hemoglobin Meter.
- For *in vitro* diagnostic use only.
- For professional use only.
- Test with capillary or venous whole blood specimens. EDTA or heparin anticoagulants can be used.
- Keep out of the reach of children.

Important Safety Instructions

- Users should adhere to Standard Precautions when handling or using this meter.
- All parts of the Hemoglobin Testing System should be considered potentially infectious and capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007.” http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.
- Misuse of electrical equipment can cause electrocution, burns, fire and other hazards.
- Use this meter only for the purpose described in the instructions for use.
- Do not use accessories that are not supplied or recommended by the manufacturer.
- Do not use the meter if it is not working properly or if it has suffered any damage.
- Do not let the meter or its flexible cord come into contact with surfaces that are too hot to touch.
- Do not use the meter outdoors.
- If the meter is used in a manner not specified by the manufacturer, the protective features of this product will be impaired.

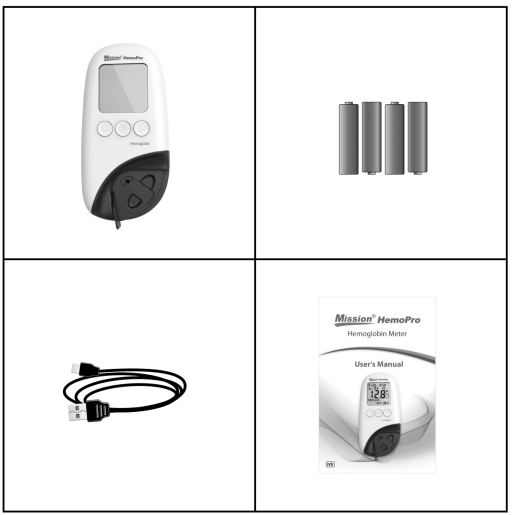
Note: Throughout this user’s manual, meter parts or functions will appear in **bold**. Items appearing on the display screen are identified in ***bold italics***.

Section 2 Overview

Check the Items

Inspect the packaging, 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 kit consists of the following:

Items Provided



No.	Component	Quantity
1	*Mission*® *HemoPro* Hemoglobin Meter	1
2	AAA Batteries	4
3	USB A/M TO MINI USB cable	1
4	User's Manual with Warranty Card	1

***Mission*® *HemoPro* Hemoglobin Meter:** Reads the Microcuvette and displays the hemoglobin (Hb) concentration and calculates the hematocrit (HCT) value.

AAA Batteries：Provides power for the Meter.

USB A/M TO MINI USB cable: Connects the terminal for data transmission and power supply.

User's Manual with Warranty Card: Provides detailed instructions on using the HemoPro Hemoglobin Meter. Warranty card should be completed and returned to the distributor to qualify for the 2-year meter warranty.

Items Not Provided (Required)

***Mission*® *HemoPro* Hemoglobin Microcuvette:** Composed of polystyrene plastic and does not contain any active ingredients, the Microcuvette is used for collecting the specimen or control soluiton, transferring it to the meter and for running the test. It is specially designed for use with the *Mission*® *HemoPro* Hemoglobin Meter. See the insert for more detailed instructions.

Lancets with Lancing Device / Safety Lancet: Used for collecting capillary blood specimen.

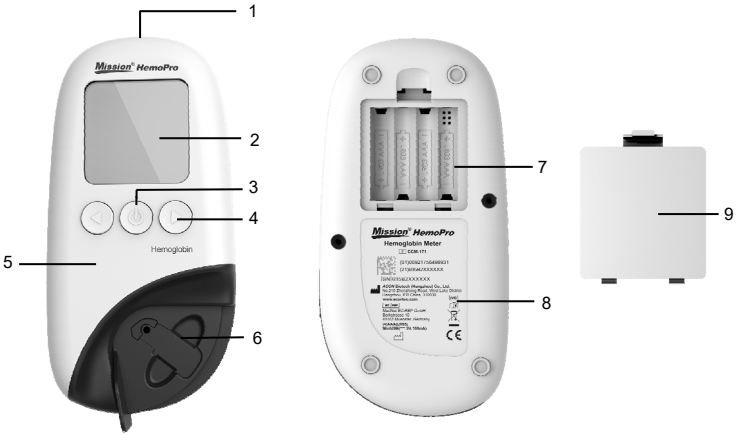
Optional Items

***Mission*® *HemoPro* Hemoglobin Control Solution:** Only use for the external quality control when it is required by local or other regulations.

USB adapter: Adjusts to rated voltage 5V and rated current 1000mA.

Meter Overview

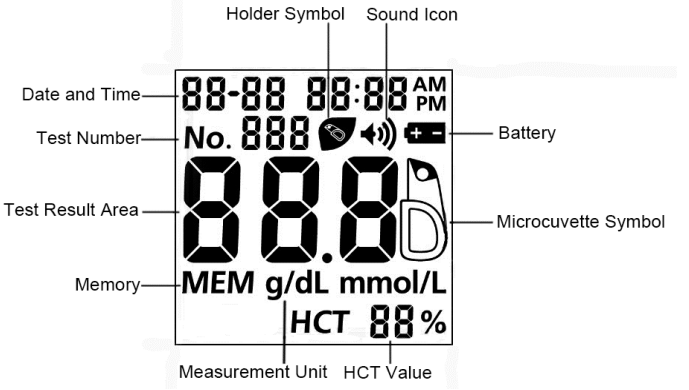
The *Mission® HemoPro* Hemoglobin Meter reads the Microcuvette and displays the hemoglobin (Hb) concentration and hematocrit (HCT) values. Use this diagram to become familiar with your meter.



1	USB Port	6	Microcuvette Holder
2	Liquid Crystal Display (LCD)	7	Battery Compartment
3	On/Off ⏻ Button	8	SN Label
4	Right Arrow ► Button	9	Battery Cover
5	Left Arrow ◄ Button		

Display Overview

During testing, the *Mission*® *HemoPro* Hemoglobin Meter will display icons showing the status, available options and prompts for testing.



Date and Time: The date and time are displayed at the top of the screen.

Test Number: The No. symbol, indicates the test ID.

Test Result Area: Displays the blood hemoglobin measurement value, error messages and other data.

Memory: The MEM symbol, indicates the meter is in memory mode.

Holder Symbol: Displays the status of the Microcuvette holder.

Sound Icon: Indicates the audio for operation is ON.

Battery: Indicates when the battery power is LOW.

Microcuvette Symbol: Displays the status of the microcuvette.

Measurement Unit: Indicates the unit of measure the meter is set at: g/dL, g/L or mmol/L.

HCT Value: Indicates the Hematocrit (HCT) result.

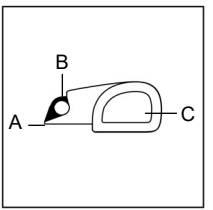
Microcuvette Overview

A. Filling end: The specimen or control solution is drawn into the microcuvette at the Filling end.

B. Optical eye: The patient specimen fills the optical eye of the microcuvette. Make sure there are no air bubbles.

C. Handheld end: The user holds this area of the microcuvette to add patient specimen and insert it into the meter for testing.

Note: Excess specimen in the Filling end should be cleaned before running a test to minimize contamination and equipment maintenance. For more detailed instructions, please refer to Section 6 **Testing** in this User's Manual.



Section 3 Getting Started

Before testing, ensure the following procedures are followed.

Power Options

The meter can be powered by batteries or connected to an external power supply through the USB interface.

- Batteries: When using battery power, open the battery cover on the back of the meter, confirm the correct direction for installation of the batteries and insert 4 AAA batteries.
- USB cable: Connect the USB port to a computer or USB adapter with the USB cable provided in the package.

OR

Turn on Meter

The meter will turn on automatically after the batteries are inserted. Then the meter will display the date and time at the Setup Screen. 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 the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on, there are no missing icons or elements, and 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 a certain period of inactivity (sleep mode can be set to activate within 5 to 60 minutes of inactivity).

Optical Path Self-check

Before entering the testing mode, the meter will enter the optical path self-check mode. The self-check steps are as follows:

1. Pull out the holder before turning on the meter. Confirm that there are no Microcuvettes or other objects on the holder.

2. Press ⏻ to wake up the meter, the screen will displays PI, and the holder symbol will flash.

3. Push in the holder and wait for the screen to display PO (with the holder symbol flashing) to indicate that the self-check has completed. Then pull out the holder and the meter will automatically return to test mode.

Note:

1. The meter will automatically shut down by default after inactivity and will go into sleep mode.

2. When the meter is in test mode, pressing and holding the power button for 2 seconds will turn off the meter.

Section 4 Meter Setup and Options

Enter Setup Mode

With the meter turned off, press and hold ⏻ for 2 seconds to enter **Meter Setup** mode shown below.

Press ◀ or ▶ to display several setup submodes:

SEt	**System Setup.** This includes: date, time, test number reset, units and sound.
No. SEt	**Test Number Setup.** The test number can be set from 1 to 999.
OPI	**Optical Path Initialization** mode.
PC	**Data Transfer** mode. Refer to Section 8.
dEL	**Memory Delete** mode. Refer to Section 8.
Elt	**Exit Setup** mode and save changes by pressing ⏻. The meter will automatically return to the Initial Screen.

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

System Setup Mode

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**.

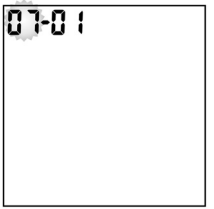
Year Setup

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 (**-**). The format is displayed as “MM-DD” with the month flashing. 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 minute will appear at the top of the display separated by a colon, with the hour flashing.

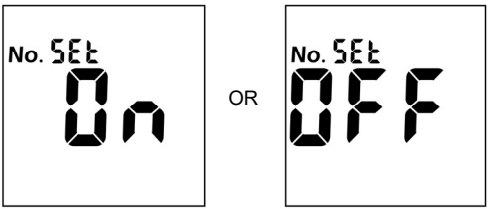
Press ◄ or ► until the correct hour is displayed. Press ⏻ to save and proceed to **Minute**.

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

Minute will flash. Press ◄ or ► until the correct **Minute** is displayed. Press ⏻ to save and proceed to Test Number Reset Setup.

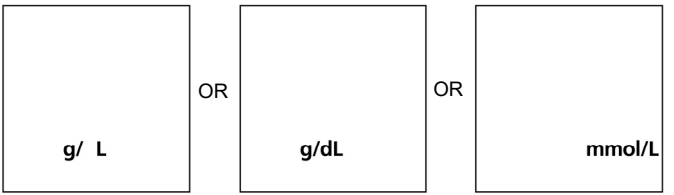
Test Number Reset Setup

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

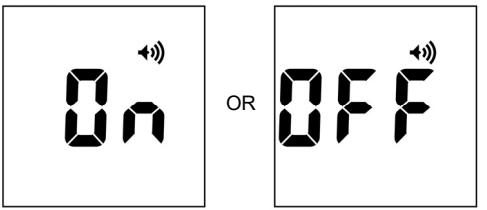
Press ◄ or ► to select either ***g/L, g/dL or mmol/L***.



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

Sound Setup

Press ◄ or ► to turn the sound ***ON*** or ***OFF***. The ***Sound Symbol*** will appear on the display when the sound is turned ***ON***. Press ⏻ to save and proceed to **Off Time Setup**.



Off Time Setup

Press ◄ or ► to increase or decrease the activation time for the automatic sleep mode, with each press increasing or decreasing by the time 5 minutes. The sleep mode activation time can be adjusted for a minimum of 5 minutes to a maximum of 60 minutes. The factory default time is 5 minutes for automatic shutdown.

Press ⏻ to save and back to the initial screen.

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 to 999 and 0 represent 1,000.

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.

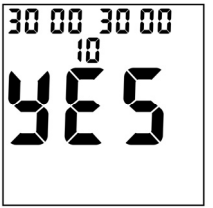
Note: Once the meter reaches test number 999, the next test number will be 0 which represent 1,000, then the next test number will be 1.

Optical Path Initialization Mode

It is a normal phenomenon that the light intensity of the meter may change after long-term use. The meter will prompt an error code of E-5 when this happens. Users can manually enter the **Optical Path Initialization Mode (OPI)** in the **Meter Setup** and perform optical path initialization according to the following steps.

1. In the shutdown state, press ⏻ and hold the button for 2 seconds to enter the **Meter Setup**, and press ◄or ► until “OPI” is displayed.

2. Press the ⏻ button, and the meter will automatically adjust the optical path. After the adjustment is completed, the screen will display "yes", and two numbers 3000 (fluctuating ±2) and a number “10” will be displayed at the top.



Press any button again to return to the **Meter Setup** interface.

Note: When entering the OPI mode, if the holder is not in the testing area, the LCD screen will display the word PI. Please push it in and be careful not to place anything inside the holder.

Note: It is recommended that the meter's optical path be initialized every six months.

PC Mode

USB data transfer mode

Please refer to **Section 8.2 Data Communication - USB Communication**

Delete Mode

Clearing Records

Be cautious when using this clear function, as it is an irreversible operation and data records cannot be restored once deleted. The specific operation is as follows:

1. Press the ⏻ button to display MEM, then press the ⏻ button to clear all records from the memory and automatically return to the menu.

2. If you enter deletion mode but do not want to delete data, please press ◄ or ► to return to the menu.

Note: This meter can automatically store up to 1000 test results. If 1000 test results have already been saved, the earliest record will be replaced by the latest test results. For example, if there are 1000 test results stored in the meter, the next test result will replace the first test result in the memory.

Section 6 Testing

The following steps provide instructions on how to use the meter, microcuvette, lancing device and sterile lancets together to measure the hemoglobin concentration.

Please make sure the meter, microcuvette and venous whole blood specimen are placed at 10-40°C (50-104 °F) for at least one hour before testing.

Step 1 - Collecting Blood Specimen

Every specimen should be handled as a potential pathogen transmission risk. Users should wash hands thoroughly with soap and water after handling the meter and microcuvette.

Note: A new pair of gloves should be worn when testing each specimen and control soluiton.

Please follow standard precautions and practice guidelines for drawing and handling blood specimen. For example:

1. *Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/bmbl5/*
2. *"Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.*

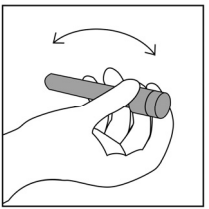
For Venous Whole Blood Specimens

Always handle specimens with care, as they might be infectious. Always wear protective gloves when handling blood specimens.

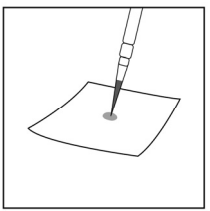
- Venous whole blood should be collected only by professionals.
- EDTA or heparin anticoagulants can be used to when collecting venous whole blood specimen.
- Venous whole blood specimen with EDTA or heparin anticoagulants can be stored in a cool, dry area at 2-30°C (35.6-86°F) for 24 hours. Store them away from heat and direct sunlight.
- Do not freeze. Frozen blood specimen is severely lysed and may lead

to incorrect results.

- Some venous whole blood specimens are easily lysed. A red color present in the plasma is a clear indication of blood lysis. If the red color is present, do not use the specimen for testing. Collect a new specimen and conduct the test immediately or within a shorter period of time.
- If the specimen has been stored in a refrigerator, allow it to warm up to 10-40°C (50-104 °F) before mixing. The blood should be well mixed for at least 15 minutes prior to testing.



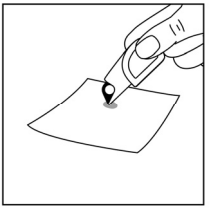
- Place at least 10 µL of blood onto a hydrophobic surface or glass slide.

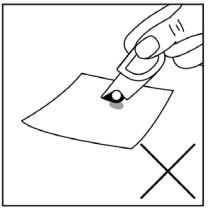


- Fill the microcuvette in one continuous process. Wipe off excess specimen from the outside of the microcuvette with a clean, lint-free wipe. If a second specimen needs to be taken, it is important that this be done after the first specimen has been tested.

  Note:

  1. ***DO NOT refill or reuse the microcuvette.***
  2. ***Do not touch the optical eye of the microcuvette.***

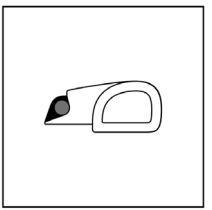




Correct **Incorrect**

- Check if air bubbles are present in optical eye of the microcuvette.

  Note: If air bubbles are present, discard it and fill a new microcuvette with a new drop of blood specimen. Small bubbles around the edge can be ignored.

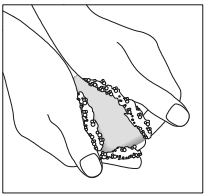


Note: Refer to NCCLS Documents H3-A6, Collection of Diagnostic Blood Specimens by Venipuncture.

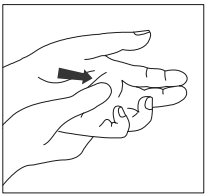
For Fingertip Blood Specimens

The *Mission*® *HemoPro* Hemoglobin Meter requires a very small drop of blood which may be obtained from the fingertip. Before testing, select a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed.

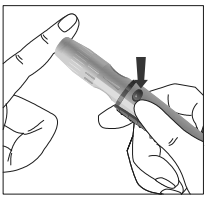
***Note*:** Prior to obtaining the blood specimen, wipe the patient's fingertip with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Then dry the hand and test site thoroughly. Make sure there is no cream or lotion on the test site.

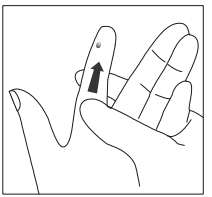


1. Prior to obtaining the blood specimen, make sure the patient‘s hand is warm and relaxed before collecting the capillary blood specimen. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.



2. Blood specimens are obtained by using the lancing device with lancets or safety lancets. Gently massage from the base of the finger to the tip of the finger to obtain the first drop of blood.



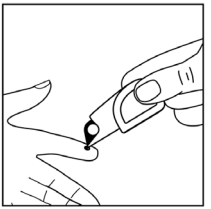


3. Wipe away the first drop of blood. Re-apply light pressure towards the fingertip until another drop of blood appears.
4. When the blood drop is large enough, fill the microcuvette in one continuous process. Wipe off excess specimen from the outside of the microcuvette with a clean, lint-free wipe. If a second specimen needs to be taken, it is important that it be done after the first specimen has

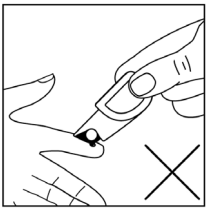
been tested.

Note:

1. ***DO NOT refill or reuse microcuvette***
2. ***Do not touch the optical eye of the microcuvette.***



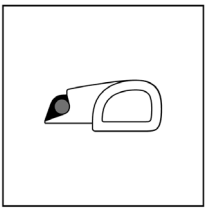
Correct



Incorrect

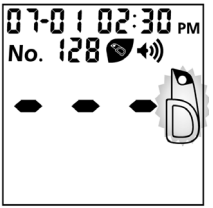
5. Check if air bubbles are present in optical eye of the microcuvette. Small bubbles around the edge can be ignored.

   Note: If air bubbles are present, discard it and fill a new microcuvette with a new drop of blood specimen.

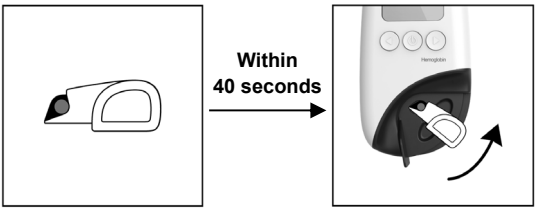


Step 2 - Testing for Hemoglobin

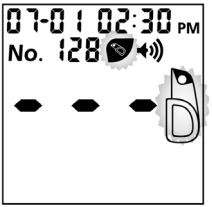
1. To perform a test, the microcuvette holder on the meter should be in its loading position. The display will show three dashes, a holder symbol and a flashing microcuvette symbol. Remove a microcuvette from the canister.



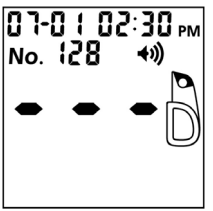
2. Perform the “Step 1 – Collecting Blood Specimen” mentioned above.
3. Place the filled microcuvette in the microcuvette holder and start the test within 40 seconds after filling.



4. When the microcuvette holder is gently pushed into the loading position, the holder symbol will flash, and the holder will automatically enter the internal test area of the instrument.



5. When the microcuvette holder reaches the testing position, the holder symbol will disappear and the microcuvette symbol will stop flashing, then the meter will start the test.

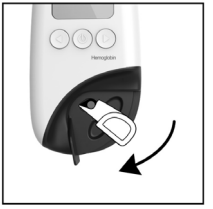


6. After approximately 2 seconds, the Hemoglobin and HCT values will be displayed. The result will remain on the display as long as the microcuvette holder is in the testing position. Do not retest the microcuvette. When operating on a battery-powered meter, if there is no operation within the set sleep time, the meter will automatically shut down.

Note: Always handle blood specimens with care, as they might be infectious.

Step 3 - Completing the Test

Discard the Microcuvette after testing as well as the lancets or safety lancets. Consult local environmental authorities for proper disposal.



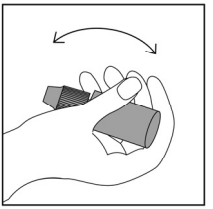
Section 7 Quality Control

Mission® *HemoPro* Hemoglobin Control Solution is used to confirm that your *Mission*® *HemoPro* Hemoglobin Meter and *Mission*® *HemoPro* Hemoglobin Microcuvette are working properly. The control solution also confirms that the test is being performed correctly. It is important to run a quality control test regularly to make sure test results are accurate.

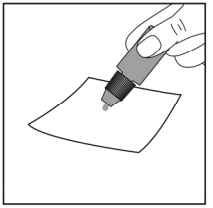
Please make sure the meter, microcuvette and control solution are placed at 10-40°C (50-104 °F) for at least one hour before testing.

QC Test

1. If the control solution has been stored in a refrigerator, allow it to warm up to 10-40°C (50-104 °F) before mixing. The control solution should be well mixed for at least 15 minutes prior to quality control testing.



2. Place at least 10 µL of control solution onto a hydrophobic surface or glass slide.

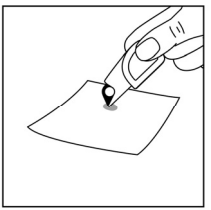


3. Fill the microcuvette in one continuous process. Wipe off excess control solution from the outside of the microcuvette with a clean, lint-free wipe. If a second QC test needs to be run, it is important that this be done after the first QC test has been completed.

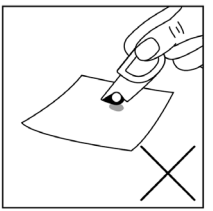
Note:

1. DO NOT refill or reuse the microcuvette.

2. ***Do not touch the optical eye of the microcuvette.***



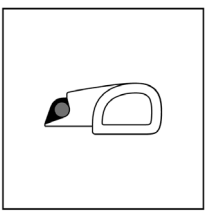
Correct



Incorrect

4. Check if air bubbles are present in optical eye of the microcuvette. Small bubbles around the edge can be ignored.

   Note: If air bubbles are present, discard it and fill a new microcuvette with a new drop of control solution.



Perform the test as instructed in Section 6 **Testing**. See the control solution package insert for more details.

QC Requirement

It is recommended that each laboratory should establish its own normal value range. Test known specimens/control solution at each of the following events in accordance with local, state, and/or federal regulations or accreditation requirements with different reference ranges in different regions and ethnic groups.

- When you suspect that the meter or microcuvettes are not working properly.
- When you suspect that your test results are inaccurate.
- If you suspect your meter is damaged.
- After performing maintenance or service on the meter.

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

- Check the expiration date of the Microcuvette and Control Solution. Make sure that the Microcuvette and the Control Solution are used within their expiration date.
- Make sure the Microcuvette canister and the Control Solution vial have been tightly capped.
- Confirm that you are using *Mission*® *HemoPro* Hemoglobin Control Solution.
- Make sure you followed the test procedure correctly.
- Make sure you are testing at a temperature between 10-40°C (50-104°F).

For customer/technical support, please contact your local distributor.

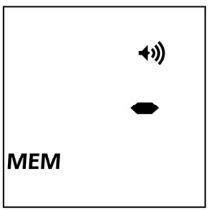
Section 8 Data/Communication

Memory/Database

From the Initial Screen (refer to Section 5 **Meter Setup and Options**), 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 in the memory the meter will display ***dash*** (**-**) and ***MEM***.



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 *Mission*® Clinical Information System software installed to receive and process the data transmitted from the meter.

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

Press ⏻ to transmit data to the external connected PC.

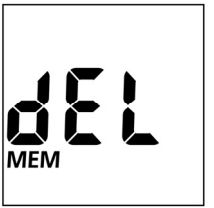
After data transmission has completed, the meter will return to the Setup Menu.

Note: Up to 1,000 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 1,000 records are stored in memory, the next test result (1,001) will replace the first result (1) and store it in memory.

Delete Data

To delete all data from the meter database, enter the Setup Menu (refer to Section 5 **Meter Setup and Options**). 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.

Section 9 Maintenance

Proper maintenance is recommended for accurate results.

Cleaning

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

Meter Surface

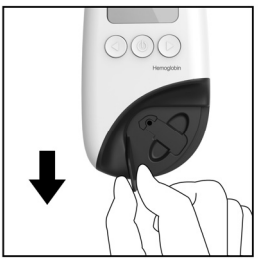
A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary.

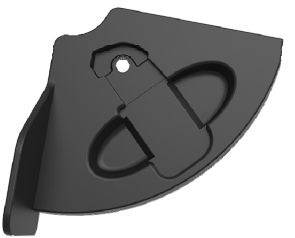
A dry, soft cloth may be used to clean the LCD and the sensor area.

Take care to avoid getting liquids, residue, or control solutions in the meter through the **Microcuvette Holder** or **USB Port**.

Microcuvette Holder

When the meter is turned off and the holder is in the specimen loading position, the holder can be pulled out with a slight downward pulling motion. Clean it with a dry, soft cloth and push it into the meter again.





Note: If necessary, use a soft cloth dipped in fresh water or maximum 75% alcohol to clean Meter Surface and Microcuvette Holder. Do not use gasoline, paint thinner and other organic solvents. This will cause damage to the meter.

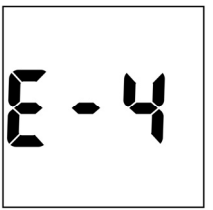
Meter Sensor Area

Remove the Microcuvette **Holder** as described in the previous section. Wipe down the **Meter Sensor Area** with a lint-free cotton swab. Do not scratch the transparent window covering the sensor.

Note: Do not use any organic solvents to clean the **Meter Sensor Area**, such as alcohol or paint thinner. This will cause damage to the meter.
For customer/technical support, please contact your local distributor.

Replacing the Batteries

When the battery icon  is flashing, the batteries are 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 batteries are replaced.



Make sure the meter is off before removing the batteries. Turn the meter over and 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 according to local regulations. Insert 4 AAA batteries and make sure these batteries are installed in the correct position.

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 with household waste. Follow local regulations for disposal.

Section 10 Precautions

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

- The protective features provided by this product 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 conditions. 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 to clean the meter surface if needed. Do not get water or other liquids inside the meter.
- Do not clean the LCD or sensor area with water. Lightly wipe with a soft, clean and dry cloth.
- The microcuvette holder must be kept clean. Lightly wipe with a soft, clean, dry cloth each day. Use fresh water to clean the microcuvette holder if needed. Refer to Section 9 **Maintenance**.
- Do not clean the unit with substances such as gasoline, paint thinner or other organic solvents to avoid any damage to the meter.
- Follow all local regulations when discarding the unit or its accessories.
- Any serious incident that has occurred in relation to the meter shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- Do not use the unit or the microcuvette outside the operating temperature ranges listed below.

  Meter: 0-40 ºC (32-104 ºF) ; ≤90% RH

  Microcuvette: 10-40 ºC (50-104 ºF) ; 5%-90% RH

Preventive Warnings Regarding EMC

1. This meter has been tested for compliance with regard to electrostatic discharge as specified in IEC 61000-4-2. However, use of this meter in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that could cause erroneous results.
2. This meter complies with the emission and immunity requirements described in EN 61326-1 and EN 61326-2-6. Do not use this meter in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the meter.
3. This meter is for professional use. The electromagnetic environment should be evaluated prior to operation of this meter.

Section 11 Troubleshooting

Display	Causes	Solution
E-1	Data processing unit error	Turn off and restart the meter. If the error still appears, please contact your local distributor.
E-2	The microcuvette holder was pulled out before the test finished.	Pull out the microcuvette holder after test result is displayed.
E-3	The meter or microcuvette shakes during the testing process	Place the meter on a fixed horizontal surface for testing, and do not touch the microcuvette holder after it enters the testing position.
	Batteries are discharged but only have 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 USB Adapter, then repeat the test.
E-5	Abnormal self-check of optical path.	Turn off and clean the meter sensor area. Refer to **Section 9 Maintenance**. Then restart the meter and perform Optical Path Initialization. Refer to **Section 4 Meter Setup and Options**. If the error still appears, please contact your local distributor.
E-6	Holder position sensor abnormal.	Turn off and restart the meter. If the error still appears, please contact your local distributor.
HI	The test result is higher than 26 g/dL (260 g/L or 16.1 mmol/L).	If the specimen is taken from a specimen container, ensure the specimen is mixed well and repeat test.

For customer/technical support, please contact your local distributor.

Section 12 Performance Characteristics

The *Mission*® *HemoPro* Hemoglobin Meter is calibrated with a automated hematology analyzer, which is traceable to the ICSH recommend international reference method.

Linearity

Ten replicate assays were drawn from three microcuvette lots and tested on the Hemoglobin Meter (y), using 12 concentration levels of EDTA-K2 preserved venous whole blood specimens. The same specimens were also tested by using a market leader automated hematology analyzer (x). Linearity results are presented below:

Microcuvette Lot	Equation	R^2
Lot 1	y = 0.9969x - 0.9798	0.9993
Lot 2	y = 0.9932x - 0.5521	0.9990
Lot 3	y = 0.9968x - 0.7914	0.9993

Precision

Fifty replicate assays were tested by using Hemoglobin meters. EDTA preserved venous whole blood specimens at three concentration levels were used with three microcuvette lots, producing the following within-run precision and total precision. Within-run precision and total precision were determined using whole blood specimens and statistical analysis, which provided the average and coefficients of variation (CV) listed below:

Microcuvette Lot	/	83 g/L (n=50)	131 g/L (n=50)	192 g/L (n=50)
Lot 1	Average	83	133	194
	CV	1.7%	1.6%	1.2%
Lot 2	Average	83	134	194
	CV	1.5%	1.2%	1.2%
Lot 3	Average	83	133	194
	CV	1.4%	1.3%	1.3%
Total precision	Average	83	133	194
	CV	1.6%	1.4%	1.2%

Accuracy

Venous whole blood specimens with EDTA-K2 anticoagulant and fingertip capillary blood specimens were collected from separate subjects. All specimens were tested with automated hematology analyzer and *Mission*® *HemoPro* Hemoglobin Microcuvette on *Mission*® *HemoPro* Hemoglobin meters. The summary of the test results is presented below

Linear regression of meter reading (y) versus reference value (x) with venous blood specimens				
Test item	Slope	Intercept	R^2	N
Hemoglobin	1.0083	-0.477	0.9975	98
Linear regression of meter reading (y) versus reference value (x) with fingertip capillary blood specimens				
Test item	Slope	Intercept	R^2	N
Hemoglobin	0.9848	1.5476	0.9812	55

Appendix 1 Specifications

Feature	Specifications
Methodology	Spectrophotometry
Specimen	Capillary and Venous whole blood
Specimen Volume	10 μL
Measurement Time	<2 seconds
Hb Measurement Range	0-26 g/dL (0-260 g/L or 0-16.1 mmol/L)
Hematocrit (HCT) Range	0-76%
Units of Measure	g/dL, g/L, mmol/L
Memory	1,000 records
Power Source	4 AAA batteries (1.5V) Powered by PC or standard USB adapter (output: 5V, 1000mA) through USB cable
Battery Life	Standby for 360 hours in sleep mode and 2,700 tests
Automatic Shut Off	5-60 minutes without activity
Meter Size	150*70*40 mm (5.9*2.76*1.57 inch)
Display Size	53*53 mm (3 inch)
Weight	270 g (without batteries)
Meter Storage Conditions	-20 - 55 ºC (-4 -131 ºF); ≤90% RH
Operating Conditions	0 - 40 ºC (32 -104 ºF); ≤90% RH (non-condensing)
Meter Connectivity	USB cable for data transfer and power supply

Appendix 2 Index of Symbols

	Consult instructions for use or consult electronic instructions for use.	IVD	*In vitro* diagnostic medical device
REF	Catalogue Number	SN	Serial Number
#	Model Number		Temperature Limit
	Manufacturer		USB Port
LOT	Batch code		Do not discard along with household waste
	Date of manufacture	EC REP	Authorized representative in the European Community/European

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 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-year 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 microcuvettes other than microcuvettes 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.

Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within 30 days of purchase. Refer to **Appendix 3 Warranty** in the Instruction Manual for details and terms of the product warranty.

Date of Purchase	Purchaser	Meter Serial Number (e.g. SN 0000000. See label on back of meter)
Organization Name		Address
Telephone Number		Email Address