

# **URIT-12 Hemoglobin Meter Operating Manual**



 **URIT Medical Electronic Co., Ltd**

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# URIT-12 Hemoglobin Meter

## Operating Manual

For in vitro diagnostic use

### Chapter One: Introduction

URIT-12 Hemoglobin Meter is designed for use only with H12 Hemoglobin Test Strip from URIT Medical Electronic Co., Ltd, for the quantitative measurement of total hemoglobin in capillary and venous whole blood.

Hemoglobin is the oxygen-carrying protein in red blood cells. The quantitative measurement of hemoglobin is indicated and clinically useful in acute illness as well as in general care. The normal range hemoglobin values reported in medical literature are gender and age dependent:

Adult males            13.5 ~ 18.0 g/dL

Adult females        12.0 ~16.0 g/dL

Infants                Ranging from 14.5 ~ 22.5g/dL after birth to 11.1 ~14.1g/dL at 6 months old.

Children              Gradually increase from infant to adult levels.

Low hemoglobin levels may indicate condition such as anemia or hemorrhage. Elevated hemoglobin levels may indicate conditions such as polycythemia. A hemoglobin test may be used as part of a general screen for many types of patient populations, including the elderly, children, and women of child-bearing age, and prior to giving or receiving transfusions. Due to differences among patient populations, we recommend that each clinical site establish its own reference ranges.

People use Hemoglobin Meter with the whole blood for local inspection or tending, which is helpful for evaluating patients' symptom quickly and providing proper treatment determination.

When test result is different from clinical symptom, repeat test. If there are still some problems, validate it by control or compare hemoglobin test methods with that of other labs.

Judge the clinical signification of test result by following the doctor's direction. Prior to any medication, treatment should be provided by doctor based on test result and clinical symptom.

### Chapter Two: Technical Specifications

Parameter: Hemoglobin in fresh whole blood

Measuring Principle: Optical reflectance

Strip: H12 Hemoglobin Test Strips

Measuring time: Less than 30 seconds

Measuring range: 4.0g/dL ~ 24.0g/dL. Results under 4.0g/dL and over 24.0g/dL will display as "Lo" and "Hi" respectively so as to indicate the result which is out of range.

Display: LCD, test result displaying in SI

Weight: < 58g (Battery included)

Outer dimension: 102mm×50mm×19mm

Power: DC 6V (Two CR2032 Battery)

Operating Ranges: 15 ~ 30°C; RH ≤80% non-condensing

Ultimate Ranges: -20 ~55°C ; RH < 90% non-condensing

Others: Internal trouble check and display

Available life: 8 years

### **Chapter Three: Principal of Operation**

The hemoglobin meter utilizes optical reflectance for determination of the total hemoglobin. The test strip is inserted into the meter when prompted, a background blank reading is automatically determined. A drop of whole blood is applied to the test spot on the strip, blood immediately disperses within the membrane, contacting the reagent, then reaction product could absorb spectrum in the range of 500nm-600nm. The meter's optical detector automatically measure the change in membrane reflectance. The intensity of reflectance is inversely proportional to the hemoglobin concentration. The meter calculates and displays the total hemoglobin concentration in gram/deciliter (g/dL) in 30 seconds based on a mathematical conversion.

### **Chapter Four: Blood Sample Collection**

1. Fresh capillary or EDTA-anticoagulated venous whole blood may be used.
2. If an EDTA-treated sample is refrigerated, allow it to come to room temperature prior to use. EDTA-treated blood samples should be mixed using end to end inversions at least 8 times prior to use, and should be tested within 24 hours.
3. For fresh venous whole blood samples, collect approximately 0.1mL into an anticoagulant-free plastic syringe.

### **Chapter Five: Note**

1. URIT-12 Hemoglobin Meter is for in vitro diagnostic use only.
2. URIT-12 Hemoglobin Meter is designed for use only with H12 Hemoglobin Test Strips from URIT Medical Electronic Co., Ltd. Prior to the first use of test strips, read the Manual carefully and input the Lot Code to the meter.
3. Insufficient blood sample volume and inadequate mixing of EDTA-treated samples may affect results.
4. As all diagnostic tests, test results should be evaluated according to the specific patient's condition. Any results demonstrating the inconsistency with the patient's clinical status should be repeated or supplemented with additional test data.
5. In order to test the hemoglobin accurately, please use and maintain the meter correctly. Review this manual prior to the first use of the meter.
6. While the test is in progress, do not disturb or move the meter or strip, even press any key.

7. Over strong electromagnetic wave will disturb its work. We recommend you to keep the distance between meter and microwave oven over 2 meters when you test in the room.
8. Over high temperature and humidity will affect its working. We recommend you not to use it in the sauna or bathroom.
9. Use it at the temperature of 15°C~ 30°C.
10. Avoid any liquid permeating the meter anytime.



**Warning:**

1. Blood plasma and serum should not be used as sample. No accurate result will be obtained if using arterial blood as sample.
2. Other than EDTA are not recommended for use, such as sodium citrate and heparin.

## Chapter Six: Appearance and function

### 1. Appearance:

The meter is composed of keys, LCD, circuitry board, optic system, strip holder, cover and battery. See the picture of appearance as follows:



### 2. Function:

**Power switch:** Turn meter on and confirm key (turning meter off is confirmation)

**▲ key:** up

**▼ key:** down.

**Strip holder:** hold strips

**SET key:** set function (under the strip holder, refer to Chapter Seven)

## Chapter Seven: Setting

### 1. Setting Meter Options

Prior to the first use of URIT-12 Hemoglobin Meter, the user must enter the following settings:

- Time and date format.
- Current time and date.

## 2. Entering Settings

Step 1: Lift the test strip holder off the meter.

Step 2: Turn the meter on by pressing the **Power switch** key. Wait until the meter displays the Lot Code, time and date.

The meter can now be customized for time and date format, current time and date.

## 3. Selecting Time and Date Format:

The user can select either display time and date in a 12-hour AM/PM time clock with mm/dd date format or in a 24-hour time clock with dd/mm date format.



**Note:** The date format only contains day and month, not year.

Step 1: Press the SET key once the date and time will display. Press and hold the SET key again until the time and date flash.

Step 2: Press the ▲ or ▼ key to select date format.

Step 3: Pressing the SET key as that step 2 in point 4 below to enter the current time and date. If entering the current time and date is not required, and then turn the meter off to accept the selected time and date format.



**Note:** Once accepted, the time and date format will be changed for all stored test results.



## 4. Entering Current Time and Date:

The user must enter the current time and date for correct stamping of test results. If proceeding from Select Time and Date Format instructions above, go directly to Step 2. Otherwise, start from Step 1.

Step 1: Press and hold the SET key until the time and date flash. Press the SET key again.

Step 2: The hour (with AM/PM if 12 hr format selected) will flash. Press the ▲ or ▼ key to enter the hour. Press the

**SET** key to accept.

Step 3: The minute will now flash. Press the ▲ or ▼ key to enter the minute. Press the **SET** key to accept.

Step 4: The first date selection will flash (**mm** or **dd**). Press the ▲ or ▼ key to enter the first date selection. Press the **SET** key to accept.

Step 5: The second date selection will flash (**dd** or **mm**). Press the ▲ or ▼ key to enter the second date selection. Press the **SET** key to accept.

Step 6: Turn the meter off to accept the entering time and date.



**Note:** Once accepted, the reporting unit will be changed for all stored test results. Once selection of meter settings has been completed, replace the strip holder onto meter.

## 5. Saving Test Results

URIT-12 Hemoglobin Meter automatically stores 250 test results with a date and time stamp. Upon storage of more than 250 test results, the oldest test result is automatically erased. Test results are stored in ascending chronological order: The first test result displaying (sequence 001) is the newest test result, and the last test result displaying (up to sequence 250) is the oldest test result. A test result is stored automatically when the meter shuts off (either by pressing the key or automatic shutoff after two minutes of inactivity).

## 6. Viewing Saved Test Results

Step 1: Turn the meter on by pressing the **Power switch** key. Wait until the meter displays the Lot Code, time and date. Press the ▲ key to display the test result and its sequence number (a flashing MEM will display to the lower left of the test result). After releasing the key, the test result with its time and date and a flashing MEM will display.

Step 2: Continue pressing the ▲ or ▼ key to scroll through test results.

Step 3: Turn meter off to exit the memory.

## 7. Deleting Test Results

Test results could be deleted by following two methods: deleting the recent results by CLE or deleting all results by CLA.

User could turn the meter off to stop deleting test results before MEM displays.

Step 1: Lift the strip holder, turn the meter on. Wait until the meter displays the Lot Code, time and date.

Step 2: Press **SET** key twice, CLE displays.

### Delete the recent results:

Step 3: Continue pressing **SET** key till CLE flashes. Release **SET** key, the last result will display. To delete this result, keep holding **SET** key and the result will flash and then be deleted.

### Delete all results:

Step 4: Press **SET** key one more time, CLA will display. Hold pressing SET key, CLA flashes, Release **SET** key, ALL will display. Continue pressing **SET** key, all the results will be changed into MEM ---.

After completing all steps, turn off the meter and cover the strip holder.



**Note:** If you want to exit CLE without deleting test results, you can shut off the meter directly.

## **Chapter Eight: Operation**

### **1. Turn the meter on**

Press the **Power switch** key to turn the meter on. The meter automatically monitors its internal circuitry and components during a brief self-check. The meter is ready when the test strip prompt, Lot Code and time/date are displayed.



**Note:** To conserve the battery, the meter will automatically shut off after 2 minutes of inactivity. If this happens, turn the meter on again.

### **2. Input Lot Code Strip**

Change the numbers as follows:

- 1) Press the **Power switch** to turn the meter off
- 2) Insert code card with the Strips correctly into the **Code slot**. Press the **Power switch** to turn the meter on, the meter will read the code automatically and display the code on the screen. After read code, the meter automatically turn off.
- 3) Remove the code card. Turn the meter on again, after check whether the code is match, accept a test.

### **3. Prepare for a Finger stick**

Make sure the patient's hand is warm and relaxed. Massage the patient's middle or ring finger from the knuckle up to the tip to stimulate blood flow. Clean the sample area with alcohol and wipe dry with a sterile gauze pad.

### **4. Prepare the Test Strip**

Take a test strip from its container. Examine the test strip. Do not use if there are tears, wrinkles or debris. Do not touch the test spot membrane. Reseal remaining test strips in the original container.

### **5. Insert the Test Strip**

Insert the test strip into the strip holder with the notched end in first and the hole facing up. The notched end on the top of the strip should no longer be visible when the test strip is inserted correctly and fully.

### **6. Prepare the Meter for Sample Application**

The meter will automatically perform a background blank reading. It will display a flashing prompt to indicate that it is ready to test a sample. The meter will allow 2 minutes for application of the blood sample.

### **7. Perform a Finger stick**

Incise the underside of the fingertip. Avoid "Milking". Apply light pressure to obtain one drop of blood.

### **8. Apply Blood Sample to the Test Strip**

Immediately apply a drop of blood to the test strip by touching the hanging blood drop to the test spot, ensure the blood drop is large enough to completely cover the test spot. A capillary transfer pipe may also be used to transfer the blood sample from the finger to the test strip.





**Note:** This product is used for testing human blood, user must prevent against possible blood infection.

- A drop of blood (refer to the instruction of Strips for detail)
- Do not use strip to touch blood, test strip must be fixed on the meter. Apply only the hanging blood to the test spot.
- Do not touch directly the test spot membrane by finger.
- Do not apply superfluous blood; the volume just covering the spot completely is enough.
- Do not apply blood on the spot obtaining blood repetitiously. Each strip is used for one test.

#### **Read Result**

The blood sample will spread and the meter will automatically begin the test. During the test, do not disturb or move the meter or strip, even press any key of meter.

The test result will be displayed in in less than 30 seconds.

After the test is completed, remove the test strip and check whether the test strip spot is covered by blood sample completely or not. Otherwise, the test result is not accurate, please test again.

After the test is finished, the meter will automatically shut off after 2 minutes of inactivity, or can be turned off by pressing the **Power switch** key. The test result will be stored automatically with its date and time.

#### **9. Disposal**

The waste should be disposed strictly according to reference requirement of local Medical Sanitary Management Department. Do not throw it optionally.

#### **10. Reportable range**

The reportable range for hemoglobin is from 4.0 g/dL to 24.0 g/dL. Results under 4.0g/dL and over 24.0 g/dL will display as “Lo” and “Hi” respectively to indicate the result out of range.

#### **Chapter Nine: Trouble-shooting**

<b>Trouble code &amp; phenomenon</b>	<b>Possible Cause</b>	<b>Correction</b>
E0, E1	Hardware or software error	Turn off and on again. If the error still exists, please contact the local distributor.
	Meter used in bright sunlight	Bright sunlight disturbs optic system of meter. Used it in room-light or shade. Turn off and on again. Repeat test with new test strip.
	Temperature out of Range	Allow meter to adjust to temperature declared in the Manual and wait until it shake down. Turn off and on again. Repeat test with new test strip.

E2	Removing the strip with sample before testing	Do not remove test strip till finishing the test. Turn off and on again. Repeat test with new test strip.
	Insufficient Sample Volume	Remove the test strip and shut off. Turn on and repeat test with new strip. Confirm the blood is sufficient.
	Strip is damaged	Remove the test strip and shut off. Turn on and repeat test with new strip. Confirm there are not tears, wrinkles or debris.
	Incorrect blood sample	Do not use other blood sample, such as plasma. Repeat test with the correct blood sample: fresh or EDTA-anticoagulated whole blood.
E4	Damaged Strip Inserted	Remove the test strip and shut off. Turn on and repeat test with new strip. Confirm there are no tears, wrinkles or debris.
	Optical detector needs cleaning	Remove strip holder and clean lenses following the direction.
	Optical detector does not read the background blank	Before finishing the background blank reading, do not apply blood sample. Do it until displaying a flashing prompt.
	Optical detector is clogged	Check the Optical detector, whether it is covered by blood or others, if yes, remove the strip holder and clean it. Refer to the Manual.
	Used strip Inserted	Remove the test strip and shut off. Turn on and repeat test with new strip.
	Inserted strip error	Review the instruction of Insert Strip. Remove the test strip and shut off. Turn on and repeat test with new strip.
	Set strip holder error	Remove strip holder and reset. Push it to the end. Do not use if it is loose or skew.
Immediately shut off once turn on or during the operation process	Replace battery	Replace battery referring to the Manual.
	Move the strip during the test	The meter will turn off automatically in 4 seconds if the strip is moved. Repeat test with new strip.

## Chapter Ten: Maintenance

### 1. Routine maintenance and cleaning

The cleaning must be done after applying superfluous blood sample every time. Hold the bottom of meter with left hand

and lift holder, then the strip holder could be removed and cleaned. Wipe away the rest blood or dirt left on the holder or meter using gauze with disinfectant (diluting 10% home bleacher, about 0.6% hypochlorite).

If there is superfluous blood on the optical detector, clean it by cotton sticker with little detergent. Wipe the strip holder and optical detector completely by cotton cloth without hemp. Avoid any liquid permeating the meter anytime.

Do not polish the surface of optical detector with any polished or corrosive detergent to avoid the damage of meter and optical detector. After cleaning, put the strip holder and display in a level, and press arc segment, the holder could be set back.

## 2. Battery replacement

Open the battery cover, take the battery out of gap, replace two new CR2032 battery, cathode is facing down, insert it into battery container, and press it down, close the cover.

### Chapter Eleven: Meaning of Markings



In vitro diagnostic medical device



Caution! Refer to accompanying documents



Biological Hazard!



Serial number



Direct current

CR2032



Use CR2032 as power supply



Manufacturer

Authorized representative in the European Community



Recovery



Protect from heat and radioactive sources



This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

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