CONTENT

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 hemoglobin in capillary and venous whole blood.

According to the conversion between normal average hemoglobin concentration and haematocrit(HCT), URIT-12 Hemoglobin Meter can obtain the hint of HCT base on determined hemoglobin concentration. 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 treatm-

ent 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.

⚠️Warning:

Please read this manual carefully before using URIT-12 Hemoglobin Meter.

1. URIT-12 Hemoglobin Meter is for in vitro diagnostic use only.

2. Insufficient blood sample volume and inadequate mixing of EDTA-treated samples may affect results.

3. 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.

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 before the first time using 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 field 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℃~30℃.

10. When equipment is at work, please do not look directly at light source.

11. Avoid any liquid permeating the meter anytime.

Chapter 2: Technical Specifications

Parameter: Hemoglobin in fresh whole blood.

Measuring Principle: Optical reflectance.

Strip: H12 Hemoglobin Test Strips.

Measuring time: Less than 12 seconds.

Haematocrit (HCT) hint: Display in percentage.

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

Display: LCD, test results display in SI.

Storage function: Save the strip code, memorize and update 250 test results automatically.
Correction function: self-correction.
Weight: < 58g (Battery included).
Outer dimension: 102mm×50mm×19mm.
Power: DC 6V (Two CR2032 Battery).
Operating Ranges: 15~30℃;RH≤80% non-condensing.
Ultimate Ranges: -20~55℃;RH<90% non-condensing.
Others: Internal trouble check and display.
Available life: 8 years.

Chapter 3: 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 12 seconds based on a mathematical conversion.

Chapter 4: 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.

1. Appearance:

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

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 6)

Chapter 6: Setting

1. Meter Options Setting

Before the first time using 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.

Now the meter can be customized for time and date format, current time and date.

3. Time and Date Format:

The user can select both 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 including 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 step 1 and 2 to enter the current time and date. If entering the current time and date is not required, and then turn the meter off to confirm the selected time and date format.

⚠️ *Note:* Once confirmed, 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 confirm.

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

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

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 confirm.

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

⚠️ *Note:* Once confirmed, 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. If the storage is more than 250 test results, the oldest test result would be automatically erased. Test results are stored in ascending chronological order: The first test result on the screen (sequence 001) is the newest test result, and the last one (up to sequence 250) is the oldest test result. A test result will store automatically when the meter shuts off (both 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 this function.

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:

Step4: 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 witho- ut deleting test results, you can shut off the meter directly.

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 prompts, 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 of the Test Strip

Input the lot code as follows:

1) Press the **Power switch** to turn the meter **OFF.**

2) Insert the code card correctly into the **C-ode slot**. Press the **Power switch** to turn the meter **ON**, the meter will read the code card automatically and display the code on

the screen. The meter will automatically turn **OFF**.

3) Remove the code card. Turn the meter **ON** again. Please verify the displayed code is match the code printed in the label of container which the test strips will be taken from.

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.

9. Read Result

The blood sample will spread and the meter will automatically begin the test. During the test, do not disturb or move the met-

er or strip, even press any key of meter.

The test result will be displayed 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**.**

10. Disposal

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

11. Reportable range

The reportable range for hemoglobin is from 4.0 g/dL to 24.0 g/dL. Results under 4.0g/dL or over 24.0 g/dL will display as "Lo"

or "Hi" respectively to indicate the result out of range.

Chapter 8: Trouble-shooting

Troublecode& phenomenon	Possible Cause	Correction
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 optical system of meter. Used it in room-light or shade. Turn off and on again. Repeat test with new test strip.
E2	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.

	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.

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 (diluenting 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 optic-

al 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 10: Meaning of Markings

IVD In vitro diagnostic medical device

⚠️ Caution! Refer to accompanying documents

☣️ Biological Hazard

SN Serial number

$=\!=\!=$ Direct current

CR2032 Use CR2032 as power supply

Manufacturer

EC REP   Authorized representative in the
          European Community

Recovery

Protect from heat and radioactive
sources

$C\,\epsilon$ This product fulfils the requirements of
          Directive 98/79/EC on in vitro iagnostic
          medical devices