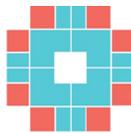


*TRUEHb* HEMOMETER

Instructions for Use



**Wrig Nanosystems Pvt. Ltd.**

Please read this manual carefully before using **TRUEHb** Hemometer

### **TrueHb Hemometer System**

This TrueHb Hemometer Kit includes:

- a) TrueHb Hemometer
- b) TrueHb control strip
- c) TrueHb Lancing Device
- d) TrueHb User manual
- e) Warranty card

If any item(s) is (are) found to be missing in the kit or if any visible damage in any item in the box is found, please contact us at [info@truehb.com](mailto:info@truehb.com).

### **Intended use**

The TrueHb Hemometer is intended to be used for the quantitative measurement of hemoglobin in fresh capillary whole blood samples taken from the forearm, upper arm, hand, thigh, calf, or fingers. The TrueHb Hemoglobin Monitoring System is intended for use outside the body (in vitro diagnostic use) by healthcare professionals and individuals. It should not be used for diagnosis of diseases or for/on newborns.

### **Test principle**

The TrueHb Hemometer System is based on the principle of reflectance photometry. A drop of blood is applied to the strip. It disperses within the hydrophilic mesh. The hemoglobin is extracted out from the RBC and is converted into a proprietary complex with the help of proprietary set of reagents, present in the strip. The TrueHb meter measures optical reflectance at the test zone of the strip. The optical reflectance is inversely proportional to the concentration of hemoglobin in the blood sample. Using this correlation, the concentration of total hemoglobin in the whole blood sample is calculated.

### **For accurate results:**

- Read instructions carefully before use
- The TrueHb Hemometer must only be used with genuine TrueHb Hemometer Test strips and TrueHb control strips.
- Test only venous or capillary whole blood specimens. EDTA or heparin anticoagulants can be used for stored blood samples.

### **Introduction**

Hemoglobin is a protein present in the red blood cells (RBCs). It is primarily associated with the transport of oxygen from lungs to different parts of the body.

Since total hemoglobin level in blood guides many clinical diagnosis and therapeutic interventions, total hemoglobin is one of the most frequently ordered laboratory tests.

Serial assessments are often made to track disease progression, blood loss and efficacy of the therapies involving restoration of hemoglobin levels to normal. Total hemoglobin level screening required for blood donors in blood banks, blood transfusion patients, dialysis patients, biliary patients, etc.

The TrueHb meter can be used for measuring Hb from samples taken from fingers, heels, forearms, upper arms, hands, thighs, or calves.

### **Normal Hemoglobin Levels**

The normal hemoglobin range (anything below or above range is low or high hemoglobin respectively) is indicated as follows:

Adult Males 13.5-18 g/dL

Adult Females 12-16 g/dL

### **Important information**

- We recommend taking blood samples from the tips of your fingers
- Severe dehydration, and excessive water loss may cause falsely elevated results.
- TrueHb meter contains small parts that may be dangerous if swallowed.

- Keep the TrueHb device and TrueHb strips out of children’s reach
- As per medical experts, one must avoid donating blood in case his/her hemoglobin level is under 12.5g/ dL.

**About TrueHb Meter**



**Display Screen:** Displays your test results, date, time, etc.

**Right, Left, Up, and Down Buttons:** To move among displayed items

**On/Off/Select button:** To turn the meter on and off, and to select displayed items.

**Test Strip Slot:** For inserting the test strip

**Mini-USB Charging Port:** For charging the battery

**Display Indications:**

**DD-MM:** Shows date and month

**Batch code:** Indicates the code number of test strips.

**Battery Symbol:** Indicates the battery level

**Strip Symbol:** Indicates when to insert test strip

**Blood Drop Symbol:** This symbol appears when the meter is ready for you to apply a blood drop.

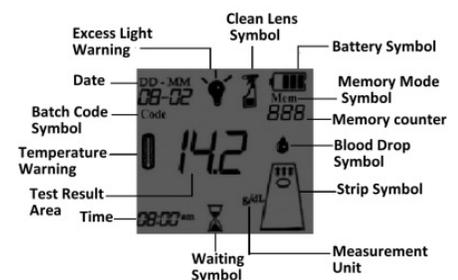
**Test Result Area:** Displays the hemoglobin level

**Measurement Units:** Indicates the units for the test result (g/dL)

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

**Light indicator:** When ambient light intensity is higher than normal

**Temperature symbol:** Appears if your meter is out of operating temperature range.



**Meter use and precaution:**

- Do not allow water or other liquids to enter the meter.
- Avoid exposing the meter to extreme temperature and humidity
- Keep the strip channel clean.
- Keep the meter out of reach of children.

**Setting up the meter:**

**Turning ON & OFF the meter:**

Long press the  button for about one second to turn ON the meter. If the meter does not turn on, try charging the device. Long press the same  button for 1 second to turn OFF the meter at any point in time.



**Setting up Date and Time:**

Time & Date should be set at the date of purchase of the meter, or when the battery is replaced. In case the meter is kept idle for over a month’s time, the date & time should be checked, and if it is found to be mismatching with the actual date and time, the same should be set. Please follow given instructions to set up the date & time of the meter:

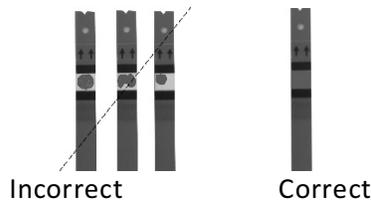
1. Turn ON the meter and long press the  &  button simultaneously for more than 1 second till symbols DD-MM start flashing.

- Use ◀ and ▶ buttons to move to the correct digit, and ▲ and ▼ buttons to set the correct value. Press ⏻ to save the date.
- Once the date has been set, the time characters will start flashing. Set the time using the arrow keys in the manner similar to that of setting date
- Save the time by pressing the ⏻ button, and restart the meter by long pressing ⏻ for over 1 second.



### Performing the Test

- Turn ON the meter. The system undergoes an autocheck and auto-calibration after which the battery level, date, time and strip's batch code are displayed within 2 seconds.
- If the displayed batch code is found to be different from the code mentioned on the strip bottle, Use ◀ and ▶ buttons to move to the correct digit and ▲ and ▼ buttons to set the correct value. Accept the batch code by pressing the ⏻ button.
- The meter would flash 'strip' symbol on the display. Insert a fresh test strip into the meter with the arrows on the strip facing up and pointing towards the display.
- Ensure the correct positioning of the strip with the guiding V notch and the positioning hole in the strip properly placed and locked.
- Do not allow fingers or other foreign objects to come in contact with the white test area of the test strip.
- Immediately after inserting the fresh test strip the display would flash the ♠ symbol. Strictly follow body puncturing instructions given in the user manual of TrueHb Test Strips for taking blood sample for Hb evaluation. Make sure the body part used for extracting blood sample is clean and disinfected.
- Ensure that there is sufficient blood (a minimum of 10µl or hanging blood drop) to completely cover the white colored test area.



- The meter will automatically start sample evaluation and display ⌚ and a time counter.
- Within a minute the test result will be displayed on the meter. The SI unit of the test result is g/dL. Upto 1000 most recent test results get automatically stored in the meter along with the date and time of the test(s).
- Remove the used test strip from the meter and dispose it as per local regulations & blood sample disposal guidelines.



### Test Results Warning

- Dehydration and low hemoglobin results: You may get falsely elevated hemoglobin results if you are severely dehydrated. If you think you are severely dehydrated, contact your healthcare professional immediately.
- If you experience symptoms that are not consistent with your hemoglobin results even after following right usage instructions in this booklet, please call your healthcare professional for assistance. We do not advise making significant changes to your medical treatment program solely based on the hemoglobin reading measured on the TrueHb hemometer.

### Viewing Results in Memory

The meter stores 1000 most recent readings with the respective values from the test, memory number of the test, and time & date of the test. Following 'first-in-first-out' logic, the oldest result automatically drops out from the memory when memory is full and a new result is recorded by the meter. To reach in the memory

mode long press left ◀ button for over a second after turning ON the meter. View recorded results of past dates follow given steps:

- i. To jump across readings stored across different dates, use ◀ and ▶ buttons to scroll through the dates.
- ii. Use ▲ and ▼ buttons to view the results of a particular date.
- iii. The readings on a particular day will be displayed. Last reading of the last date would be displayed first. You may move across dates to view the days' entries.
- iv. Press the centre button to return to the batch code state.

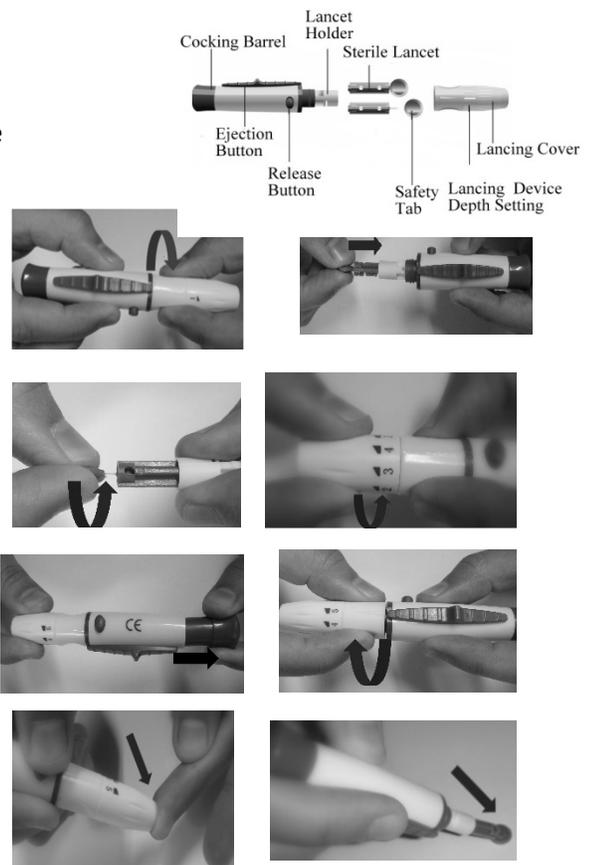
### **Caring For Your Meter**

- The meter should be cleaned after each use to remove any excess blood.
- Remove any residual blood or other matter on the outside of the meter by using a gauze or cloth dampened with an appropriate disinfectant, such as a mild detergent/mild soap and water.
- Clean the optical lens regularly using a water moist cotton cloth everyday, or in case where dust or dirt has fallen on the optical lens. Make sure you do not scratch the optical lens' surface as damaging the lens may lead to inconsistent results.
- Do not use alcohols to clean the meter. Alcohols damage the meter and the optical lens.
- Do not use strong, abrasive or corrosive cleaning solutions as they can damage the meter and the optical lens.
- Never dip or immerse the device in disinfectant solution
- 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 let any liquids, dirt, dust, blood, or control solution spill inside the meter as it may damage the electronics of the meter.
- Remove the batteries if the device is not in use for a long period of time. Charge your meter regularly to enjoy a long battery life.
- Store your meter, strips and other items in your carrying case after each use in a cool, dry place below 30°C, but do not refrigerate.
- Do not store the device close to strong magnetic fields, wireless systems, or mobile telephones, as this may interfere with the proper operation of the meter.
- Clean your hands properly before performing the test.
- Do not touch the strip where blood sample is to be applied.
- Only use genuine strips with the meter for accurate results.
- Please check the expiration date of the strips provided on the test strip container before using them for testing the hemoglobin.
- Store test strips only in their original vial.
- Do not let water and other liquids inside the meter.
- Keep the strip channel clean.

## TRUEHb Lancing Device

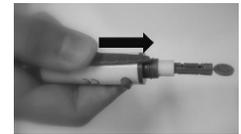
### How to use TRUEHb Lancing Device:

1. Before testing wash your hands with soap water.
2. Unscrew the lancing device cover from the body of the lancing device
3. Insert a fresh lancet firmly into the white lancet holder cup.
4. Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens. Pull the safety tab off the lancet. Save the safety tab for lancet disposal.
5. 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
6. Adjust the puncture depth by rotating the lancing device cover. TrueHb Lancing Device provides five different puncture depth levels. To reduce discomfort, use the lowest penetration level adequate for drawing a drop of blood. Higher level indicates higher penetration.
  - Use settings 3 or 4 for pediatric patients, and 5 for adult patients.
  - To lance your finger, we recommend that you start at level 5
7. Pull the cocking handle back until it clicks (If it does not click, it may have been cocked when you inserted the lancet.) The device is now ready for pricking the body to derive a drop of blood.
8. Press the mouth of TrueHb Lancing Device against the body part and press the release button to make prick the surface.



### Disposal of a Lancet

1. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully pierce the lancet needle into the safety tab so that the needle is inserted in the safety tab and is harmlessly unexposed.
2. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward and eject the used lancet into a disposal bin. Place the lancing device cover back on the lancing device.



### WARNINGS

- a. Disinfect the lancing device before & after usage
- b. Never reuse a lancet

**Warning:** Do not use your test strips if your vial is damaged or left open to air. This could lead to error messages or false readings.

The TrueHb monitoring system contains small parts that may be dangerous if swallowed

**Error Messages****Error 1****What it means**

Test strip was  inserted before test strip symbol appeared on display screen

**What to do**

Take out the strip and wait until you see the test strip symbol on the display before inserting a strip.

**Error 2**

Lo along with the  battery symbol

**What it means**

The battery is  exhausted

**What to do**

Kindly charge the battery.

**Error 3**

Lo along with the  temperature symbol.

**What it means**

Temp is lower than the normal operating temperature.

**What to do**

Kindly perform the test at a temperature between 5-45°C.

**Error 4**

Hi along with the  thermometer symbol

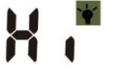
**What it means**

Temp is higher than the normal operating Temperature

**What to do**

Kindly perform the test at temperature between 5-45°C.

**Error 5**

Hi along with light  indicator

**What it means**

Ambient Light intensity is higher, or the meter is directly facing a light source

**What to do**

Move meter away from highly lit areas to a normal lit area and continue testing

**SPECIFICATIONS**

Assay method	Reflectance Photometry
Automatic shutoff	Yes
Battery life	500 cycles
Display	LCD
Measurement units	(g/dL)
Memory	1000 blood sample test with date and time
Operating Relative Humidity	5% to 90% (non condensing)
Operating temperature	5 to 45°C
Power Source	One 3.6 volt Lithium-ion rechargeable battery
Result Range	0 to 25 g/dL
Sample	Venous & Capillary Whole blood
Storage Conditions of Strips	0 to 30°C
Testing Time	20 to 59 Sec

**SMART SHORTCUTS**

Shortcut	Stage	Action
Long press ►	After performing a test	To perform tests repeatedly without setting batch code
Long press ▲ & ◀	Upon starting the meter	For time & date setting
Long press ◀	Upon starting the meter	For viewing memory

**TROUBLESHOOTING**

<b>I. Meter does not turn ON</b>	
Probable Cause	What to Do
The battery is discharged	Charge the meter
The battery is installed incorrectly	Take out the battery & reinsert
There is no battery in the meter	Install the battery
Meter doesn't charge	Call customer care
The display is damaged	Call customer care
Defective meter	Call customer care
<b>II. Wide/Unexpected variance in results</b>	
Probable Cause	What to Do
Optical Detector is not clean	Properly clean meter with damp cloth
Incorrect blood sampling method followed	Strictly follow the blood sampling procedure of finger prick test
Insufficient amount of blood	Make sure test region is completely reddened with enough blood sample (min. 10µl)
Test strips expired, damaged or poorly stored	Use a fresh test strip/ Use a fresh strip stock
Meter body damaged or hardware problem	Contact your distributor

**Symbols**

Consult instruction for use



Manufacturer



For in vitro diagnostic use only



Storage Temperature Range



Catalogue Number



Do not reuse



Expiry Date



Keep away from sunlight and heat



Do not discard along with household waste



Sterilized by irradiation



Test per kit



Serial number



Code number

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