

# CERA-CHEK™ Hb Plus

## User Manual

### 1 Important safety instructions

- Please read the following instructions carefully before using the CERA-CHEK™ Hb Plus.
- Close supervision is necessary when this testing device is used by children or patients.
  - This product is intended for in vitro (external) use.
  - Use only with CERA-CHEK™ Hb Plus Hemoglobin Test Strips.
  - Do not let the device come into contact with hot surfaces.
  - Do not expose the device to dust or other contaminants.
  - Avoid high humidity. This system may result in inaccurate measurements when used with high humidity.
  - Stop using the system when there is an operational failure or damage to the product. Keep the user manual nearby the device and consult it whenever needed.

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### 3 Introduction

Thank you for choosing the CERA-CHEK™ Hb Plus Hemoglobin Measuring System. The CERA-CHEK™ Hb Plus measures accurately and quickly the concentration level of hemoglobin that carries oxygen in your blood. It measures your hemoglobin level with as little as 1 µl of blood within 5 seconds.

Please read the manual thoroughly and be acquainted with the purpose of the product and how to use and maintain it before you start using the system.

#### 3-1. Intended use

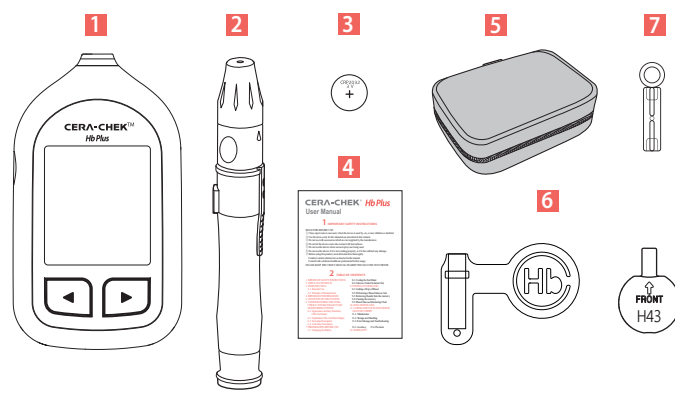
The CERA-CHEK™ Hb Plus Hemoglobin Measuring System is designed for the use of the general public as well as medical professionals to measure the hemoglobin levels. This product is for in vitro diagnostic use only using whole capillary blood or whole venous blood.

#### 3-2. Principle of Measurement

The CERA-CHEK™ Hb Plus test meter analyzes the hemoglobin levels employing an electrochemical method. Electric current occurs when hemoglobin in blood reacts with the reagent of the test strip. The system converts the generated electric current to a hemoglobin measure using a mathematical formula equipped in the meter and it shows you the converted hemoglobin measure.

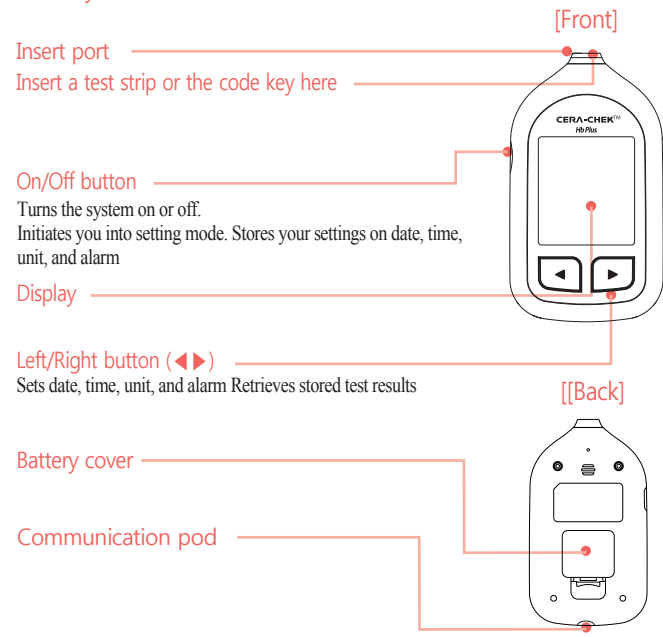
### 4 Contents of the system

- Test meter
- Lancing device
- Battery
- User manual
- Carrying case
- CERA-CHEK™ Hb Plus Hemoglobin Test Strips and Code key (sold separately)
- Sterile lancet (optional)

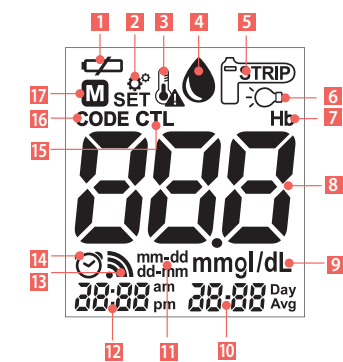


### 5 Understanding the CERA-CHEK™ Hb Plus

#### 5-1. Key functions of the test meter



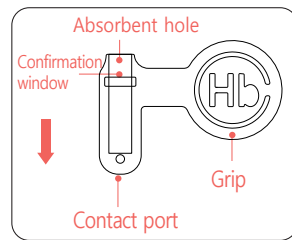
#### 5-2. Explanation of the test meter display



- Battery icon: indicates low battery.
- Set: indicates you are in the setting mode.
- Thermometer icon: indicates the temperature is too high or too low.
- Blood drop icon: indicates when to apply a blood sample.
- Test strip icon: indicates when to insert a test strip.
- Light bulb icon: appears if you have chosen signal in setting mode.
- Hb: indicates you are in hemoglobin measure mode.
- Hemoglobin measure: displays a test result or an error message.
- Measurement Unit: displays the unit of measurement of your choice.
- Displays date
- Date type: displays date type of your choice. You may choose either <mm-dd> or <dd-mm> in setting mode.
- Time
- Sound: appears while you are setting sound option in setting mode.
- Alarm: appears while you are setting the alarm or when the alarm is ringing
- CTL: appears when the test result with control solution is being displayed.
- Code: appears when a code number is being displayed
- M: Memory icon. Indicates a test result stored in memory

#### 5-3. Test strips description

Contact port: Insert or withdraw this end into or from the test meter.

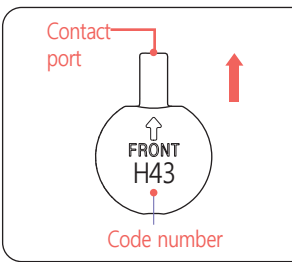


Grip: Grab this part to insert or withdraw a test strip.

Confirmation window: Through this window you may check if enough blood has been absorbed

Absorbent hole: Let this part touch your blood sample for absorption.

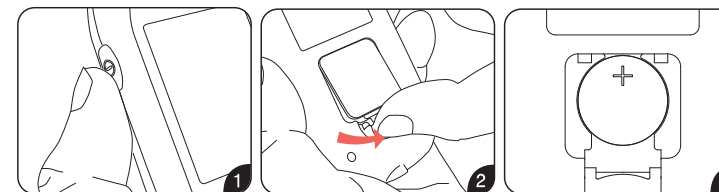
#### 5-4. Code key description



When using the CERA-CHEK™ Hb Plus Hemoglobin Measuring System for the first time, or before using a new box of test strips, you will need to calibrate the test meter. The code key must match the code numbers on the test strip vial and LCD display.

### 6 Preparation before use

#### 6-1. Changing the battery



- Make sure the power of the system is off.
- Pull the buckle on the battery cover and pull the cover forward.
- Insert a new battery with the positive (+) sign facing up.
- Close the battery cover.

#### Caution

- The following may lead to a loss of your personal setting:
- Contact the internal metal parts with hand or other metal
  - Delayed battery changing time over 1 minute
  - Battery inserted incorrectly
  - A used-up battery inserted

#### Warning

- Keep batteries away from children.  
If a battery is swallowed, consult a doctor immediately.

#### Tips

- Automatic shut-off: the system will turn off if not being used over 2 minutes.
- Battery change signal: the system allows up to 20 more tests after the first signal. However, it is recommended to replace the battery as soon as you see the signal. When the battery is used up, the system will display ( ) and become inactive.
- Discard battery: please discard the used battery in a designated place.

#### 6-2. Set-up the test meter

Set up date and time when using the system for the first time or after changing a battery. You may not start measuring hemoglobin until you have finished your personal settings. Press the power button for 3 seconds to enter setting mode when the system is off or when there is no test strip inserted in the system. Press the power button for 3 seconds at any point during set-up, and the system will save your personal settings up to that point.

1) Measurement mode: As the set mode starts, 'Hb' icon will appear on the screen. Press the Power button to select the measurement mode of hemoglobin.

2) Set Year: The 'Year' signal starts to flash once measurement mode has been set. Set year using left/right button (◀, ▶) and then press the power button to save it and proceed to 'month' set.

3) Set Month: Set month using left/right button (◀, ▶) and then press the power button to save it and proceed to 'day' set.

4) Set Day: Set hour using left/right (◀, ▶) button and then press the power button to save it and proceed to 'minute' set.

5) Set Hour: Set hour using left/right (◀, ▶) button and then press the power button to save it and proceed to 'minute' set.

6) Set Minute: Set minute using left/right (◀, ▶) button and then press the power button to save it and proceed to 'sound' set.

7) Set Sound: Choose sound either on or off and then press the power button to save it and proceed to 'light signal' set.

8) Set Date Type: When flashing, choose signal either on or off and then press the power button to save it and proceed to 'date type' set.

9) Set Date Type: Choose your preferred date type using left/right (◀, ▶) button and then press the power button to save it and proceed to 'time type' set.

10) Set Time Type: Choose your preferred time type using left/right (◀, ▶) button and then press the power button to save it and proceed to 'unit' set.

11) Set Unit: Choose your preferred measurement unit using left/right (◀, ▶) button and then press the power button to complete your setting. All settings have been saved now. The system will automatically turn off.

#### Warning

Measurement values are presented differently according to the measurement unit of your choice. You may want to discuss with your healthcare provider if you are unsure about the unit of your hemoglobin measures.

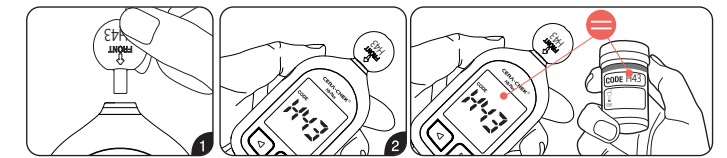
#### Tip

In setting mode, the system will automatically turn off if it is not used for 2 minutes.

### 7 Testing your hemoglobin

#### 7-1. Coding the test meter

Enter the code key with the code facing up. The code will appear on the display once calibration is done. Confirm the match between the numbers on display and on the code key. If they do, you may begin measurement.



#### Important

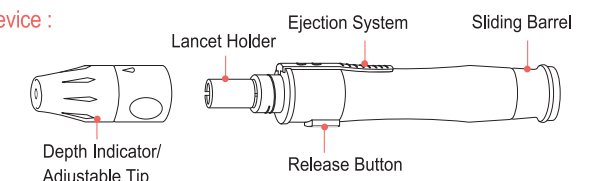
If the numbers do not match, insert the code key again for recalibration. If you still experience the same problem, please contact your nearest customer service.

#### 7-2. Obtaining a blood sample

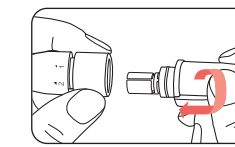
#### Important

Be sure to wash and dry your hands before obtaining a blood sample.

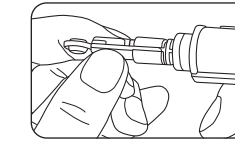
Lancing Device :



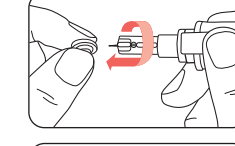
Lancet : Protective Cap



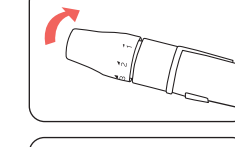
1) Screw off the cap of the lancing device.



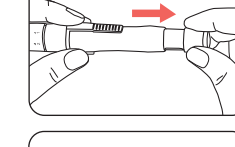
2) Insert a lancet into the lancet holder and push down firmly until it is fully seated.



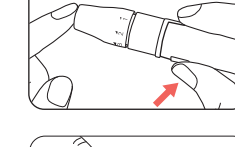
3) Twist the protective cap until it is separated from the lancet.



4) Twist the adjustable tip in either direction until the desired number lines up with the arrow.

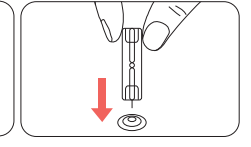
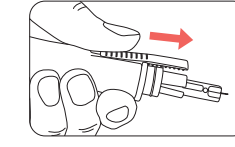


5) Pull the sliding barrel until it clicks.



6) Hold the lancing device against your fingertip and press the rectangle button. Gently squeeze the punctured area to obtain a blood sample.

Please be careful not to contaminate the blood.



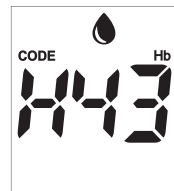
7) Remove the protective cap and press the release button to remove the lancet. Discard the used lancet with the protective cap on at the exposed tip.

## Warning

A lancet should only be used once. Please discard the used lancet.  
A lancet should never be shared to avoid the risk of infection with another person.

## 7-3. Testing your hemoglobin level

If a test strip has been exposed on the outside without being used for a long time, you may not get an accurate result. Try again with a new test strip.



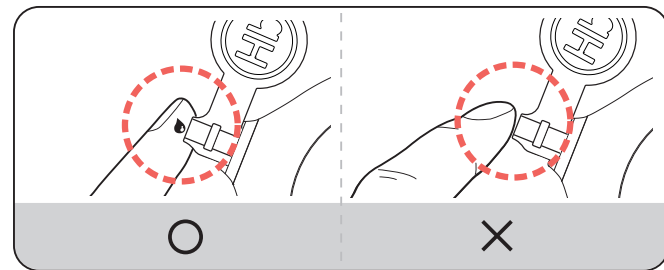
1) When a test strip has been inserted into the test meter, a code appears on the display with the blood drop icon. If this code does not match the one on the test strip vial, initiate recalibration as instructed in '7-1 Coding the test meter.

## Tip

If you do not apply a blood sample in 2 minutes after a test strip was inserted into the meter, the system will automatically turn off. To reactivate it, remove the test strip from the meter and put it back in.

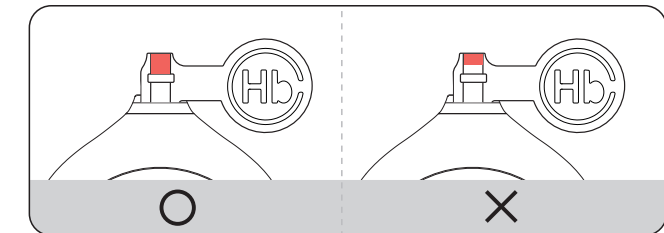
2) Be ready with the lancing device and begin collecting a blood sample according to the instruction in '7-2 Obtaining a blood sample.

3) Apply your blood sample to the Absorbent hole of the test strip. Make sure that the confirmation window of the test strip is fully filled. Once the blood sample has been applied properly, measurement will begin with the countdown signal on the display.



## Warning

In case blood has not completely filled the confirmation window, you may not get the accurate test result.



4) Test result will appear on the display in 5 seconds, which will be stored in the built-in memory with the test date and time.



## Warning

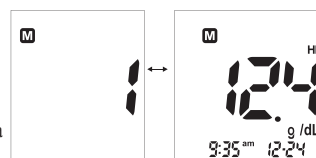
Please discard the used test strip after use. Do not reuse the test strip.

## 8 Memory

### 8-1. Reviewing data

CERA-CHEK™ Hb Plus Hemoglobin Test Meter stores up to 1,000 test results, and for your review it reviews the test results in order from the most recently stored one.

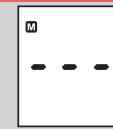
If you press either the left (◀) or right (▶) button for a short time, the latest record will appear on the display when the system is on.



The system will show a memory number for 1 second and then display a series of test results with the test date and time. If you press the left (◀) button for a short time, you can review the records one by one from the newest to the oldest and if you press the same button for a longer time, you can do a quick search.

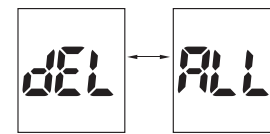
## Tip

When no test result is stored in the memory, a sign shown on the right will appear on the display.  
When there are more than 1000 stored measures, the system will automatically delete from the oldest measure.



### 8-2. Clearing the memory

1) In Retrieving mode, press the left (◀) and the right button (▶) simultaneously for 3 seconds, and 'dEL' and 'ALL' signs will appear alternately.



\* If you do not want delete the records, press the power button and turn the system off.

2) If you do want to delete the records, press the left (◀) (◀) and the right button (▶) simultaneously for 3 seconds. The system will begin deleting all saved test results and it will automatically turn off.

## Warning

Pay special attention when deleting stored test results since the data will not be recovered once deleted.

### 8-3. Hemoglobin reference chart

Measurement Range 5-26g/dl(3.1~16.1mmol/L)

	Normal hemoglobin Results
Newborns	10.5 ~19.5 g/dL
Infants/children (Ages 1~9)	11.0 ~14.0 g/dL
Children (Ages 10~12)	11.5 ~15.0 g/dL
Adult males	13.0 ~18.0 g/dL
Adult females	12.0 ~16.0 g/dL
Pregnant women	11.0 ~14.0 g/dL

Wallach, J. Interpretation of Diagnostic Tests, 2nd ed., pg-6, Table2., Little, Brown and Company, Boston MA 02106

## 9 Transferring data

For users' convenience, CERA-CHEK™ Hb Plus provides a special hemoglobin management program that transfers the data stored in the test meter to a personal computer, which enables you to review your hemoglobin measures at a glance.

※ If you would like this management program, you should purchase a CD for program installation and the USB data transfer cable.

1) Make sure that the test meter is turned off. (Data can not transfer when the device is still on.)

2) After executing the management program on your PC, connect the PC and the test meter using the transfer cable.

3) Once connected correctly, "PC" sign will appear on the display of the test meter.

## Warning

Data transfer cannot be completed if the cable is disconnected at any point during the transfer. Please keep the transfer cable intact until the transfer is completed.

4) After the data transfer is completed, you can release the transfer cable.

If you need more information on CERA-CHEK™ Hb Plus Hemoglobin Management program, please contact your retailer

## 10 Maintaining your test meter

Please wash and dry your hands when you use the test meter and test strips to avoid contamination

### 10-1. Cleaning

Pay attention to keep the insert port of the meter clean from blood or any potential contamination sources. Always wipe the external of the meter clean with soft and dry cloth.

### 10-2. Storage

1) Test Meter  
-Store it at -10°C~60°C (14°F~140°F).  
-Keep it from dust.  
-Avoid storing it in the kitchen, bathroom, or laundry room where high humidity and severe temperature changes are expected.  
-Avoid storing it near TV, cell phone, or microwave where strong magnetic fields exist.  
-Be cautious for damage from strong physical impact.

2) The test strips  
-Store them at 1°C~32°C (33.8°F~89.6°F).  
-Store them below 85% relative humidity.  
-Avoid storing them in the kitchen, bathroom, or laundry room where high humidity and severe temperature changes are expected.  
-Keep them away from direct sunlight or heat.  
-Close the cap tightly right after taking a test strip out of the vial.  
-Use a test strip immediately after taking it out of the vial.  
-Use all test strips within 4 months after first opening the vial.  
-Do not use test strips after expiration date.  
-Keep them away from children's reach.  
-When a test strip is swallowed, consult a doctor immediately.

### 10-3. Error messages and troubleshooting

Message	Meaning	Solution
	A test result is over 26 g/dL (16.1 mmol/L)	Check the expiration date of the test strip and retest with a new strip.
	A test result is below 5 g/dL (3.1 mmol/L)	Check the expiration date of the test strip and retest with a new strip
	Recommends battery change (Approximately 20 more tests are remaining)	It is recommended to change the battery.
	The battery power is too low for testing	You should change the battery.
	The surrounding temperature has exceeded the operational temperature range (4°C~40°C (39°F~104°F))	Keep the test meter at the operational temperature range (4°C~40°C (39°F~104°F)) for at least 30 minutes and then retest with a new test strip
	Calibration has not been done..	Initiate and complete calibration using the code key attached to the test strips now in use.
	A used test was inserted.	Discard the old test strip and insert a new test one.
	A contaminated or damaged test strip was inserted	Discard the old test strip and insert a new test one.

	The test strip was removed from the test meter before the measurement was completed	Discard the old test strip and insert a new test one.
	The code key was not identified.	Insert the code key again. If the problem still remains, contact your nearest customer service

## 11 Specifications

Product Name: CERA-CHEK™ Hb Plus Hemoglobin Measuring System

Model: H 400

Measurement Method: Electrochemical Method

Testable Blood: Whole capillary or venous blood

Blood sample amount: 1.0 µl

Test Time: Within 5 seconds

Measurement Range: Hemoglobin: 5~26 g/dL (3.1~16.1 mmol/L)

Measurement Unit: g/dL, mmol/L

Weight: 40g

Package Unit: 1 SET

Rating: DC 3V-Lithium Battery (CR2032)

Display: LCD

Memory: A total of 1,000

Battery Life: Over 3,000 tests possible

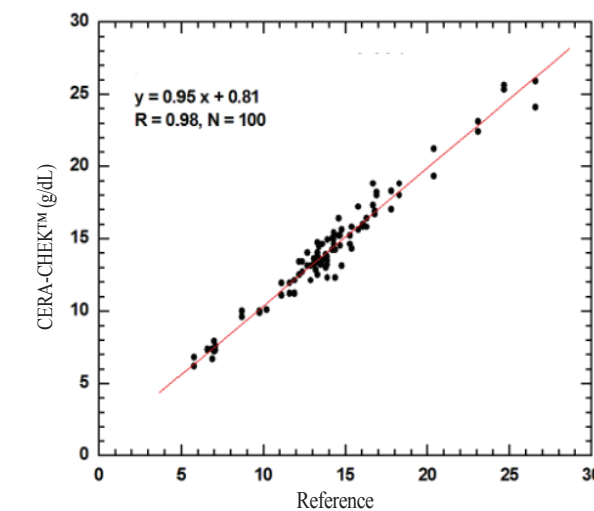
Auto Off: Shuts down after 2 minutes of inactivity

Software: H 400 version 1.0

Test meter storage/transportation: -10~60°C (14~140°F), Below 85% relative humidity or less, 700~1060 hpa

## 12 Performance characteristics

### 12-1. Accuracy



CERA-CHEK™ Hb Plus has shown as presented above, when it was tested with a sample of one hundred adults, children, and infants in the standard experimental facility.

### 12-2. Precision

1) Within Run Precision (venous blood)

Hemoglobin concentration	Mean	SD	C.V(%)	n
8.3 g/dL	8.6	0.40	4.7	60
13.1 g/dL	13.8	0.54	4.0	60
18.2 g/dL	18.7	0.70	3.7	60
22.3 g/dL	23.2	0.78	3.4	60

2) Day to Day Precision (hemoglobin control solution)

Sample	Mean	SD	C.V(%)	n
Control solution 1	9.7	0.45	4.6	120
Control solution 2	14.4	0.61	4.3	120

## 13 Warranty

This medical device has passed the internal quality control test. In case of a functional failure, please contact your retailer with the product warranty with you.

Product Name: CERA-CHEK™ Hb Plus Hemoglobin Measuring System

Manufacturing Number:

Date of Purchase:

Purchase Place:

Warranty: 3 years from date of purchase

Customer Name:

Phone Number:

Address:

## Warning

Be sure to keep the product warranty since no replacement or repair will be provided without the warranty. Date the warranty when you purchase the product.  
Should you have any questions or experience any inconvenience, please call a salesperson or our service center. We will gladly address your concerns in detail.

## 14 Symbols for proper usage

Symbol	Referent
	In vitro diagnostic medical device
	Do not reuse
	Consult instructions For use
	Temperature limitation
	Use by
	Date of manufacture
	Batch code
	Manufacturer
	Serial Number
	Power Button
	Authorised representative in the european community
	Do not dispose the instrument with the urban waste
	Caution, consult accompanying documents
	Direct current
	This product fulfills the requirements for Directive on in vitro diagnostic medical devices.

The device has been certified to meet the following standard:  
98/79/EC, EN 60601-1+A1+A2, EN 60601-1-2, EN 60601-1-4, ISO 14971, EN376, EN 13532, EN 13612, ISO 15197, ISO 17511, IEC 61326, EN 592, ISO 15223, EN 61010-2-101:2002, EN 13640, EN 1658

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