

# Hemoglobin Testing System



5 seconds



1 µL sample



5 - 26 g/dL



(Model: HG 400)

is the most convenient and cost-effective way to test hemoglobin levels in the blood.

Lab.-quality accuracy and precision with new electrochemical biosensor technology.

- Immediate Testing: **5 seconds**
- Small Blood Sample: **only 1 µL**
- High Precision: **Total CV ≤ 3%**
- Wide Measurement Range: **5 ~ 26 g/dL**

**+1** more benefit

Dual Featured with Blood Glucose Monitoring System  
**1Code** (Model: 400)  
is available for blood glucose testing



# Hemoglobin (Hb) Testing System



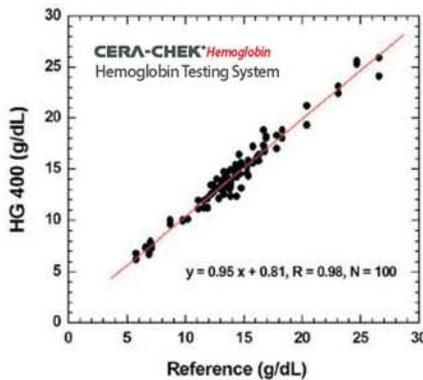
## Performance

- Wide measurement range of 5 ~ 26 g/dL with hematocrit range of 10 ~ 70%
- Total Precision CV ≤ 3%
- Calibrated to hematology analyzers

## Convenience

- **1  $\mu$ l sample volume**
- **Results in 5 seconds**
- Big strip prevents infection from blood contamination
- Sip-in blood absorption
- Indicating LED light guides to easy operation.
- For both capillary and venous blood
- 24 months shelf-lifetime under room temperature storage
- (Optional) Individual foil-wrapping
- 1 coin battery

## Accuracy and Precision



### Within run precision test (Sample: Whole blood, N = 80)

Testing for 20 replicates on each of 4 meters

Whole blood	Mean (g/dL)	*SD (g/dL)	**CV (%)
9.8 g/dL	9.5	0.28	2.9
14.5 g/dL	14.1	0.41	3.0
17.9 g/dL	17.4	0.51	2.9

### Total precision test (Sample: Control solution, N = 80)

Testing with 4 meters over 20 days using 2 levels of a control solution

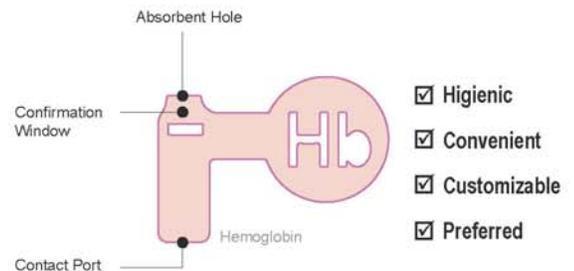
Control solution	Mean (g/dL)	*SD (g/dL)	**CV (%)
low control	9.3	0.26	2.8
normal control	14.4	0.43	3.0

\* SD = Standard Deviation \*\* CV = Coefficient of Variation

## Specifications

Feature	Technical Specifications
Model No.	HG 400
Methodology	Electrochemistry
Measurement Time	5 seconds
Blood Sample Volume	1 $\mu$ l
Sample Type	Capillary and venous blood
Measurement Range	5 ~ 26 g/dL (3.1 ~ 16.1 mmol)
Memory	Total 1,000 (Hb: 500 + Glc: 500)
LED Indicator	Indication LED lighting
PC Interface	RS-232C
Calibration	Code-key
Operating Conditions	4 ~ 40 °C, < RH 85 %
Storage Conditions	Meter: 0 ~ 50 °C, Strip: 1 ~ 32 °C
Battery	CR-2032 (1 Coin battery)
Battery Life	3,000 Tests (with LED lighting: 1,000 tests)
Meter Dimensions (W x L x T)	58 mm x 101.5 mm x 12.5 mm
Weight	40 g (with battery)

## Big Strip, Easy Grip



(Model: 400)

Strip is inter-changeable for blood glucose testing.

※ For blood glucose testing, **CERA-CHEK<sup>®</sup> iCode** (Model: G 400) strip can be used.



THE NEW BENCHMARK IN HEALTHCARE

## HbA1c &amp; Hemoglobin Analyzer



HbA1c  
Hemoglobin



Model: 2000

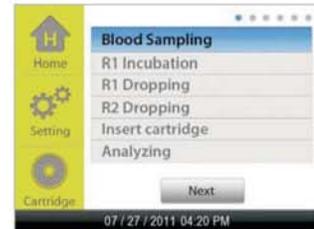
-  Full Color Touch Screen
-  Built-in Printer
-  Multi-Lingual Operation
-  Voice Guide
-  Patient ID
-  Large Memory Capacity

**Test Procedures**

## Step 1

### Blood Sampling

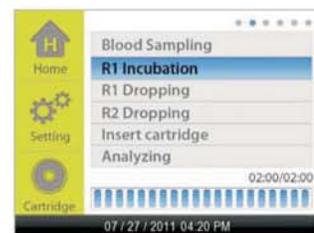
Collect  $5\mu\text{l}$  of blood using a capillary tube. Lancets and capillary tubes should be disposed after usage.



## Step 2

### R1 Incubation

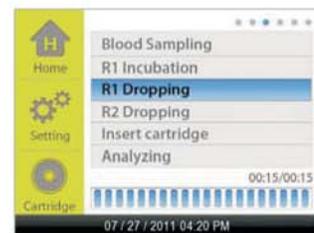
Put the capillary tube into the R1/Reagent tube, shake it up and down for 5 seconds. Tap "R1 Incubation" to start the incubation timer. Stand the tube for 2 minutes for the incubation.



## Step 3

### R1 Dropping

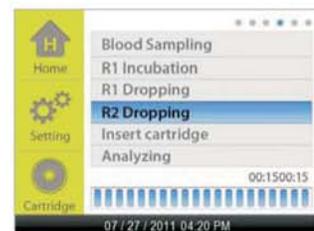
Apply  $25\mu\text{l}$  of the reaction mixture to the membrane of the cartridge.



## Step 4

### R2 Dropping

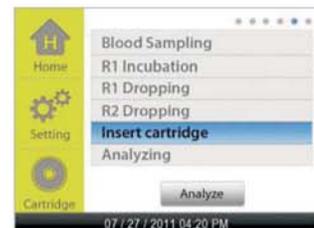
After 10 seconds, apply  $25\mu\text{l}$  of the R2/Reagent to the membrane of the cartridge.



## Step 5

### Insert Cartridge

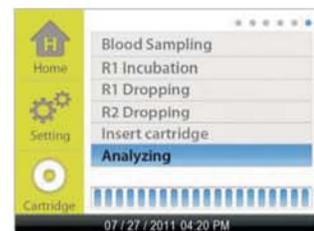
Open the tray and put the cartridge in the tray.



## Step 6

### Analyzing

Tap "Analyze" to insert the tray into the Analyzer. The result will be shown within 7 seconds.



## Ordering Information



### Analyzer

2 analyses in 1: Two tests of hemoglobin and hemoglobin A1c at the same time.

Reference #	Product Name	Contents
CS2000M10	Analyzer	HbA1c analyzer 1 battery 1 power adaptor 1 printer paper roll 1 calibration plate 1 user manual

\* Analyzer contents: 1 analyzer, 1 battery, 1 power adaptor, 1 printer paper roll, 1 calibration plate and 1 user manual



### Test Kit

When you order your Analyzer, it comes with the Test Kit to facilitate your tests.

Reference #	Product Name	Contents
2000S10	Test Kit	24 tubes of Reagent 1 24 cartridges 1 bottle of Reagent 2

\* Test kit contents : 24 tubes of Reagent 1 (0.2ml /tube), 24 cartridges and 1 bottle of Reagent 2 (2ml)



### Accessories and Spare parts

We can offer you the necessary laboratory material for the test procedures (sold separately).

The following are the accessories and spare parts:

Reference #	Product Name	Contents
2000A12	Pipette	25 $\mu$ l, 1 each
2000A10	Capillary tubes	5 $\mu$ l, 200 pieces/vial
2000A11	Capillary tube holder	1 each
2000A13	Pipette tip	1,000 pieces/pack
2000A14	Printer paper	1 roll
2000A17	Lancet	200 pieces
2000A18	Lancing device	1 each



### Control Solution

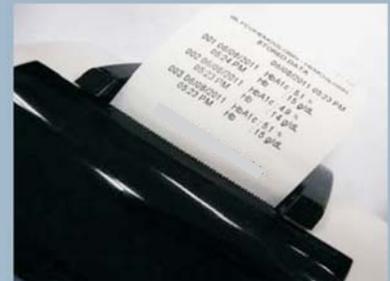
Reference #	Product Name	Contents
2000A16	Control Solution	2 levels x 1.5ml/ea (level 1 & 2)



**3.5" FULL COLOR TOUCH SCREEN**  
High resolution GUI (graphic user interface)



**BUILT-IN PRINTER**  
Easy patient management



**AUTOMATIC TRAY LOADING**



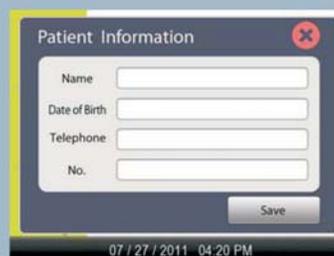
**MULTI-LINGUAL OPERATION**  
English, Spanish, Chinese and Portuguese



(EN) English (ES) Español (ZH) Chinese (PT) Portuguese

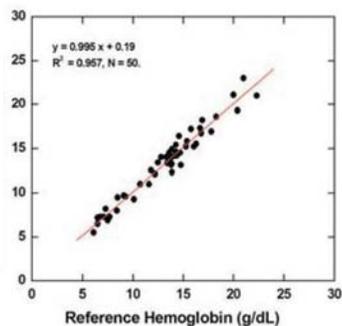
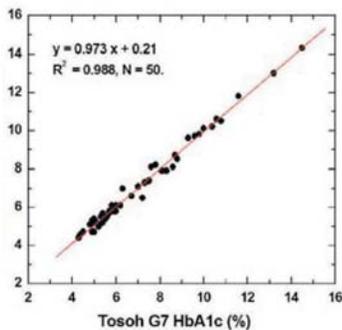
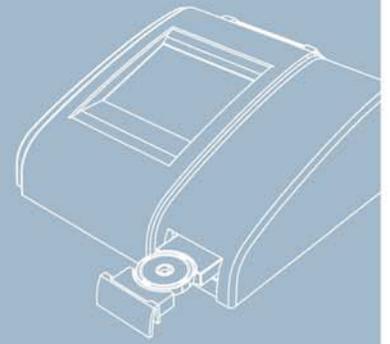


**PATIENT ID**  
Better management of patients' ID



**VOICE GUIDE**  
Guide to procedures for accurate testing





**2 analyses in 1 analyzer** give accurate HbA1c and Hemoglobin testing at the point-of-care. In the point-of-care testing, it is needed to balance high speed with performance of quality. We offer this analyzer where immediate results are required and where turnaround times are crucial.

**User's convenience by the design** enables the operational demands to be satisfactory. It has remarkable functions such as full color touch screen, voice guidance with multi-languages, easy setting, large memory capacity and inputting patient ID.

**Built-in printer** allows your patients to manage their records. Your patients do not need to memorize their testing time and results in mind. Results can be read and handed out to each patient for better compliance.

**International Standards are satisfied** by calibration of the Diabetes Control and Complications Trial (DCCT) standard for greater confidence. Also it uses the precision studies modeled from the NGSP (National Glycohemoglobin Standardization Program, USA)<sup>1)</sup> and certified. It is traceable to the reference method of International Federation of Clinical Chemistry (IFCC) for the readings of HbA1c<sup>2)</sup>.

<sup>1)</sup>NGSP certification at the time of this update (July 2011)

<sup>2)</sup>American Diabetes Association Clinical Practice Recommendation, January 2011;33(supplement1)

300

**LARGE MEMORY CAPACITY**

Store and recall up to 300 test results with date & time and patient ID.

**SETTING****Print**

Auto mode is to print the result automatically after test. Manual mode is for the user to select whether to print or not.

**Unit**

Select the measuring unit (% or mmol/mol).

**Sound**

Adjust the speaker volume.

**Brightness Control**

Adjust the LCD brightness.

**Time & Date**

Touch  $\Delta$   $\nabla$  to set time & date.



Model: MH 200

For measuring HbA1c only

**Specifications**

<b>Methodology</b>	Boronate affinity chromatography
<b>Display and User Interface</b>	Touch screen (3.5 inch)
<b>Assay Time</b>	3 minutes
<b>Measurement Time</b>	7 seconds
<b>Measuring Method</b>	Optical Reflectance
<b>Temperature Range</b>	10 °C ~ 40 °C / 50 °F ~ 104 °F
<b>Sample Volume</b>	Whole Blood, 5 $\mu$ l
<b>Measurement Range</b>	HbA1c: 4 % ~ 15 %, Hemoglobin: 5 ~ 26 g/dL
<b>Memory</b>	300 test results
<b>Units</b>	HbA1c: Either % or mmol/mol Hemoglobin: Either g/dL or mmol/L
<b>Operation Condition</b>	Temperature : 20 °C ~ 25 °C / 68 °F ~ 77 °F Humidity : 15 % ~ 75 %
<b>Printing Method</b>	Direct thermal line printing
<b>Dimensions</b>	178 x 195 x 77 (mm)
<b>Weight</b>	730 g (exclude adapter)

**FAQ (Frequently Asked Questions)****What is HbA1c?**

HbA1c also known as hemoglobin A1c, glycosylated hemoglobin, is a minor hemoglobin component that are adducts formed from hemoglobin and various sugars (glucose). It is a reflection of the mean blood glucose levels during the last 6-12 weeks so the HbA1c test is an important blood test used to determine how well the diabetes is being controlled.

**Is there a relation between % HbA1c and glucose?**

Yes, studies have shown that the level of glycohemoglobin (HbA1c) is an index of mean blood glucose over the preceding 120 days.

The mean glucose (MPG) and HbA1c has been established by linear regression analysis using data (n=1441) from the DCCT study. The relationship may be used to estimate MPG over the last 60-90 days and may be used to set up day to day target based on HbA1c goals. (DCCT= Diabetes Control and Complications Trial)

**What is the normal HbA1c value?**

The recommended target of 6.5 % now corresponds to a value of 48 mmol/mol. If you have diabetes and your HbA1c is below the target of 6.5 % of the total amount of hemoglobin in the blood it is likely that your diabetes is in good control. However, if your HbA1c rises above 6.5 %, you are at increased risk of developing long term complications such as eye disease, kidney disease or nerve damage.

**Are there warning signs for abnormally low hemoglobin levels?**

Some warning signs are fatigue, fainting, pallor, and shortness of breath.

Some of the behind causes can be from nutritional deficiency (iron, vitamin B12, folate), bone marrow problems (replacement of bone marrow by cancer), loss of blood (traumatic injury, surgery, bleeding colon cancer or stomach ulcer), kidney failure and abnormal hemoglobin (sickle cell anemia).

**What is the normal hemoglobin value?**

The hemoglobin level is expressed as the amount of hemoglobin in grams (gm) per deciliter (dl) of whole blood, a deciliter being 100 milliliters.

The normal range is:

Newborns: 17-22 g/dL  
Children: 11-13 g/dL  
Adult males: 14-18 g/dL  
Adult women: 12-16 g/dL

**What is hemoglobin?**

Hemoglobin is the protein molecule in red blood cells that carries oxygen from the lungs to the body's tissues and returns carbon dioxide from the tissues to the lungs. Hemoglobin is made up of four protein molecules (globulin chains) that are connected together. The normal adult hemoglobin molecule contains 2 alpha-globulin chains and 2 beta-globulin chains.

In fetuses and infants, there are only a few beta chains and the hemoglobin molecule is made up of 2 alpha chains and 2 gamma chains.

**How is hemoglobin measured?**

Hemoglobin is usually measured as a part of the complete blood count (CBC) from a blood sample. Several methods exist for measuring hemoglobin, most of which are done currently by automated machines designed to perform several different tests on blood. Within the machine, the red blood cells are broken down to get the hemoglobin into a solution. The free hemoglobin is exposed to a chemical containing cyanide which binds tightly with the hemoglobin molecule to form cyanmethemoglobin.

By shining a light through the solution and measuring how much light is absorbed (specifically at a wavelength of 540 nanometers), the amount of hemoglobin can be determined.



THE NEW BENCHMARK IN HEALTHCARE

## Blood Glucose Monitoring System

### High Concept

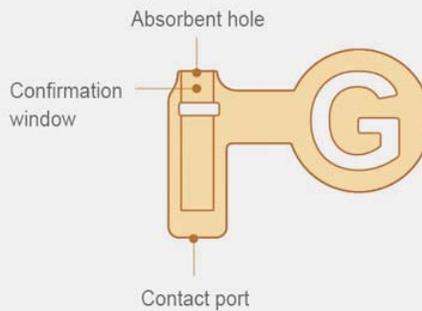
#### Benefits to End-Users

- Infection control with hygienic grip.
- Bending-free convenience and easy handling

#### Benefits to Customers

- Successful sales by customizable features
- End-user preferred design with high loyalty

## Big Strip, Easy Grip

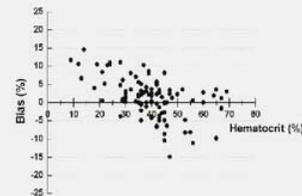
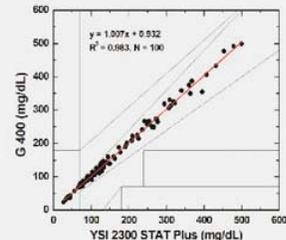


- Hygienic
- Convenient
- Customizable
- Preferred

### High Performance

- Code Free
- Wide Hematocrit Range: 10 ~ 70 %
- Wide Measurement Range: 10 ~ 900 mg/dL
- 5 seconds
- 0.5 $\mu$ l Sample Volume

#### System Performance

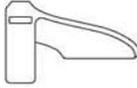
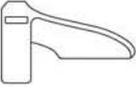
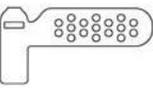


**Top:** Error-Grid Analysis. All the results are fall into region with  $\pm 15\%$  error.

**Bottom:** Hematocrit Bias (%). All the results are less than  $\pm 15\%$  in all range of hematocrit.

# Models



Model #	MG 200	MG 220	G 300	G 400	G 420	G 500
Strips						
Product Name	<b>GOLD</b>	<b>Wing</b>	<b>1070</b>	<b>1code</b>	<b>Mini</b>	<b>3sec</b>
Specifications						
Enzyme	FAD-GDH	FAD-GDH	FAD-GDH	FAD-GDH	FAD-GDH	FAD-GDH
Measurement Time	5 seconds	5 seconds	5 seconds	5 seconds	5 seconds	3 seconds
Sample Volume	1 µl	1 µl	1 µl	0.5 µl(AST)	0.5 µl(AST)	0.5 µl(AST)
Hematocrit Range	20 ~ 60 %	20 ~ 60 %	10 ~ 70 %	10 ~ 70 %	10 ~ 70 %	10 ~ 70 %
Measurement Range	20 ~ 600 mg/dL	20 ~ 600 mg/dL	10 ~ 900 mg/dL	10 ~ 900 mg/dL	10 ~ 900 mg/dL	10 ~ 900 mg/dL
Calibration	Code-Key	Code-Key	Code-Key	Code Free	Code-Key	Code Free
Memory	500	500	1,000	1,000	1,000	1,000
LED Indicator	-	-	YES	YES	-	YES
LCD Backlight	-	-	-	-	-	YES
PC Interface	-	-	YES	YES	YES	YES
Operating Temperature	10 ~ 40 °C	10 ~ 40 °C	4 ~ 40 °C	4 ~ 40 °C	4 ~ 40 °C	4 ~ 40 °C
Humidity	< 80 %	< 80 %	< 85 %	< 85 %	< 85 %	< 85 %
Altitude	3,000 M	3,000 M	4,000 M	4,000 M	4,000 M	4,000 M
Battery	1 Coin Battery	1 Coin Battery	1 Coin Battery	1 Coin Battery	1 Coin Battery	2 Coin Batteries
Battery Life	> 3,000	> 3,000	> 3,000	> 3,000	> 3,000	> 3,000
Expiry date after vial opening	4 months	4 months	4 months	4 months	4 months	4 months
Storage Temp. (For Strip)	2 ~ 30 °C	2 ~ 30 °C	1 ~ 32 °C	1 ~ 32 °C	1 ~ 32 °C	1 ~ 32 °C
Strip Shelf-Lifetime	18 months	18 months	24 months	24 months	24 months	24 months
Individual Foil-wrapping	Available	Available	Available	Available	-	Available
Weight (with Battery)	36g	27g	35g	40g	40g	45g
Meter Dimension(mm)	53.5 x 92.5 x 24.6	23.6 x 106.8 x 17	53.6 x 94 x 14.9	58 x 101.5 x 12.5	27 x 107 x 12.5	55.5 x 105 x 13.5



Model: MW 200



Model: MW 220



Model: MW 300



Model: MW 400



Model: MW 420



Model: MW 500

“ *Create Your Strip, Build Your Identity.* ”

## Your own strip

Imagine your unique strip that boosts your business. The moment your customers meet the unique strip, they will think this product is customized exclusively for them. It will build your identity and differentiate your sales from the sales of conventional “me-too strips”.

We create a whole new range of strips for you. You can have the world’s most innovative strip, this will lead you to take the superior position in the competitive BGMS market. Make your successful story.



Alphabet



Wing vertical



Medical cross



Hearty vertical



Music note



Company symbol

## Diagnostics Products

Diabetes	Cardiovascular disease	Cancer marker Panels	Esthetic
Blood glucose HbA1c u-albumin	Cholesterols & Lipids hs-CRP Troponin-I	PSA CEA AFP	Light Therapy

Take an attractive business opportunity with us.

## Blood Glucose Monitoring System



**Excellent Performance!**  
**Code FREE!**  
**Hematocrit FREE!**



- **Innovating Biosensor Technology!**
- **Code FREE!**
- **Hematocrit FREE!**
- **Measurement Range: 10 ~ 900 mg/dL**



Model: MW 400