

GlucoAlpha™ ENHANCE

Blood Glucose Monitoring System



User Guide



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About GlucoAlpha™ ENHANCE

INTENDED USE

The GlucoAlpha™ Enhance Blood Glucose Monitoring System (The GlucoAlpha™ Enhance System) is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes for self-testing or by healthcare professionals for monitoring glucose in the home or in healthcare facilities. The device is indicated for professional use and over-the-counter sale.

ABOUT THE SYSTEM

The GlucoAlpha™ Enhance System uses the latest technology in blood glucose monitoring to provide you with easy and comfortable testing. The system requires only a 1.5µL of blood sample to complete the testing in only 15 seconds.

- The GlucoAlpha™ Enhance System consists of
- 1) GlucoAlpha™ Enhance Blood Glucose Meter,
 - 2) GlucoAlpha™ Blood Glucose Test Strips,
 - 3) GlucoAlpha™ Check Strip
 - 4) GlucoAlpha™ Control Solution.

These products are intended to be used together to get accurate blood glucose test results. Do not use other test strips or control solutions with your meter.

IMPORTANT INFORMATION

IVD GlucoAlpha™ Enhance System is intended for in vitro diagnostic use with capillary whole blood. The system should not be used for diagnosis of diabetes or for testing newborn infant (neonatal testing).

CAUTION

- The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
- Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
- Severe dehydration or excessive water loss may cause false, low results. Call your doctor right away if you believe you are suffering from dehydration.
- A sample with large amount of reducing substances such as ascorbic acid and uric acid may cause result slightly higher than the actual glucose level.
- A red blood cell count (hematocrit) that is either very high (over 55%) or very low (under 30%) can cause false result.
- High altitudes above than 2,750 meter (8,800 feet) may affect the test results.
- Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test results.

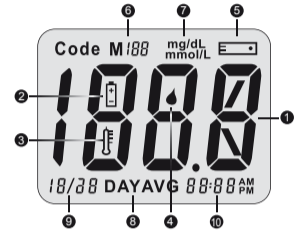
GlucoAlpha™ ENHANCE BLOOD GLUCOSE METER

Study this diagram and become familiar with all parts of your GlucoAlpha™ Enhance Blood Glucose Meter.



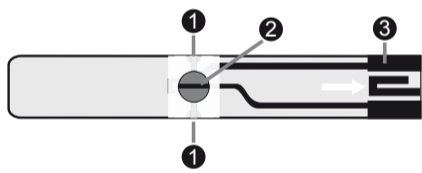
1. **DISPLAY:** The large, easy to read display shows blood glucose results, messages, glucose results stored in memory, time and date.
2. **S BUTTON:** Press S button to enter code setting and when you need to decrease values in setting mode.
3. **M BUTTON:** Press M button to enter memory recall mode and to increase values in setting mode.
4. **STRIP SLOT:** Holds a GlucoAlpha™ Blood Glucose Test Strip and Check Strip in place when you perform blood glucose test or perform check test.
5. **BATTERY COMPARTMENT:** Holds ONE 3v Lithium battery (CR2032). The battery is not yet installed into meter when new purchasing. By using the meter, please install the battery first. Refer to Section "TAKING CARE OF YOUR METER" of the manual for more information.

GlucoAlpha™ ENHANCE LCD WINDOW



1. **TEST RESULT**
2. **BATTERY SYMBOL:** Appears when battery is weak.
3. **THERMOMETER SYMBOL:** Appears when ambient temperature is above or below the acceptable range needed for testing.
4. **BLOOD SYMBOL:** Appears when the test strip is inserted and meter is ready for blood testing.
5. **STRIP SYMBOL**
6. **M188:** Memory capacity is 153 entries. The display shows M188 to ensure that all digits are working properly.
7. **mg/dL mmol/L:** The meter has two units of measurement to choose from.
8. **DAY AVG:** Appears when the meter is in Memory Mode. The meter automatically calculates your 7/14/30 days before meal (AC) and after meal (PC) test averages if you preset correct time and date.
9. **DATE:** Month/date.
10. **TIME:** The meter is programmed for a 12 hours period format.

GlucoAlpha™ BLOOD GLUCOSE TEST STRIP



1. **Aperture:** apply the blood from either side of strip.
2. **Test Confirmation Window:** make sure the part is filled up with blood to ensure the correct result.
3. **Gray Electrode End:** insert this end of test strip into meter.

IMPORTANT TEST STRIP INFORMATION

1. GlucoAlpha™ Enhance System measures the amount of glucose in capillary whole blood. Blood can be applied both to the right or left side of the test strip's apertures and is automatically drawn to the test confirmation window where the reaction takes place.
2. GlucoAlpha™ Blood Glucose Strips are intended for in vitro diagnostic use with capillary whole blood or GlucoAlpha™ Control Solution. Results will not be accurate if used with plasma or serum samples.

3. Do not use glucose strips beyond the expiration date indicated on the strip vial label.
4. The discard date for glucose strips is 90 days after first opening the vial. Record the discard date on the vial, when you open a new vial of glucose strips.
5. GlucoAlpha™ Blood Glucose Strip can be damaged by heat and light. Keep them sealed in the original vial.
6. Store the vial in a cool, dry place below to 40°C/104°F and above to 10°C/50°F. Do not refrigerate.
7. Do not use damaged glucose strips or glucose strips changed in any way. Use glucose strip immediately after removing it from the vial; replace the vial cap and close it tightly.
8. Do not transfer glucose strips to a new vial. Always carry glucose strips in their original vial.
9. Do not place in direct heat or sunlight.
10. Do not carry loose glucose strips in your carrying case.
11. Blood glucose test strips are for single use only.
12. Do not use fluoride or iodoacetic acid as a preservative for blood specimens.

GlucoAlpha™ CHECK STRIP

The GlucoAlpha™ Check Strip can be used in 2 ways:

1. To check that the meter is operating properly. Use when performing quality control check on your meter.
2. To change the measuring unit of your meter.

HOW TO CHECK METER BY CHECK STRIP

- Step 1: Insert the check strip into strip slot with label side up as above.
- Step 2: You should obtain an acceptable "OK" reading within 3 seconds, which mean your meter is working properly.
- Step 3: Remove the check strip to exit. Meter will automatically off.

NOTE: IF YOU DO NOT GET "OK" READING BUT APPEAR OTHER ERROR MESSAGE, REMOVE CHECK STRIP TO TURN OFF THE METER FIRST. THEN REPEAT THE TEST. IF THE SECOND RESULT PERSISTS, PLEASE CONSULT YOUR LOCAL DISTRIBUTOR FOR HELP.

How To Change Measuring Unit

The meter has two measuring units to choose from, mg/dL and mmol/L. The default unit is mg/dL if you do not change. Consult your doctor for the proper unit in your country.

- Step 1: Insert check strip into strip slot with label side up.
- Step 2: After "OK" displayed, press S button for 3 seconds until flashing mg/dL shows up.

- Step 3: Press S button to switch from mg/dL to mmol/L. Wait the new setting flash 4 times to validate the new setting. Meter will display "OK" before OFF, and the unit is been changed successfully.
- Step 4: Remove the check strip from the meter.

SETTING TIME AND DATE

Time and date should be set prior to testing if you plan to review your 7/14/30 days test average in before meal (AC) and after meal (PC) reading or if you want to download the results into computer or to review your memory to check when a test was done.

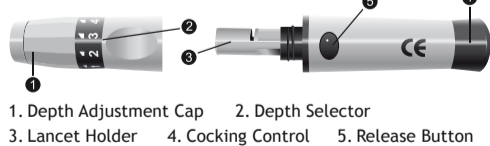
TO SET THE TIME AND DATE

1. Make sure the meter is turned off.
2. Let the front of the meter rest in the palm of your hand.
3. Slide battery compartment door open and you will find a "RESET" hole above the battery.
4. Prink the "RESET" hole to enter time and date setting.
5. At the beep sound, the year will flash - for example for the year 2006, number "06" will appear.
6. Press S or M BUTTON to obtain the desired year.
7. Wait the new setting flash 4 times to confirm and move to next setting.
8. Repeat to set the month, day, hour and minute.
9. After minute is set, the meter displays OK and turn off automatically.

PREPARE FOR BLOOD SAMPLING

Your lancing device and lancets are used for obtaining capillary blood samples from the fingertip.

ADJUSTABLE LANCING DEVICE



1. Depth Adjustment Cap
2. Depth Selector
3. Lancet Holder
4. Cocking Control
5. Release Button

Important

- The lancing device is in conformity with MDD 93/42/EEC. Refer to package insert for contact information of manufacturer and CE marking.

LANCET

Important

- Lancets are for single use only.
- Keep lancing device and lancets clean.
- Use caution when removing the used lancet from the device and when disposing the used lancet.
- The lancets are in conformity with MDD 93/42/EEC. Refer to product labels for contact information of manufacturer and CE marking.

SET LANCING DEVICE

1. Remove the depth adjustment cap. Insert a lancet into the lancet holder and push down until it is fully seated (FIG 1).

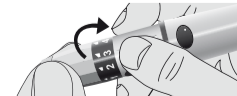


2. Twist off the protective cap until it separates from the lancet (FIG 2).



3. Replace the depth adjustment cap and set the puncture depth to the desired number (FIG 3).

NOTE: The Larger The Number Setting The Deeper The Puncture.



4. Pull back the cocking control until it makes a click, and then release (FIG 4). If it does not click, the device may have been cocked when the lancet was inserted.



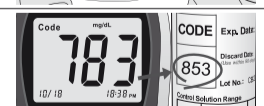
CODING YOUR METER

Before you use your meter for the first time and every time you open a new box of test strips, you need to set the meter to "match" the strips. This is called coding.

1. Insert the test strip into the strip slot (FIG 1) to turn on the meter. Then the last code number will appear on the screen.



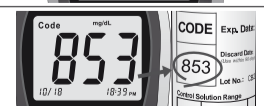
2. Compare the code number shown on the meter display against the code number on the test strip vial (FIG 2). If the two numbers match you may begin blood testing. Otherwise continue to the next step.



3. Press S button to enter the code mode and the code value flashes (FIG 3).



4. Press S or M button to obtain the code number indicated on the new test strip vial (FIG 4).



5. Upon obtaining the right code, waiting new setting flash 4 times to validate the change. After screen shows the proper code and a blinking blood symbol shows up (FIG 5), your meter is ready to perform blood test.



NOTE: when the meter is OFF, you can also press and S button for 3 seconds to code the meter directly. The coding procedures are the same as above step 4 and 5.

PERFORM BLOOD TEST

1. Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow (FIG. 1).



2. Remove new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert test strip immediately into strip slot as illustrated. The meter turns on automatically (FIG. 2).



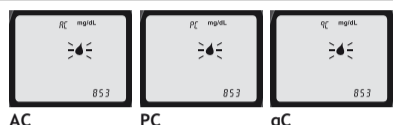
3. Check that the code number in the meter matches the code on the vial of test strips you are using (FIG 3).



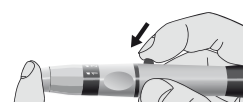
4. When the blood symbol flashes, you are ready to perform the blood glucose test (FIG. 4).



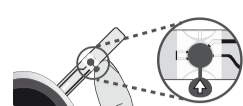
5. By applying blood sample to the aperture of the test strip, you can press M button to set the test as BEFORE MEAL TEST(AC), or AFTER MEAL TEST(PC)(test be done in 2 hours after meal), or a CONTROL SOLUTION TEST(qC). If not setting, the default of the meter is (AC)(FIG. 5)



6. Use the loaded lancing device to obtain a drop on the side of your finger (FIG. 6). Hold the device firmly against the side of your finger. Press the release button. Gently massage your finger to obtain the required blood volume. To perform the test, you need only 1.5µL of blood sample resting on your finger.



7. Apply the blood to the aperture of strip and make sure that the blood drop has saturated the test confirmation window. When blood is applied to the strip, the meter will be started automatically. (FIG. 7)



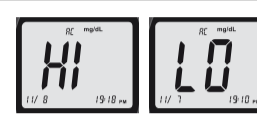
8. Test result will show up in 15 seconds (FIG 8). Before removing strip from the meter, check if the AC/PC/qC setting is correct, if not, please press M button to correct the setting.



9. Remove the strip from meter (FIG 9), and discard the used strip and lancet safely in a puncture resistant container.



10. Testing range of the meter is 20-600mg/dL (1.1-33.3 mmol/L). If HI is displayed, your blood glucose result may be higher than 33.3 mmol/L or 600 mg/dL. If LO is displayed, your blood glucose result may be lower than 1.1 mmol/L or 20 mg/dL (FIG 10). Refers to page19 for details.



MEMORY RECALL

The GlucoAlpha™ Enhance Blood Glucose Meter automatically stores 153 test results, letting you review them in order from the most recent to the oldest. If you have set the AC/PC and time/date feature, the AC/PC and time/date of the results are also displayed. If the memory is full and a new result is added, the meter deletes the oldest result.

The meter also calculates and displays your previous 7-, 14- and 30-day before meal (AC) and after meal (PC) test averages if you preset correct time and date.

TO RECALL RESULTS STORED IN MEMORY

- Turn meter on by press M button 3 seconds to turn on the meter. The first result displayed on the screen is your latest test result.
 - By pressing M button, you will see your test record from the most recent to the oldest.
 - By pressing S button you will obtain your 7 days before meal (AC) setting. You can press S button again to obtain your 7 days after meal (PC) setting.
 - Following press S button to review your 14 days and 30 days before meal and after meal averages.
- NOTE: ANYTIME IN MEMORY MODE, YOU CAN PRESS S BUTTON TO EXIT AND TURN OFF THE METER.**

TO DELETE MEMORY

- While in the memory mode, select the test result you wish to delete and display it on the screen.
- Press M button until you hear a beep sound. The blink "dEL" symbol will appear on the meter.
- Press M button again until the "OK" symbol appears which confirms that the selected test result has been deleted successfully.
- The meter will return to memory mode and display next result after deleting.

DATA DOWNLOAD

You may download test results to your computer. To transfer test results to a computer, you need to download GlucoAlpha™ Software from our web site or from the CD provided by us. Use the interface cable provided with CD to download your test results to computer.

UNUSUAL TEST RESULT

NORMAL BLOOD GLUCOSE RANGE

The normal blood glucose range is 70 to 105 mg/dL (3.8 to 5.8 mmol/L)1 for a fasting, non-diabetic adult, but less than 140 mg/dL (7.7 mmol/L)2 two hours after meals. Consult your healthcare professional to find out your target blood glucose value.

If your blood glucose result seems unusually high or low, or inconsistent with your previous results, check the following:

- Does the code number on the strip vial match the code number on the meter?
- Was the blood sample applied immediately to the glucose strip after removing it from the vial?
- Was the size of the blood sample sufficient?
- Was the test strip vial cap tightly sealed?
- Was the test strip used before the expiration date?
- Were the test strips stored away from extreme temperatures in very cold or hot weather or from areas of high humidity?

Then run a quality control check with your GlucoAlpha™ Control Solutions and a new test strip. (The information of how to do the control test, please refer to your control solution package insert for more information.) If the control test result is within the acceptable range, review testing procedure and repeat your blood glucose test with a new

test strip. If your blood glucose value is still inconsistent with your previous results, glucose trend, or how you feel, contact your doctor for help immediately.

SYSTEM SPECIFICATIONS

- Assay Method:** Electrochemical biosensor
- Test Sample:** Capillary Whole Blood
- Test Result:** Plasma / Serum glucose
- Sample Size:** Less than 1.5 µL
- Measuring Range:** 20 - 600 mg/dL or 1.1 - 33.3 mmol/L
- Measuring Time:** Less than 15 seconds
- Memory Capacity:** 153 test results with time and date
- Average Display:** 7, 14, 30-days AC and PC test average
- Result Setting:** AC, PC and qC setting
- Power Supply:** One 3-volt Lithium Battery (CR2032)
- Battery Life:** Approximately 1000 tests
- Operating Temp. Range:** 10°C to 40°C (50°F - 104°F)
- Hematocrit Limit:** 30% to 55%
- Operating Relative Humidity:** 20% - 80% RH
- Automatic shut-off:** In 10 minutes

DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

When any of the following messages appears, there is a problem with your GlucoAlpha™ Enhance Blood Glucose Meter or the way in which you are performing a test. These messages will help you to identify certain problems. If error messages appear that are not listed on the following pages, please contact us for help.

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display All	If some parts of the display are not working. Contact us or your local distributor for help.
	Blood glucose result may be higher than 600 mg/dL (33.3 mmol/L)	If the reading is "HI" and you do not experience any hi blood glucose symptoms, review proper testing procedure (refers to page 13) and perform a quality check (refers to page 7 and 8). Repeat test, if the result persists, contact your medical professional for help.
	Blood glucose result may be lower than 20 mg/dL (1.1 mmol/L)	If the reading is "LO" and you do not experience any low blood glucose symptoms, review proper testing procedure (refers to page 13) and perform a quality check (refers to page 7 and 8). Repeat test, if the result persists, contact your medical professional for help.
	Temperature is above or below the operating range of test strips.	The result you have obtained may not be accurate. Move to an area with temperature within the test strip's operating range temperature between 10°C to 40°C (50°F - 104°F). Do not artificially heat or cool the meter.
	Battery is low.	Change battery soon.

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Battery is dead.	Change battery now.
	Test strip may be damaged.	Perform the test with a new test strip only.
	Test strip is used or test was not performed correctly.	Perform the test with a new test strip only and follow the chapter of perform blood glucose test.
No responses when strip is inserted	1. Battery dead 2. Wrong strip inserted 3. Meter defective	1. Replace battery 2. Insert the test strip correctly 3. Contact us for help
No responses after sample is applied	1. Sample not sufficient 2. Meter defective	1. Repeat test with sufficient sample 2. Perform Meter Quality Check

NOTE : If there is any error message displayed but not listed here, or your meter shut down for no reason, you can reset the meter by following two ways:

- Replace the battery.
- Use a lancet to prink the "reset" hole (with a reset mark) beside the battery component.

REFERENCE

- Tietz N.W. textbook of Clinical Chemistry, P.2190 (1994)
- American Diabetes Association Position Statement, Diabetes Care Vol. 19 (Suppl.1), p.54 (1996)

PERFORMANCE EVALUATIONS

PRECISION

Tests were carried by trained technicians in the laboratory setting. The venous whole blood from one subject was adjusted to 3 different levels. Strips out of a single lot were tested. The results are shown in the following table.

Level	No. of tests	Mean[mg/dL]	Mean[mmol/L]	WithinRun[C.V.(%)]
Low	20	43	2.4	3.4
Normal	20	109	6.0	3.6
High	20	324	18.0	2.4

ACCURACY

Tests were performed at hospital by healthcare professionals and diabetic patients. Fresh capillary finger whole blood samples were tested with the GlucoAlpha™ Enhance System; plasma samples from the subjects were tested with YSI Model 2300 Glucose Analyzer as reference. The results are shown in the following table.

Slope	1.003
y-intercept	-1.07 mg/dL ; -0.06 mmol/L
Correlation Coefficient (R)	0.991
Number of tests	150
Range tested	84 - 489 mg/dL ; 4.7 - 27.2 mmol/L

SYMBOLS CONVEY

Information Essential For Proper Use

	For in vitro diagnostic use.
	Lot number
	Use by /Expiry date
	Temperature limitation / Store at
	Do not reuse
	Please consult instructions for use
	Caution, consult accompanying document
	Manufacturer
	EC representative
	This product fulfils the requirements of Directive 98/79/EC in vitro diagnostic medical device.

TAKING CARE OF YOUR METER

REPLACING THE BATTERY

The GlucoAlpha™ Enhance Blood Glucose Meter comes with a battery (pre-installed when new purchasing).

Battery life will vary depending on usage, so always keep a spare on hand.

The battery should last about 12 months when testing 3 times a day. When the battery symbol (FIG. 1) appears on the meter display, battery is getting low.

You will still be able to test with low battery, but you should replace it as soon as possible. When battery symbol appears flashing on the display, the meter will no longer give results and you must replace the battery immediately.

TO REPLACE THE BATTERY

- Make sure the meter is turned off.
- Let the front of the meter rest in the palm of your hand.
- Slide battery compartment door open.
- Remove the old battery and insert the new 3-volt Lithium battery (CR2032) into the battery compartment, being sure to align the plus (+) and minus (-) signs correctly.
- Slide battery compartment door closed. Check to see that your meter is working. If it fails to turn on, the battery may have been inserted incorrectly. Remove the battery and reinsert it.

NOTE: EVERY TIME WHEN YOU REPLACE THE BATTERY, THE METER WILL TURN ON AUTOMATICALLY AND ENTER TO THE TIME/DATE SETTING. PLEASE SET CORRECT TIME AND DATE BEFORE TESTING.

CLEANING

Clean the outside of the meter with a soft cloth, slightly dampened with water. Do not get moisture into the strip slot and data port.

STORAGE AND HANDLING

Keep your meter free of dust. Protect it from extreme temperature and humidity.

CUSTOMER SERVICE

Distributed by
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www.in4-technology.com

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