



eBcarryon

Blood Glucose Monitoring System

User's Manual



Welcome

Thank you for purchasing the **eBcarryon** Blood Glucose Monitoring System.

The Blood Glucose Monitoring System is designed for both people self-testing with diabetes or healthcare professionals to measure glucose concentration in capillary whole blood from the fingers only. These test strips are for *in vitro* diagnostic use only. The test results are whole blood-calibrated. The measuring range of glucose concentration in capillary whole blood is from 20 to 600 mg/dL (1.1 to 33.3 mmol/L). This booklet has important information you must know about **eBcarryon** Blood Glucose Monitoring System. Please read it carefully.

Test Principle

eBcarryon Blood Glucose Monitoring System is an electrochemical glucose monitoring system. It operates on the principle when blood glucose reacts with the reagent immobilized on the reaction area of the test strip, a small electrical current is being produced. By analyzing the current, **eBcarryon** can detect to the amount of glucose in the blood.

Accuracy (method comparison)

The system (test strip) is calibrated by means of the glucose oxidase method, which is traceable to a NIST standard Reference 965. The whole blood was used for calibration.



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1. **eBcarryon** blood glucose monitoring system

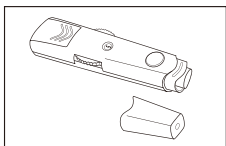
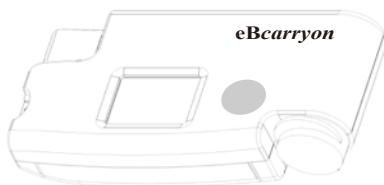
1.1. The blood glucose monitoring system.

The blood glucose monitoring system contains lancing device, lancets, and one vial of 10 strips. It is portable and easy to use.

eBcarryon meter uses capillary whole blood to measure blood glucose with **eBcarryon** and **eBcarryon II** strips.

1.2. Accessories

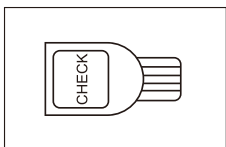
On your first purchase, please check if **eBcarryon** contains the following accessories. If any accessory is missing, please contact local distributor or the store you purchase **eBcarryon** from.



lancing device



User's manual



Check card



Warranty

Additional accessories

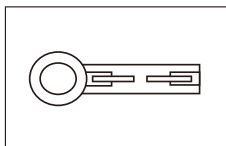
(not included in the bag with **eBcarryon**. If needed, please contact local distributor for ordering)

* **eBcarryonII** test strips 15/vial, 4 vials in a box

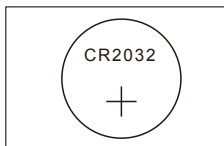
* **eBcarryonII** test strips 15/vial, 2 vials in a box

* Control solution (2 different concentrations of

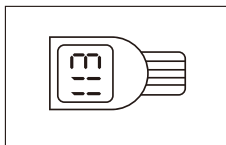
eB-series control solutions are used, ie., 100 and 300 mg/dL)



lancet



Lithium battery



Code card



eBcarryonII test strips



Control solution

1.3. Product Specifications

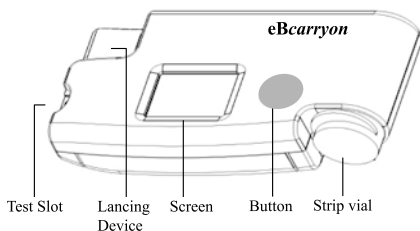
Strip Series	eBcarryon	eBcarryon II
1. Blood Volume	2.5 μ l	0.5 μ l
2. Measuring Time	10 seconds	5 seconds
3. Blood Sample	Capillary Whole Blood	
4. Hct Range	20~60 %	
5. Measuring Range	20~600 mg/dL (1.1~33.3 mmol/L)	
6. Measureing Unit	mg/dL or mmol/L	
7. Memory Capacity	70 blood glucose results	
8. System Operating Temperature	10 ~ 40°C	
9. System Operating Humidity	< 85%	
10. Meter Storage Temperature	0 ~ 50°C	
11. Meter Storage Humidity	< 95%	
12. Size	110 X 58 X 25 mm	
13. Weight	63 g	
14. Power Supply	CR2032 (3V, lithium battery)	

Note:

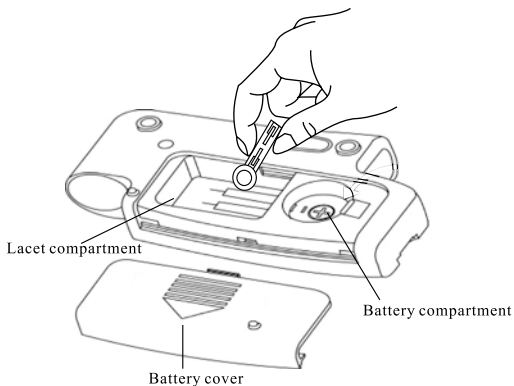
- 1. Before using eBcarryon , please read every detail in the user's manual.**
- 2. Age of 18 or under, Procedures must be demonstrated by parents.**

2. About eBcarryon blood glucose monitoring system

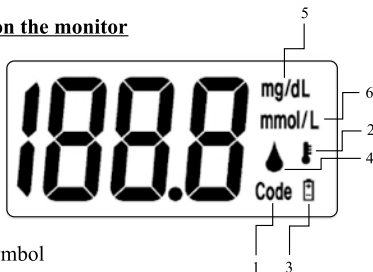
The front side of the Meter



The back side of the Meter



Symbols on the monitor



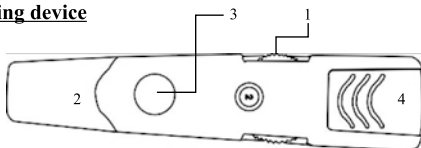
1. Code symbol
2. Thermograph symbol
3. Battery signal
4. Blood drop signal
5. Measuring unit : mg/dL
6. Measuring unit : mmol/L

Test strip



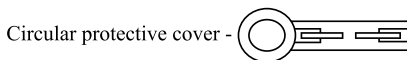
1. Top edge
Apply a drop of blood or control solution to the semicircle-shaped cutout.
2. Electrical contacts
Face these contacts up and insert into the meter.
3. Indication slot
To indicate if blood has been applied enough to fill the reaction area.

Lancing device

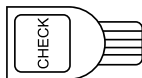


- 1.Depth selector
- 2.Cap
- 3.Release button
- 4.Cocking mechanism

Lancet



Check card

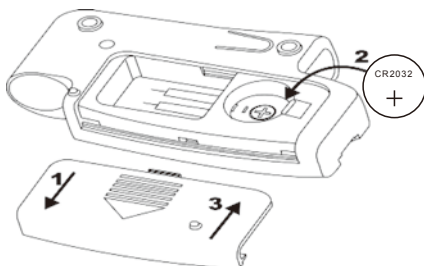


3. Operating methods

3.1. Before testing

3.1.1. Installing battery

The meter requires one 3 volt CR2032 Lithium battery.



Step 1. Open the battery cover.

Step 2. Put one 3 volt CR2032 Lithium battery.

Step 3. Place the battery cover back on.

When the battery power is low, a battery sign will be shown on the screen. Follow the steps above to replace the battery.

Note:

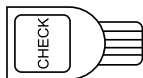
If not using the meter for a while, please take out battery from battery socket, in case of leaking and causing damage to the meter.

3.1.2. Check card

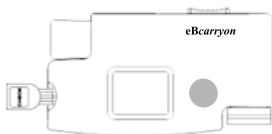
The check card is used to check whether your meter functions properly. please read the following steps.

3.1.2.1 Steps of conducting the check card

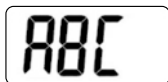
Step 1 : Take out the check card from lacet compartment.



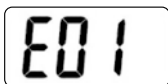
Step 2 : Insert the check card into the test slot.



Step 3 : If a mark of "ABC" is shown on the screen with a beep sound, it indicates that the function of the meter is normal.



If shown “E01” indicates that the meter does not function properly. Please contact local agent.



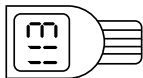
Step 4 : After check the meter, remove the check card from the meter.

3.2. Start Testing

3.2.1. Coding the Meter

For accurate results, your meter should be coded with the code card every time you open a new vial of tests trips. After you code the meter with code card, it is time to start testing your blood glucose.

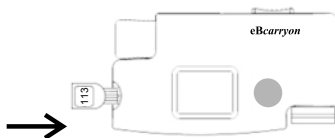
Step 1 : Open a new vial of blood glucose test strip and take out the code card from the vial box.



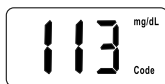
Step 2 : Insert the code card into the test slot.

eBcarryon

Blood Glucose Monitoring System



Step 3 : You can hear a “ beep ” sound and a code number appears on the screen (for example, 113) appears.



If inserted a wrong code card, “E10” will appear on the screen.



Step 4 : Check the code number on the screen with the number on the test strip vial. These two numbers have to be the same. If not, please stop testing and contact your local agent.

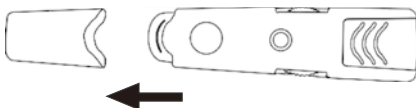
Step 5 : Remove the code card and you are ready for blood glucose testing.

3.2.2 Testing your blood glucose

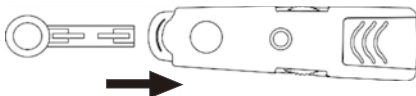
After checking the code number, you may now start testing blood glucose.

Step 1 : Take out the lancing device located at the side of the meter.

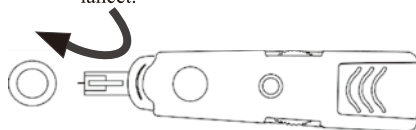
Step 2 : Remove the cap from the lancing device.



Step 3 : Insert a lancet into the lancing holder and push it down until it is fully seated.

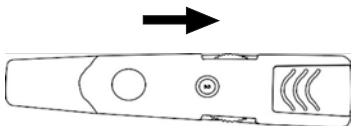


Step 4 : Twist off the circular protective cover from the lancet.

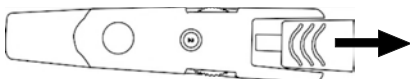


Step 5 : Push the cap back onto the lancing device.

Step 6 : You have to adjust the depth setting of lancing device before use. There are 5 adjustable setting depths. Level 1 is being slightest to Level 5 deepest respectively.



Step 7 : Slide the ejection/cocking control back until it triggered .



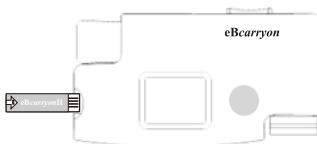
Step 8 : Wash your hands with warm, soap water.
Rines and dry thoroughly.




Step 9 : Open a new vial of test strips. Take out a test strip from the vial and close the cap properly.



Step 10 : Make sure the triangle sign on the test strip is facing up and insert the electrical contact fully into the test slot .



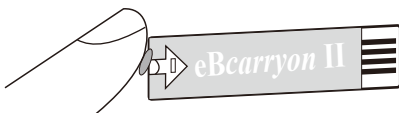
Step 11 : After inserting the test strip, the code number will be shown on the screen. The blood drop sign  will flash. Please apply blood within 3 minute or meter will turn off automatically.



Step 12 : Press the lancing device against your fingertip and pull the trigger (press the release button) on the lancing device. The lancet will prick your skin.

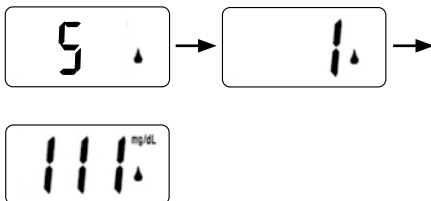


Step 13 : To obtain a drop of blood, squeeze your finger gently to form a small drop of blood. Apply the blood onto the semicircle-shaped cutout on the top edge of the test strip.



Step 14 : The blood will be drawn into the strip automatically. The blood has to fulfill the indication slot. If you have enough blood on the strip, the indication slot turns red (filled with blood). If the indication slot is not completely filled with blood before the count down begins, do not add more blood to the strip. Discard the strip and repeat the test using a new test strip again .

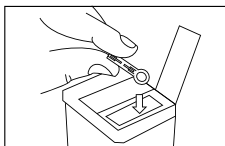
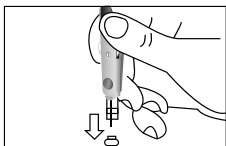
Step 15 : When the meter beeps, it starts counting down from 5 to 1. After counting down to 1, your test result appears on the Screen.



Step 16 : The meter will be turned off by removing the test strip. Dispose the used test strip in a sealed container.



Step 17 : Remove the cap from the lancing device. Put the protective cover back onto the lancet. Grip the lancet holder firmly and pull the lancet out. Dispose the used lancet in a sealed container.



4. eBcarryon memory uses

Step 1. Press ● button to enter memory mode. the “01” is flashing following by the last glucose results.



Step 2. Press the ● button again to obtain the second last glucose results.



step 3. You may obtain all 70 records by pressing the ○ button.

step 4. After the oldest result is shown, the meter will turn off automatically.



5. Check eBcarryon Blood Glucose Monitoring System (Optional)

using test strip you can use **eB-series** control solution to ensure the test strip is working properly with the meter. **eB-series** control solution is used to check the functionality of the monitoring system (meter working together with test strips).

When to do a control solution test:

1. When you open a new vial of test strips.
2. Whenever you suspect that the meter or test strips are not working properly.
3. When your blood glucose test results are not consistent with how you feel, or when you think your results may not be accurate.
4. If you drop the meter.

5.1. Steps of performing a control solution test

Step 1. Remove a test strip from the vial and close the cap Properly. Make sure the triangle sign on the test strip is facing up.

Step 2. Insert electrical contact fully into the test slot. The meter will turn on automatically and the code number will be shown on the screen with a beep sound. Make sure this number matches the code number on the test strip vial.

Step 3. Open a bottle of control solution. The storage period of control solution is 3 months after the first opening or up to the expiry date, whichever comes first.

Step 4. Always write down the opening date on the Bottle.

Step 5. Hold the bottle and gently squeeze the bottle to form a small drop of control solution on the tip of the bottle. note: always shake the bottle gently; discard the first drop before applying the control solution.

Step 6. Apply a drop of control solution to the semicircle - shaped cutout on the top of the test strip.

Step 7. The control solution will be drawn into the strip automatically. Make sure the indication slot is fulfilled with the control solution.

Step 8. The meter starts counting down from 5 to 1.

Step 9. At the end of the count down, your test result will appear on the screen.

Step 10. Compare the result with the expected range printed on the vial of the test strips. The result should be within the range.

Control solution and test strips are necessary but not provide and must be purchased separately. For more information on the control solution and where to purchase them, please contact local agent.

6. A range of expected values

Blood glucose monitoring requires the help of healthcare professionals in setting the expected range of your own blood glucose values, arranging your testing times, and discussing the meaning of your blood glucose results.

Expected blood glucose levels for people without diabetes¹ :

* Fasting and before meals : Less than 100 mg/dL
(5.6 mmol/L)

* 2 hours after meals : Less than 140 mg/dL
(7.8mmol/L)

Remember to repeat the test if the test result fall outside the expected range.



Caution :

If you get unexpected results:

Low or high blood glucose readings can indicate a potentially serious medical condition. Please consult your healthcare professional and follow his or her treatment advice.

Reference:

American Diabetes Association (2010), Clinical Practice Recommendation, Diabetes Care 34 (Supplement 1) : S11-S61.

7. Limitation

Blood Glucose Monitoring System will give accurate results when the following limitations are observed:

- The test strips should not be used for the testing of neonate.
- The test strips are for single use only. DO NOT reuse.
- Handle the meter with care. DO NOT drop the meter or apply a strong force to the meter.
- DO NOT disassemble the meter.
- DO NOT use code card from other glucose meter system.
- DO NOT operate the meter placed on hot or cold surface.
- The test result could be different from the laboratory result due to normal variation. However, the 2 results should be within 20% of each other.
- Always store the meter in the carrying case when not using.
- Keep away from dust or dirt.
- DO NOT let water into the meter. This can result in an inaccurate result, even after you dry the meter.
- DO NOT remove the strip while the measurement is in processing.
- The test strips are used only with fresh capillary whole blood from finger. DO NOT use serum or plasma.
- Hematocrit values less than 20% may cause falsely high test results; hematocrit values higher than 60% may cause falsely low test results (consult your healthcare professionals regarding your hematocrit value).
- Allow approximately 20 minutes before using the meter to ensure adjustment to room temperature. Neglecting to do so may cause incorrect test results.








- DO NOT use the meter close to a TV, microwave oven, cellular telephone, etc. Malfunction may occur.
- Follow the regulations in your area to dispose the used test strips and lancing materials.
- Avoid direct sunlight.
- The altitudes that are up to 8000 feet have no effect on **eBcarryon** blood glucose measurements.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with blood glucose meters.
- Use universal blood precautions. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection.
- The meter has to be used in an environment that the humidity less than 85%.
- It is suggested to operate the meter between 10~40°C (50~104°F) in surrounding temperature. (Meter will automatically be off when temperature goes below 4°C or above 42°C)
- The meter has to be recycled in a container which is WEEE directive.
- Follow proper precautions in accordance with local regulations when disposing of all materials.
- This unit is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

- Interferences: Acetaminophen, Pralidoxime iodide, Glutathione and Uric acid. Please see the table below for the certain concentrations which can affect the function of the meter.

Substance	No interference
Acetaminophen	< 13 mg/dl
Ascorbic acid	< 3 mg/dl
Creatinine	< 10 mg/dl
Dopamine	< 0.09 mg/dl
Glutathione	< 70 mg/dl
Maltose	< 300 mg/dl
Pralidoxime iodide	< 5 mg/dl
Uric acid	< 15 mg/dl





8. Troubleshooting

following table is a summary of all display messages. This table can help you to identify the problems. However, the message may not appear every time when the problem occurs. Improper use may cause inaccurate result without showing an error message or a symbol.

Message	Cause	Action
	The meter is abnormal	The meter needs to be repaired. Please contact our authorized distributors
	The battery power is low.	Replace with new battery
	No battery power. The meter will be turned off automatically	Replace with new battery
	The meter will display "LO" with a thermometer sign when temperature goes below 10°C, when the temperature goes below 4°C (39.2°F) the meter will turn off automatically	Repeat the test in warm place between 10°C ~40°C (50°F ~104°F)
	When the surrounding temperature goes above 42°C (107.6°F) the meter will display "HI" and be off automatically.	Repeat the test in a place between 10°C ~40°C (50°F ~104°F)

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	Your blood glucose level is higher than 600 mg/dL (33.3 mmol/L)	Re-check your blood glucose level. If “HI” is displayed again, Please call your doctor immediately
	Your blood glucose level is Lower than 20 mg / dL (1.1 mmol/L)	Re-check your blood glucose level. If “LO” Is displayed again, please call your doctor immediately
	The code card is inserted improperly	Make sure the code card is inserted into the test slot completely
	The test strip is abnormal	Please use a new test strip



Do not reuse



Consult operating instructions



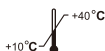
Keep dry



Caution, consult accompanying documents



In-Vitro diagnostic



Operating temperature limitation



Store temperature limitation



Manufacturer



Keep away from sunlight



Batch number



EU Representative



please do not dispose this meter with other household or municipal waste. Please follow regulation to dispose the meter at desinated recycling facility, or return it back to your original purchasing site.



Use by



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Florida 33162, USA



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