eB-P01

Blood Glucose Monitoring System

GDH

User's Manual

easy Blood monitoring

Welcome

Thank you for selecting the eBfine Blood Glucose Monitoring System. This manual provides all the information you need to get accurate test results. Please read this entire manual carefully before you proceed with testing.

At Visgeneer, we believe in the value of early prevention over later treatment. eBfine Blood Glucose Monitoring System is developed under this vision and is manufactured and supported by us. For any questions or concerns, please feel free to reach out to us or our local agent. Our contact information is located in the back cover of this manual.

Intended Use

The eBfine Blood Glucose Monitoring System is designed for people self-testing with diabetes to measure glucose concentration in capillary whole blood from the fingers and venous whole blood. 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).

Test Principle

The technology used for the eBfine Blood Glucose Monitoring System is based on the principle that small electrical currents are produced when blood glucose reacts with the reagent immobilized on the reaction area of the eBfine test strip and the current change is proportional to the amount of glucose in the blood.

Accuracy (Method Comparison)

The eBfine Blood Glucose Monitoring System is calibrated by means of glucose oxidase method to display plasma equivalent results, which is traceable to an NIST standard SRM917d. The whole blood was used for calibration.

Table of Contents

1. eBfine Blood Glucose Monitoring System

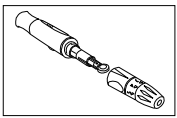
1.1 The eBfine System

The eBfine system is intended to monitor blood glucose in fresh capillary whole blood and venous whole blood. The system is used outside the body only. Also, please do the test only with eBfine test strips.

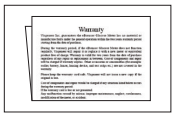
1.2. Equipments in Package

Please check the kit package for the eBfine Blood Glucose Monitoring System which should include the following items. If not, please contact our local agent or exchange at the original purchased store.

Meter



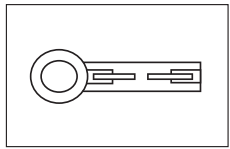
Lancing Device



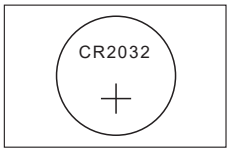
Warranty

Optional items (not included in the kit package, contact our local agent for ordering)

- eBfine Blood Glucose Test Strips 50 pcs/vial.
- eB-series glucose control solution.



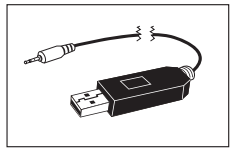
Lancet



Lithium Battery

Control Solution

Blood Glucose
Test Strips



USB PC Interface

1.3. Product Specification

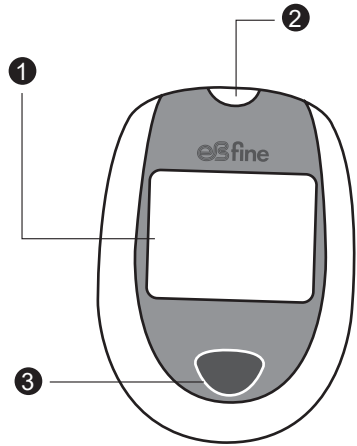
Strip series	eBfine
1. Blood volume	0.5 μL
2. Measuring time	5 seconds
3. Blood sample type	Capillary and venous whole blood
4. Acceptable hematocrit range	20～60 %
5. Measuring range	20～600 mg/dL (1.1～33.3mmol/L)
6. Measuring unit	mg/dL and mmol/L (Interchangeable)
7. Memory capacity	180 results with time and date
8. Time display	24H
9. Operating temperature range	10 ~ 40 °C
10. Relative humidity operating range	Below 85%
11. Meter storage condition	0～50 °C
12. Meter storage humidity range	Below 95%
13. Dimensions L x W x H (mm)	85 x 63 x 15 mm
14. Weight	≦ 50g
15. Power supply	One 3 Volt lithium battery (CR2032)
16. Data output	USB PC Interface

Note :

Please read all the instructions carefully in this booklet before you start using the System. Parental guidance is advised with use including minors (below 18 years).

2. About eBfine Glucose Monitoring System

The front side of the meter

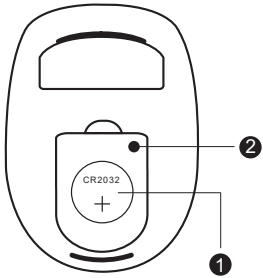


1 Screen
Shows blood glucose result, messages and blood glucose results stored in memory

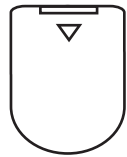
2 Test Slot
Insert test strip and Code card here

3 Button
Used to recall stored test results or to change the values in the set mode (time date) and Measurement Unit.

The back side of the meter

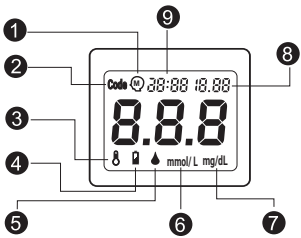


Battery cover



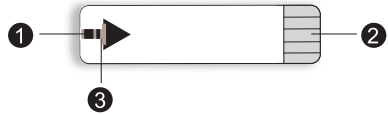
1. **Battery Slots**
   Use one 3 volt CR2032 Lithium battery.
2. **Setting Knob**
   For setting up year , time , date and measurement unit.

The screen of the meter



1. Memory Symbol
2. Code Symbol
3. Thermograph
4. Battery sign
5. Blood drop sign
6. Measuring unit: mmol/L
7. Measuring unit: mg/dL
8. Date
9. Time

Test strip



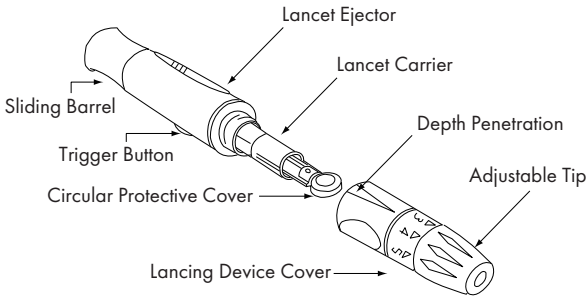
1 Top Edge
Apply a drop of blood or control solution to the cutout on the top of the narrow channel of the test strip

Electrical Contacts
2 Face these contacts up and insert into the meter

Indication Slot
3 To indicate if blood has been applied enough to fill the reaction area

Lancing set

Lancing device



Lancet

3. Operating Procedure

3.1 Before Testing

3.1.1. Installing Battery

The meter requires one 3-volt CR2032 lithium battery.
Step 1. Open the battery slot.
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 to prevent leakage and damage to the meter.

3.1.2 Setting the Time and Date

The time and date should be set before testing and whenever you change the battery. Setting the time and date is important for reviewing the results stored in memory. Please note that the time is set in 24 hours.

Step 1. Open the battery cover and find a setting knob on the top right side above the battery slot.

Step 2. Press and release the setting knob, the year digits start flashing on the screen.

Step 3. Press and release the button to djust the digits until the correct year is shown on the screen.

Step 4.Press and release the setting knob, the month digits start flashing on the screen.

Step 5.Press and release the button to adjust the digits until the correct month is shown on the screen.

Step 6.Press and release the setting knob, the day digits start flashing on the screen.

Step 7.Press and release the button to adjust the digits until the correct day is shown on the screen.

Step 8.Press and release the setting knob, the hour digits start flashing on the screen.

Step 9.Press and release the button to adjust the digits until the correct hour is shown on the screen.

Step10.Press and release the setting knob, the minute digits start flashing on the screen.

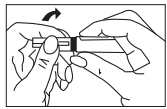
Step11.Press and release the button to adjust the digits until the correct minutes are shown on the screen.

Step12. Press and release the "setting" knob to set the Measurement Unit : Press the button for 3 seconds to switch the measurement unit between mg/dL and mmol/L.

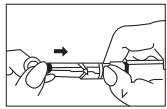
Step13.Press and release the setting knob, "OFF" will appear on the screen to exit the time and date setting mode.

3.2 Start Testing

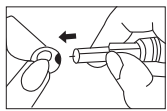
Step 1.Remove the cap from the lancing device.



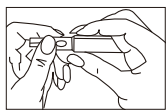
Step 2.Insert a lancet into the lancing holder and push it down until it is fully seated.



Step 3.Twist the circular protective cover in the front of the lancet. Then, remove the protective cover from the lancet.

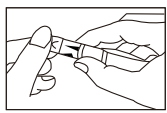


Step 4.Put the cap back onto the lancing device.

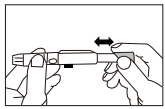


Step 5.You have to adjust the depth setting of lancing device before using. There are 5 levels of depth you can choose. Level 1 is for people with very thin skin. Level 5 is for people with very thick skin.

Step 6.Choose a desired skin penetration depth for yourself by rotating the depth selector until the depth selection window displays your desired depth setting.



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

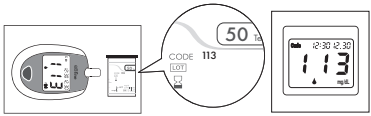


Step 8. Wash your hands with warm, soapy water. Rinse and dry thoroughly.

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

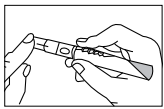
Step10. Make sure the triangle sign on the test strip is facing up and insert the electrical contact end of the test strip fully into the test slot. The blood drop sign will flash until your blood fulfills the indication slot.

Step11. Then, the meter will turn on automatically and the code number will be shown on the screen with a "beep" sound (for example, 113). Please make sure that this number matches the code number on the vial of test strips.



Step12. Put your hands on a table and press the lancing device against your fingertip.

Step13. Push the trigger on the lancing device and the lancet will prick your skin.



Step14.To obtain a drop of blood, squeeze your finger gently to form a small drop of blood.

Step15.Touch the drop of blood to the cutout on the top of the narrow channel of the test strip.

Step16. 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 completed filled with blood before the meter begins to count down, do not add more blood to the strip and discard the strip. Please repeat the test.

Note: Please do not drop the blood from above.

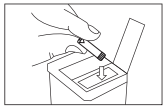
Step17.Hold your blood to the strip until after the meter beeps.

Step18.The meter starts counting down from 5 seconds.

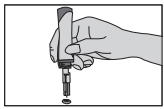
Step19. After counting down from 5 to 1, your test result appears on the screen (for example, 100) and is stored automatically in the meter's memory.

Step20.The meter will be turned off by removing the test strip.

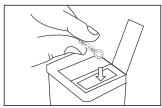
Step21.Dispose the used test strip in a sealed container.



Step22. Remove the cap from the lancing device.Put the protective cover back onto the lancet.



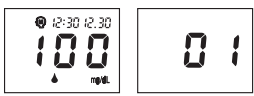
Step23.Push the ejector forward and dispose the lancet to a sealed container.



4. Accessing the Meter Memory

Your Blood Glucose Meter stores 180 most recent glucose results with date and time in the memory. When the memory is full, the most recent result is added to the memory and the oldest result is deleted from the memory.

Step 1.You may enter the memory mode by press the ⌓ button. "01"will flash followed by the latest glucose results with date and time.



Step 2.Press the ⌓ button again to obtain the second record.

Step 3.You may obtain all 180 records by pressing the ⌓ button.

Step 4.After the oldest result is shown, the symbol "OFF" will appear on the screen to exit the memory mode and then the meter will be turned off automatically.

5. Quality Control Testing (Optional)

You can use control solution to ensure the test strip is working together with the meter properly.

eB-series Glucose Control Solution is used to check that if the monitoring system (meter working together with test strips) is functioning properly.

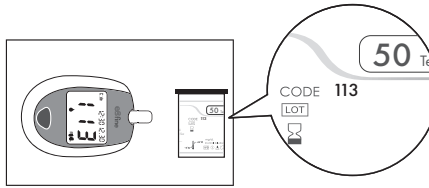
When to do a control solution test:

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.

Steps of Performing a Control Solution Test

Step 1: Take out 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 the electrical contact end of the test strip 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 vial of test strips.



Step 3: Open a bottle of Control Solution. The storing period of Control Solution is good for only 3 months after the first opening or upto 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: Touch the drop of control solution to the cutout on the top of the narrow channel of the test strip.

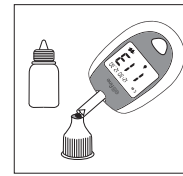
Step 7: The control solution will be drawn into the strip automatically. Make sure the indication slot is fulfilled with the control solution.

Step 8: The meter starts counting down from 5 seconds.

Step 9: After counting down from 5 to 1, your test result appears on the screen.

Step10: 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 may not be provided and must be purchased separately. For more information on the control solution and where to purchase them, please contact our local agent.



6. 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 frequency of tests, and discussing the meaning of your blood glucose results.

Expected blood glucose levels for people without diabetes[1]:

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

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

REMEMBER TO REPEAT THE TEST IF THE TEST RESULT FALLS OUTSIDE THE EXPECTED RANGE

If you get unexpected results:
Low or high blood glucose readings can indicate a potentially serious medical condition. Please consult your healthcare rofessional and follow his or her treatment advice.

Reference:

1. 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.
- Always store the meter in the carrying case when not using.
- Keep away from dust or dirt.
- **DO NOT** drop the meter into water or let water enter into the meter. This can result in an inaccurate result, even if you dry it.
- **DO NOT** remove the strip while the measurement is in processing.
- If the surface of meter gets dirty, you may gently wipe with 70% alcohol soft cloth and avoid liquid into the test slot or transmission slot.
- 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 professional 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 or cellular telephone. 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 eBfine 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 suggest 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 a flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Interferences: Pralidoxime iodide, Gentisic acid, Hemoglobin and Glutathione. Please see the table below for the certain concentrations which can affect the function of the meter.

Substance	No Interference
Acetaminophen	< 20 mg/dL
Creatinine	< 10 mg/dL
Dopamine	< 0.09 mg/dL
Galactose	< 15 mg/dL
Gentisic acid	< 2 mg/dL
Glutathione	< 70 mg/dL
Hemoglobin	< 800 mg/dL
Maltose	< 250 mg/dL
Pralidoxime iodide	< 10 mg/dL
Uric acid	< 23 mg/dL

8. Troubleshooting

The following table is a summary of all display messages. It 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 local agent.
	The battery power is low.	Replace with one 3 volt CR2032 Lithium battery.
	The surrounding temperature is too low (4°C~ 9°C) or too high (41°C~ 42 °C) to perform a test.	Repeat the test in a place between 10°C~40°C (50°F ~104°F).
	No battery power. The meter will turn off automatically.	Replace with one 3 volt CR2032 Lithium battery.
	When the temperature goes below 4°C(39.2°F) the meter will turn off automatically.	Repeat the test in a place between 10°C ~ 40°C (50°F~104°F).
	The surrounding temperature is too high to perform a test.	Repeat the test in a place between 10°C ~40°C (50°F ~104°F).

Message	Cause	Action
	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 (1.1mmol/L).	Re-check your blood glucose level. If "LO" is displayed again, please call your doctor immediately.
	The test strip is used or damp.	Please use a new test strip.
	The code card is damaged or a wrong code card is used.	Please contact our local agent.

9. Labeling and Information

	Use by date	SN	Serial number
	Do not re-use	EU REP	Authorized representative in the European Community/European Union
	Keep dry		Caution, consult accompanying documents
LOT	Batch number		Consult instructions for use
	Manufacturer		Operating temperature limitation
	Recycling		Store temperature limitation
IVD	In vitro diagnostic medical device		Keep away from sunlight

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

CE This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices.

Lancet CE 0197 and Lancing Device CE
Beijing Ruicheng Medical Supplies Co., Ltd.
Building 5, No. 8, Yanqi West Road, Yanqi Economic
Development Zone, Huairou District, 101407 Beijing, P.R. China

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