



eB sensor eB-G

Blood Glucose Monitoring System

GOD

User's Manual

VISGENEER INC.

No. 335, Sec. 6, Zhonghua Rd.,
30094 Hsinchu City, Taiwan

Tel : 886-3-5181918

Fax : 886-3-5181908

E-mail :

eB@visgeneer.com

Website :

www.eB-monitor.com

www.visgeneer.com



CE 0123



Ver.12
1320014

eB monitor
easy Blood monitoring

Welcome

Thank you for selecting the eBsensor Blood Glucose Monitoring System. This booklet has important information you must know about blood glucose monitoring system. Please read it carefully.

[Intended Use]

The eBsensor 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).

[Test Principle]

The technology used for the eBsensor Blood Glucose Monitoring System is based on the principle that a small electrical current produced when blood glucose reacts with the reagent immobilized on the reaction area of the eBsensor II Blood Glucose Test Strip and the current change is proportional to the amount of glucose in the blood.

[Accuracy (Method Comparison)]

The eBsensor Blood Glucose Monitoring System is calibrated by means of glucose oxidase method to display plasma equivalent results, which is traceable to an NIST standard SRM917c. The whole blood was used for calibration.

Table of Contents

1. eBsensor Blood Glucose Monitoring System	3
1.1. The eBsensor System	3
1.2. Equipment in Package	3
1.3. Product Specification	6
2. About eBsensor Blood Glucose Monitoring System	7
3. Operating Methods	12
3.1. Before Testing	12
3.1.1. Installing the Batteries	12
3.1.2. Setting the Time and Date	12
3.1.2.1. Steps of Setting the Time and Date	13
3.1.3. Measurement Unit Switch	14
3.1.3.1. Steps of Selecting Measurement Unit	14
3.1.4. Check Card (When Provided)	15
3.1.4.1. Step of Conducting the Check Card	15
3.2. Start Testing	16
3.2.1. Coding the Meter (When Provided)	16
3.2.1.1 Steps of Coding the Meter	16
3.2.2. Testing Your Blood Glucose	17
3.2.2.1 Steps of Blood Glucose Testing	17
4. Using the Meter Memory	22
4.1. Steps of Reviewing the Stored Results in Memory	22
5. Data Transmission	22
5.1. Steps of Transmitting the Data	23
6. Checking eBsensor Blood Glucose Monitoring System (Optional)	24
6.1. Steps of Performing a Control Solution Test	24
7. Range of Expected Values	25
8. Limitation	26
9. Troubleshooting	29
10. Labeling and Information	31

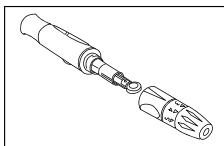
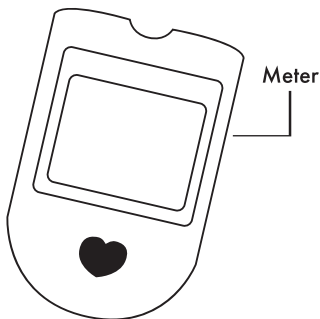
1. eBsensor Blood Glucose Monitoring System

1.1. The eBsensor System

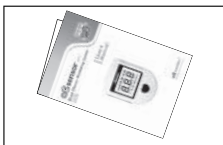
The eBsensor system is intended to monitor blood glucose in fresh capillary whole blood. The system is used outside the body only. Also, please do the test only with test strips.

1.2. Equipments in Package

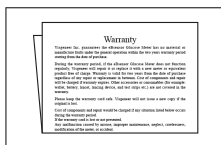
Please check the kit package for the eBsensor Blood Glucose Monitoring System which includes the following items. If not, please contact the local agents or exchange at the original purchased store.



Lancing Device



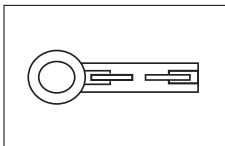
User's Manual



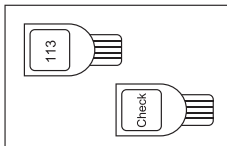
Warranty

Optional items (not included in the kit package, contact your local agents for ordering)

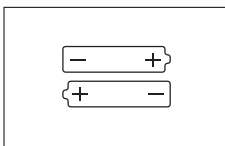
- Blood Glucose Test Strips 50 pcs/vial.
- Control Solution. (Two different concentrations of control solutions are used, ie. 100 and 300 mg/dL)



Lancet



Code Card /
Check Card



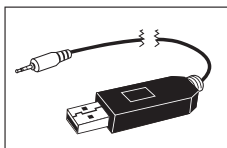
Two 1.5-volt AAA
Alkaline Batteries.



Control Solution



Blood Glucose Test
Strips



USB PC Interface

1.3. Product Specification

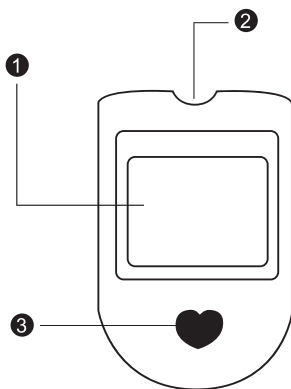
Strip Series	eBsensor II
1. Blood Volume	0.5 µl
2. Measuring Time	5 seconds
3. Blood Sample Type	Capillary whole blood
4. Acceptable Hematocrit Range	20-60 %
5. Measuring Range	20-600 mg/dL (1.1-33.3mmol/L)
6. Measuring Unit	mg/dL and mmol/L (Interchangeable)
7. Memory Capacity	180 results with time 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)	87 x 60 x 21 mm
14. Weight	≤ 80g
15. Power Supply	Two 1.5-volt AAA alkaline batteries
16. Data Output	USB PC Interface

Note :

1. 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).

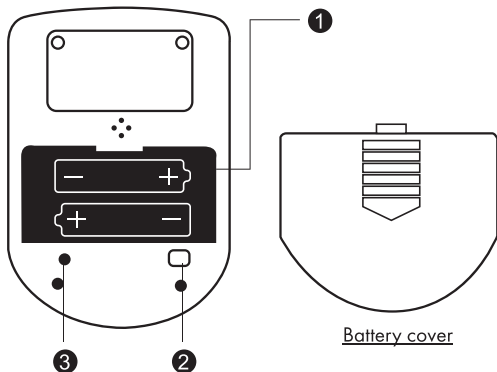
2. About eBsensor Blood Glucose Monitoring System

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

The back side of the meter



1 Battery Slots

Use two 1.5-volt AAA alkaline batteries.

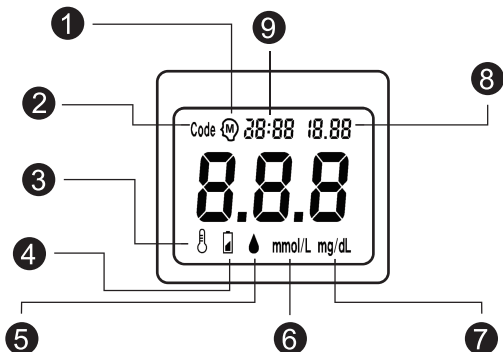
2 Unit switch

For adjusting the measure unit of the meter.

3 Clock setting knob

For setting up time and date

The screen of the meter



① Memory symbol

② Code symbol

③ Thermograph

④ Battery sign

⑤ Blood drop sign

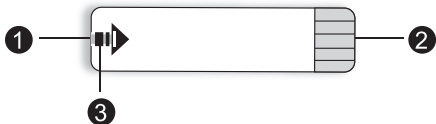
⑥ Measuring unit: mmol/L

⑦ Measuring unit: mg/dL

⑧ Date

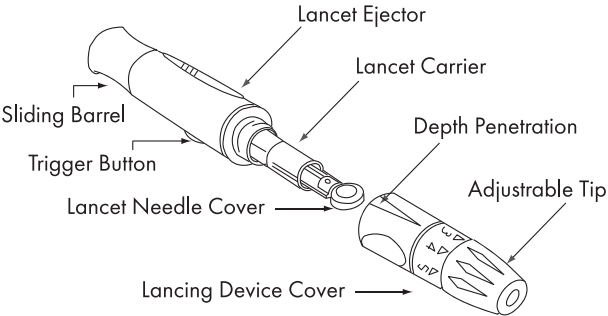
⑨ Time

Test strip

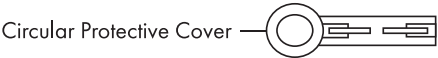


- ① Top edge
Apply a drop of blood or control solution to the semicircle shaped cutout on the top of the narrow channel of the test strip.
- ② Electrical contacts
Face these contacts up and insert into the meter.
- ③ Indication slot
To indicate if blood has been applied enough to fill the reaction area.

The lancing set



Lancing device



Lancet

3. Operating Methods

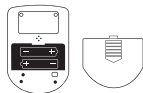
3.1. Before Testing

3.1.1. Installing the Batteries

The meter requires two two 1.5-volt AAA alkaline batteries.

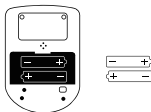
Step 1. Open the battery cover.

Step 2. Two battery slots inside and each with battery direction signs.



Step 3. Follow the positive "+" and negative "-" signs of the battery.

Step 4. Put batteries into the slots individually and the two batteries are installed in the opposite direction.



Step 5. You can hear a "beep" sound after two batteries are installed properly.

Step 6. Set the time and date. Please refer to 3.1.2. in this booklet.

Step 7. Place the battery cover back.

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

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.

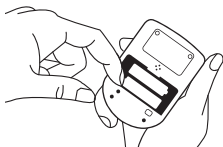
3.1.2. Setting the Time and Date

The time and date should be set before testing 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.

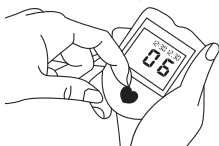
3.1.2.1. Steps of Setting the Time and Date

Step 1. Open the battery cover and find a clock setting knob on the left bottom side below the battery slot.

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



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



Step 4. Press and release the clock 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 clock 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 clock 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.

Step 10. Press and release the clock setting knob, the minute digits start flashing on the screen.

- Step 11. Press and release the ♥ button to adjust the digits until the correct minutes are shown on the screen.
- Step 12. Press and release the clock setting knob, the “OFF” appears on the screen to exit the time and date setting mode.



3.1.3. Measurement Unit Switch

The meter is designed to show glucose values in two different measurement units. These units are milligrams per deciliter (mg/dL) and millimoles per liter (mmol/L).

3.1.3.1. Steps of Selecting Measurement Unit

- Step 1. Open the battery cover and find a switch on the right bottom side the battery slot.
- Step 2. Move the switch to the right if you select milligrams per deciliter as your measurement unit; the unit of mg/dL will be shown on the screen. Move the switch to the left if you select millimoles per liter as your measurement unit; the unit of mmol/L will be shown on the screen.



You may skip Step 3.1.4 of the instruction, when the meter is equipped with automatic checking function. The check card will not be provided.

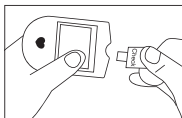
3.1.4. Check Card (When Provided)

The check card is used to check whether your meter functions properly.

3.1.4.1. Step of Conducting the Check Card

Step 1. Take out the check card from the carrying case.

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



Step 3. If a mark of "ABC" is indicates that the function of the meter is normal.



If a mark of "E01" is shown on the screen, it indicates that the meter does not function properly. Under this situation, please remove the check card from the meter and put it back to the package.



In the meanwhile, the meter is not ready for blood glucose testing. Please call the authorized distributor.

Step 4. After check the meter, remove the check card from the meter and put it back to the package. The meter is then ready for blood glucose testing.

You may skip Step 3.2.1 of the instruction, when new vial of strips users the same code that was previously set on the meter.

3.2. Start Testing

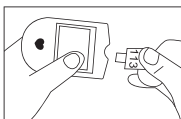
3.2.1. Coding the Meter (When Provided)

For accurate results, your meter should be calibrated with the code card every time when you open a new vial of test strips. After you calibrate the meter with the code card, it is the time to start testing your blood glucose.

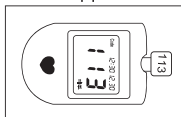
3.2.1.1. Steps of Coding the Meter

Step 1. Open a new box of eBsensor II Blood Glucose Test Strip and take out the code card from the box.

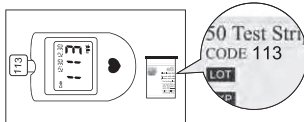
Step 2. Insert the code card into the test slot.



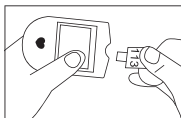
Step 3. You can hear a "beep" sound and a code number appears on the screen (for example, 113).



Step 4. Check the code number on the screen with the number on the vial of test strips. 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.



Note:

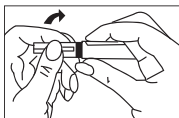
When the meter is equipped with automatic checking function. Insert the code card/strip into the test slot. "CH-" will be shown on the screen and the meter will do self-detection. If the self-detection fails, "E01" will appear on the screen. The code number will be shown on the screen in normal circumstances.

3.2.2. Testing Your Blood Glucose

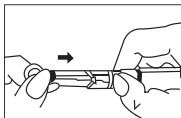
Now you are ready for testing your blood glucose by using eBsensor meter.

3.2.2.1. Steps of Blood Glucose Testing

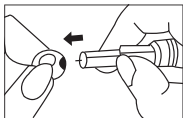
Step 1. Remove the cap from the lancing device.



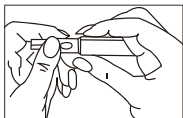
Step 2. Insert a lancet into the lancing holder and push it down until it is fully seated.



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

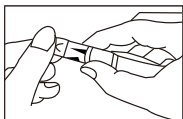


Step 4. Put the cap back onto the lancing device.

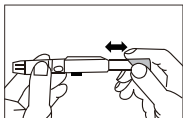


Step 5. You have to adjust the depth setting of lancing device before using. There are 5 levels of depth you can choose. Level 1 is for people with very thin skin. Level 5 is for people with very thick skin.

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 triggered.



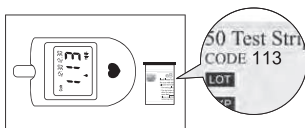
Step 8. Wash your hands with warm, soapy water. Rinse and dry thoroughly.



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

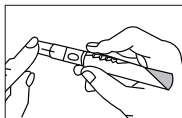
Step 10. Make sure the triangle sign on the test strip is facing up and insert the electrical contact end of the test strip fully into the test slot. The blood drop sign will flash until your blood fulfills the indication slot.

Step 11. 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.



Step 12. Put your hands on a table and press the lancing device against your fingertip.

Step 13. Push the trigger on the lancing device and the lancet will prick your skin.



- Step 14. To obtain a drop of blood, squeeze your finger gently to form a small drop of blood.
- Step 15. Touch the drop of blood to the semicircle-shaped cutout on the top of the narrow channel of the test strip.
- Step 16. 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 bring the test strip close to the blood sample for absorption.

- Step 17. Hold your blood to the strip until after the meter beeps.
- Step 18. The meter starts counting down from 5 seconds.
- Step 19. 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.

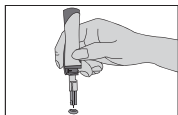


- Step 20. The meter will be turned off by removing the test strip.

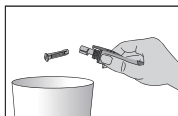
Step 21. Dispose the used test strip in a sealed container.



Step 22. Remove the cap from the lancing device. Put the protective cover back onto the lancet.



Step 23. Push the ejector forward and dispose the lancet to a sealed container.



4. Using 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.

4.1. Steps of Reviewing the Stored Results in Memory

Step 1. You may enter the memory mode by press the ♥ button. The "01" is flashing following 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. Data Transmission

eBsensor allows users to transmit the test results stored in the meter memory to the PC. Users can also print out the test results through the PC to provide more data to their doctors. Computer software and USB cable designed specifically for meter are required for data transmission from meter to PC.

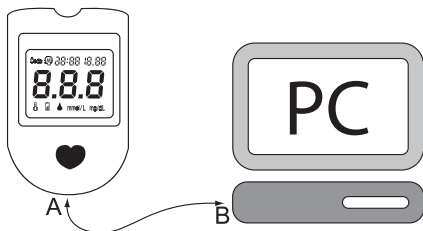
Note:


- Users must use software and USB cable specifically designed for meter to upload the data to PC.
- Users cannot proceed with blood glucose tests during data transmission.
- If more information is needed, please contact your doctor or our local distributor.

5.1. Steps of Transmitting the Data

Install the glucose data analysis software on your PC and have the USB cable (to purchase separately) ready.

Step 1. Plug the port A of USB cable to data transmission slot of meter and port B to your PC (see sketch below). When connect successfully, "on line PC " will appear on the screen.



Step 2. Run the glucose data analysis program and "  " indicator diagram will appear on your PC screen. That means the data is under transmission, and please wait for the transmission to complete. When the transmission is successfully completed, all blood glucose test results and testing time (including year, month and day) will appear on the PC screen.

6. Checking eBsensor Blood Glucose Monitoring System (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 tests trips) is functioning properly.

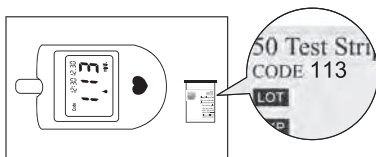
When to do a control solution test:

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.

6.1. 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 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 only for 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. Touch the drop of control solution to the semicircle-shaped 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 fully filled 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.
- 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 provided and must be purchased separately.

For more information on the control solution and where to purchase them, please contact local agent.

7. Range of Expected Values

Blood Glucose Monitoring System 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 diabetes ⁽¹⁾ :

- Fast 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 professional and follow his or her treatment advice.

Reference:

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

8. 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.
- If the surface of meter gets dirty, you may gently wipe with 70% alcohol soft cloth avoid liquid into the test slot or transmission slot.







- **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 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 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 eBsensor 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 where the humidity is 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: 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

9. 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 authorized distributors.
	The battery power is low.	Replace with two new 1.5-volt AAA alkaline batteries.
	No battery power. The meter will be turned off automatically.	Replace with two new 1.5-volt AAA alkaline batteries and reset the time and date.
	The surrounding temperature is too low (4-9°C) or too high (41-42°C) to perform a test.	Repeat the test in a place between 10-40°C (50-104°F).
	When the temperature goes below 4°C (39.2°F) the meter will turn off automatically.	Repeat the test in a place between 10-40°C (50-104°F).
	When the temperature goes above 42°C (107.6°F) the meter will turn off automatically.	Repeat the test in a place between 10-40°C (50-104°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 (1.1 mmol/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 damaged or using a wrong code card.	Please contact our authorized distributors.

10. Labeling and Information



Do not re-use



Consult operating instructions



Keep dry



Caution, consult accompanying documents



In vitro diagnostic medical device



Operating temperature limitation



Store temperature limitation



Use-by date



Keep away from sunlight



Batch number



Serial number



Authorized representative in the European Community/ European Union



Manufacturer



Paper recycling



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



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.

 **Lancet**  **0197** and Lancing Device 
Beijing Ruicheng Medical Supplies Co., Ltd.
No. 558 Zhangzikou, Yangsong Town,
Huairou District, 101400 Beijing, China



Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

 **VISGENEER INC.**

No. 335, Sec. 6, Zhonghua Rd.,
30094 Hsinchu City, Taiwan
Tel : 886-3-5181918
Fax : 886-3-5181908
E-mail : eb@visgeneer.com
Website : www.eb-monitor.com | www.visgeneer.com

EC	REP
-----------	------------

MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster, Germany

 **0123**