Welcome

Thank you for selecting the **eB*fresh*** Blood Glucose Monitoring System.

The **eB*fresh*** 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 **eB*fresh*** Blood Glucose Monitoring System. Please read it carefully.

Test Principle

The technology used for the **eB*fresh*** 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 **eB*fresh*** Test Strip and the current change is proportional to the amount of glucose in the blood.

Accuracy (method comparison)

The **eB*fresh*** Blood Glucose Monitoring System is calibrated by means of glucose oxidase method to display plasma equivalent results, which is traceable to an NIST standard SRM917. The whole blood was used for calibration.

Table of contents

1. eB*fresh* Blood Glucose Monitoring System 4
   1.1. The eB*fresh* System 4
   1.2. Equipments in package 4
   1.3. Product Specification 7

2. About eB*fresh* Glucose Monitoring System 8

3. Operating methods 13
   3.1 Before Testing 13
      3.1.1. Installing the batteries 13
      3.1.2. Setting Mode 14
      3.1.3. Coding the Meter 17
   3.2 Start testing 20

4. Using the meter memory 28
   4.1 Reviewing the stored results in memory 28

5. Data Transmission 29
   5.1 Steps of transmitting the data 29

6. Check **eB*fresh*** Glucose Monitoring System (Optional) *31*
6.1 Steps of performing a control solution test *32*

7. A range of expected values *33*

8. Limitation *34*

9. Troubleshooting *37*

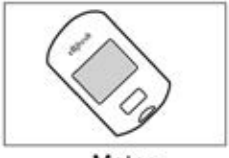
1. eB*fresh* blood glucose monitoring system

1.1. The eB*fresh* System

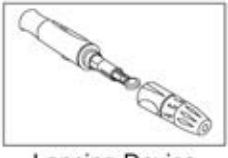
The **eB*fresh*** system is intended to monitor blood glucose in fresh capillary whole blood. The system is used outside the body only. Also, please do the test only with **eB*fresh*** test strips.

1.2. Equipments in package

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



Meter



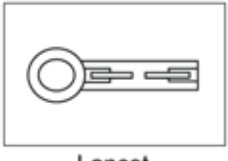
Lancing Device

Warranty

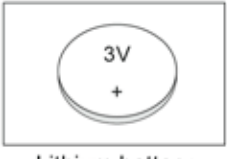
User's Manual

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

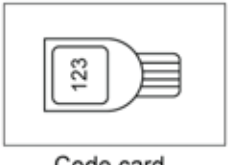
- **eB*fresh*** Blood Glucose Test Strips 50 pcs/vial.
- Control Solution. (Two different concentrations of eB-*series* control solutions are used, ie. 100 and 300 mg/dL)



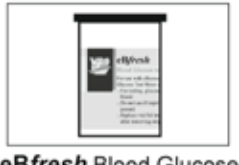
Lancet



Lithium battery

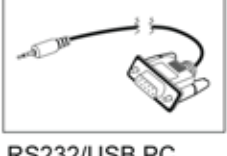


Code card



eB*fresh* Blood Glucose Test Strips

The control solution



RS232/USB PC Interface

1.3. Product Specification

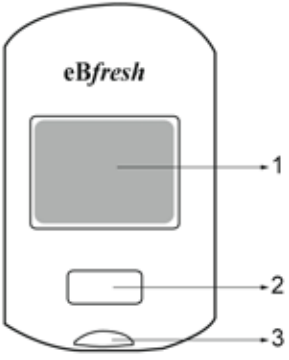
Item	eB*fresh*	Specification
1	Blood Sample Type	Capillary Whole Blood
2	Blood Volume	0.5 µl
3	Acceptable Hematocrit Range	20 % ~ 60 %
4	Measuring Range	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)
5	Measuring Unit	mg/dL and mmol/L (Interchangable)
6	Measuring Time	5 seconds
7	Memory Capacity	450 results with time and date
8	Average Display	7, 14 and 28 days
9	Time Display	12H
10	Operating Temperature Range	10 ~ 40 ℃
11	Relative Humidity Operating Range	Below 85 %
12	Meter Storage Condition	0 ~ 50 ℃
13	Meter Storage Humidity Range	Below 95 %
14	Dimension	99X61X16mm
15	Weight	≤50 g
16	Power Supply	CR2032 (3V, lithium battery)
17	Data Output	RS232/USB PC Interface
18	Control Solution Test	Control solution test results will not be calculated into day average
19	Alarm Function	Alarm clock
20	Meter Ready for Blood Test	Indicating with flashing test strip symbol
21	Temperature Unit	℃ and ℉ (Interchangable)

Note:

1. **Please read all the instructions carefully in this booklet before you start using the eB*fresh* System.**

2. About eB*fresh* glucose monitoring system

The front side of the meter

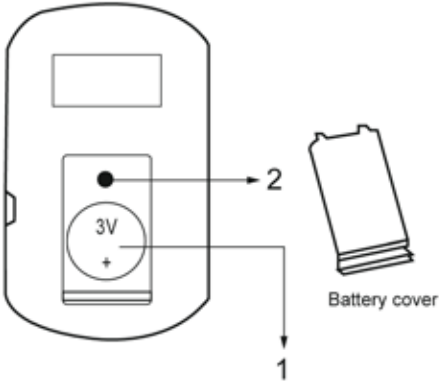


1. Screen
Shows blood glucose result, messages and blood glucose results stored in memory

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

3. Test Slot
Insert test strip or Calibration card here

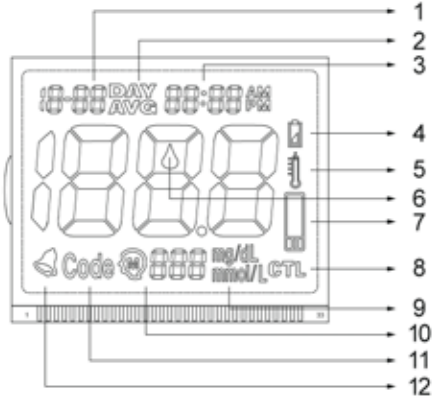
The back side of the meter



1. Battery Slots
Use one 3 volt CR2032 Lithium battery.

2. Setting knob
For setting up time , date and performance

The Screen of the meter



1. Date
2. Average Display-7, 14 and 28 days
3. Time
4. Battery sign
5. Thermograph
6. Blood drop sign
7. Test strip sign
8. Control solution test model
9. Measuring unit : mg/dL and mmol/L
10. Memory Number
11. Code Number Symbol
12. Alarm clock Symbol

Test strip

1. Top edge

Apply a drop of blood or control solution to the semicircle-shaped cutout.

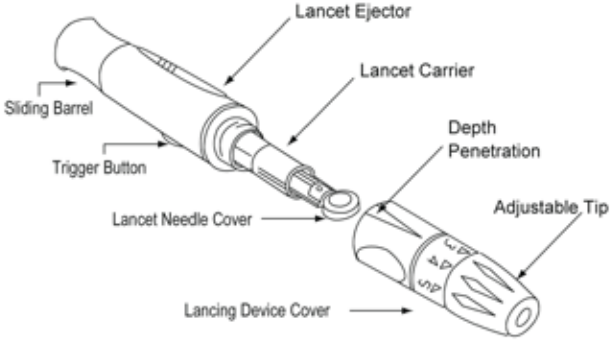
2. Electrical contacts

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



Lancet

Circular protective cover

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 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, in case of leaking and causing damage to the meter.

3.1.2. Setting Mode

Open the battery cover and press the “setting” knob at the left bottom to enter setting mode.

After pressing the “setting” knob to enter setting mode:

Step 1. Press and release the “setting” knob to set the Year :

Press and release the M button to adjust the year until the correct year is show on the screen. The Year setting range is 2010:2050.

Step 2. Press and release the “setting” knob to set the Month :

Press and release the M button to adjust the month until the correct month is show on the screen.

Step 3. Press and release the “setting” knob to set the Day :

Press and release the M button to adjust the day until the correct day is show on the screen.

Step 4. Press and release the “setting” knob to set the Hour :

Press and release the M button to adjust the hour until the correct hour is show on the screen. The meter is with 12H system.

Step 5. Press and release the “setting” knob to set the Minute :

Press and release the M button to adjust the minute until the correct minute is show on the screen.

Step 6. Press and release the “setting” knob to set the Measurement Unit :

Press the M button for 3 seconds to switch the measurement unit between mg/dL and mmol/L.

Step 7. Press and release the “setting” knob to set the Temperature Unit :

Press the M button for 3 seconds to switch the temperature unit between ˚C and ˚F.

Step 8. Press and release the “setting” knob to enter Memory Date Deletion Mode :
Press the M button for 3 seconds to delete the memory date and enter the alarm clock mode.

Step 9. Press and release the “setting” knob to enter Alarm Clock Setting Mode :

When the alarm clock is “OFF” : shown on upper left corner : , press M button to switch it to “On” and enter the Hour and Minute setting mode. The setting method is the same as setting the clock.

If the alarm clock is in “On” mode, press M button to switch it to “OFF” mode.

Press and release the “setting” knob. “OFF” will appear on the screen and the meter will turn off automatically.

You may skip Step 3.1.3 of the instruction, when new vial of strips uses the same code that was previously set on the meter.

3.1.3. Coding the Meter

1. For accurate results, your meter should be calibrated with the Code Card every time you open a new vial of test strips. After you calibrated the meter with the Code Card, you can start testing your blood glucose.
2. Insert the Code Card into the test slot."CH-" will be shown of the screen and the meter will self-detection. If the self-detection fails, "E01" will appear on the screen. If the meter is normal, the code of the Code Card will be shown on the screen.

If the Code Card stays inside the test slot for 1 minute, the meter will automatically turn off.

Step 1 : Open a new vial of **eB*fresh*** Blood Glucose Test Strip and remove the Code Card (fig.1) from the box.

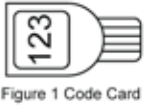


Figure 1 Code Card

Step 2 : Insert the Code Card into the test slot as shown in Figure 2.

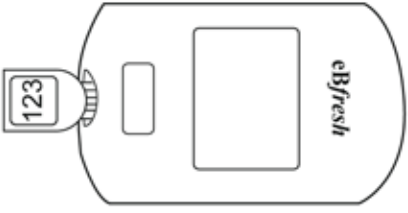


Figure 2 Insert the Code Card

Step 3 : You can hear a “beep” and a code number will appear on the screen (for example, 123) as shown on Figure 3.

Figure 3 Displaying the code number

If shown “E01”as Figure 4, indicates that the meter does not function properly. Please contact local agent.

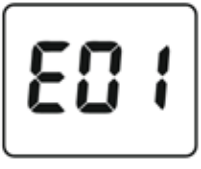


Figure 4 E01 shown on the screen

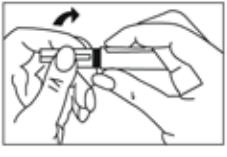
Step 4 : Check the code number on the screen with the number on the vial of test strips. These two numbers have to be the same. If not, please stop testing and contact your local agent.

Step 5 : Remove the code strip and you are ready for blood glucose test

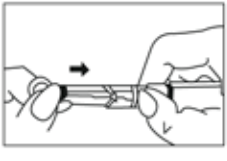
3.2. Start testing

After checking the code number, you may now start testing blood glucose. **eB*fresh*** can be used at anywhere.

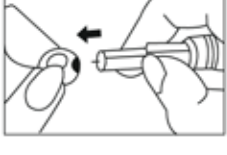
Step 1 : Remove the cap from the lancing device.



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



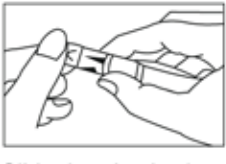
Step 3 : Twist the circular protective cover in the front of the lancet. Then, remove the protective cover from the lancet.



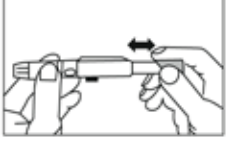
Step 4 : Put the cap back onto the lancing device.

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 have very thin skin. Level 5 is for people have very thick skin.

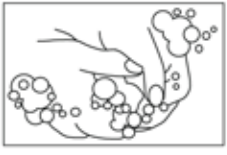
Step 6 : Choose a desired skin penetration depth for yourself by rotating the depth selector until the depth selection window displays your desired depth setting.



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

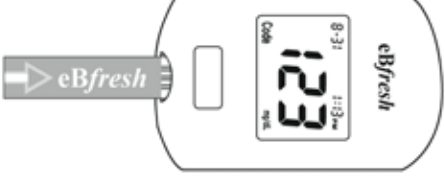


Step 8 : Wash your hands with warm, soapy water. Rinse and dry thoroughly.



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

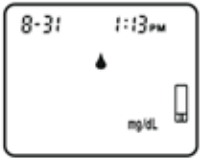
Step 10 : Make sure the triangle sign on the test strip is facing up and insert the electrical contact fully into the test slot.



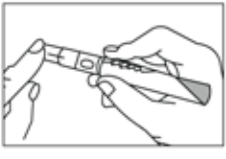
Insert the test strip into test slot. The symbol "CH-" will appear on the screen, then the meter will automatically detect the followings :

1. Test Strip Type Detect : You will hear a "beep" sound upon insert of test strip
2. Battery Voltage Detect: If battery power is low, "E-b" will appear on the screen.
3. Test Strip Detection: If the test strip had been used, "E-U" will appear on the screen.
4. Environment Temperature Detection: The current temperature will appear on the Screen for 1 second. If the environment temperature is below 4℃ or above 42℃, "E-t" will appear on the screen and the meter will automatically turn off.
5. When the self-detection is completed, the blood drop symbol will be flashing on the Screen, and the current code will appear on the Screen for 5 seconds.

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 2 minutes or the meter will turn off automatically.



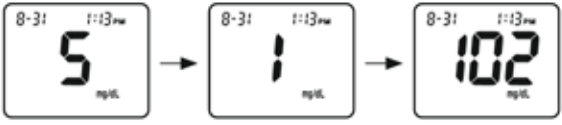
Step 12 : Press the lancing device against your fingertip and push the trigger on the lancing device. The lancet will prick your skin.



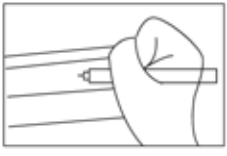
Step 13 : To obtain a drop of blood, squeeze your finger gently to form a small drop of blood. Apply the blood onto the semicircle-shaped cutout on the top edge of the test strip.

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 meter begins to count down, do not add more blood to the strip and discard the strip. Please repeat the test.

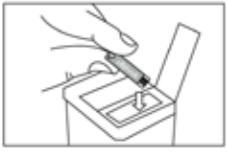
Step 15 : When the meter beeps, it starts counting down from 5 to 1. After counting down to 1, your test result appears on the screen.



Step 16 : Record the glucose value in your log book.

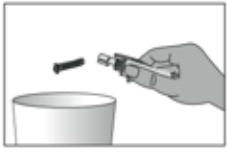


Step 17 : The meter will be turned off by removing the test strip. Dispose the used test strip in a sealed container.



Step 18 : Remove the cap from the lancing device. Put the protective cover back onto the lancet.

Step 19 : Push the ejector forward and dispose the lancet to a sealed container.



4. Using the meter memory

Your **eB*fresh*** Blood Glucose Meter stores 450 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 Reviewing the stored results in memory

Step 1 : Press M button for 2 seconds to start up the eBfresh.
Step 2 : Press M button again to enter memory mode. The following results will be displayed in order: 7 days average, 14 days average, 28 days average and individual test results.
Step 3 : To turn off the meter, please press M button for 3 seconds until "OFF" appears on the LCD

* If the meter is idle for 1 minute, the meter will turn off automatically.

5. Data Transmission

eB*fresh* 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 RS232/USB cable designed specifically for **eB*fresh*** are required for date transmission from **eB*fresh*** to PC.

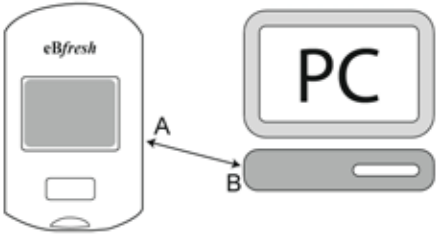
Note:

- ＊Users must use software and RS232/USB cable specifically designed for **eB*fresh*** 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 RS232/USB cable (to purchase separately) ready.

Step 1 : Plug the port A of RS232/USB cable to Data Transmission slot of **eB*fresh*** and port B to your PC (see sketch below) when **eB*fresh*** is in OFF mode. When connect successfully, "on line PC'' will appear on the screen.



Step 2 : Run the Glucose Data Analysis program. "PC" will appear on the screen of your **eB*fresh***, and "Data Transmitting" wording 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. Check eBfresh Glucose Monitoring System (Optional)

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

6.1. Steps of performing a control solution test

Step 1. After inserting a test strip into the test slot, "CH-" will appear on the screen, and the meter will start the auto-detection. When the auto-detection completes, the meter will show the current environment temperature, and then the blood drop symbol will flash, and the code number of the test strip will appear on the screen.

Step 2. Press the M button again, "CTL" will appear at the right bottom corner underneath the test strip symbol, then control solution test can be started.

Step 3. Apply a drop of control solution onto the test strip.
Note: Always shake the bottle gently, discard the first drop before applying the control solution.

Step 4. After counting down from 5 to 1, your test result appears on the screen.

Step 5. 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.

* Always write down the opening date on the bottle.
* Please apply control solution within 2 minutes or the meter will automatically shut off.
* Test results will not be calculated into the days average under the control solution test mode.

7. 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 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.

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.

8. Limitation

eB*fresh* 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 of 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.
- 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.
- DO NOT let water into the meter. This can result in an inaccurate result even after you dry the meter.

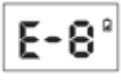
- DO NOT remove strip while device is under process.
- The test strips are used only with fresh capillary whole blood from finger. DO NOT use serum or plasma.
- Hematocrit values less than 20% may cause falsely high test results; hematocrit values higher than 60% may cause falsely low test results (consult 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 **eB*fresh*** 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.

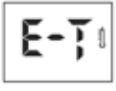
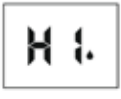
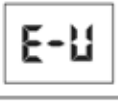
- Critically ill patients should not be tested with blood glucose meters.
- Use universal blood precautions. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection.
- The meter has to be used in an environment that the humidity less than 85%.
- The meter has to be used in an environment that the temperature is between 10~40℃ (50~104℉).
- 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

9. Troubleshooting

The 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.
	No battery power. The meter will be turned off automatically.	Replace with one 3 volt CR2032 Lithium battery.
	The battery power is low.	Replace with one 3 volt CR2032 Lithium battery.
	The surrounding temperature is too low or too high to perform a test.	Repeat the test in a place between 10℃~40℃ (50℉~104℉)

Message	Cause	Action
	When the temperature goes above 42℃ (107.6℉) or below 4℃(39.2℉) the meter will turn off automatically.	Repeat the test in a place between 10℃~40℃ (50℉~104℉).
	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.

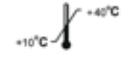
Do not reuse

Consult operating instructions

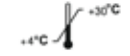
Keep dry

Caution, consult accompanying documents

IVD *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 orignal purchasing site.

Use by

Lancet CE 0197

Beijing Ruicheng Medical Supplies Co., Ltd.
No. 558 Zhangzikou, Yangsong Town,
Huairou District, 101400 Beijing, China

EC REP

Lotus Global Co., Ltd
1 Four Seasons Terrace West Drayton, Middlesex London,
UB7 9GG United Kingdom

Lancet CE 0123

Shandong Lianfa Medical Plastic Products Co., Ltd.
No.1 Shuangshan Sanjian Road, 250200 Zhangqiu City
Jinan, Shandong, China

EC REP

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Eiffestaβe 80 20537 Hamburg GERMANY

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