Foreword

Dear FED BGM-II Type Blood Glucometer Owner:

Thank you for choosing FED BGM-II Type Blood Glucometer (hereinafter referred to as Blood Glucometer). The Blood Glucometer attaches importance to such features as convenience, speediness, accuracy and humanization in the aspect of design and is mainly used for clinical routine blood glucose test and diabetes patients' self-blood glucose test.

This manual includes the detailed procedures and precautions in your use of Blood Glucometer; please read all contents carefully so as to master operating essentials of the Blood Glucometer and get correct test results. Monitoring blood glucose can help understand your blood glucose control status and guide a doctor's medication. Only when the blood glucose is controlled properly can the occurrence of complications of diabetes be reduced and the quality of life improved. If there is anything you don't understand, please call our guest service No.: 400-688-2098.

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I. Detection Principle

Blood Glucose Test Strip (hereinafter referred to as Blood Glucose Strip or Strip) adopts the new biosensor technology and siphon principle. Glucose oxidase and conductive medium is immobilized in the surface of the electrode; when the glucose in the blood contacts with the enzyme on the electrode and the conductive medium, specific reaction will be initiated and instantaneous current will be produced; the size of current is directly proportional to the glucose concentration, and through the Blood Glucometer, the current signal is converted into blood glucose value, which is displayed on the screen.

Glucose + Potassium Ferricyanide $\xrightarrow{\text{Glucose Oxidase}}$ Gluconic Acid + Potassium Ferrocyanide

Potassium Ferrocyanide $\longrightarrow$ Potassium Ferricyanide+e^-

II. Composition & Schematic Diagram of Blood Glucometer

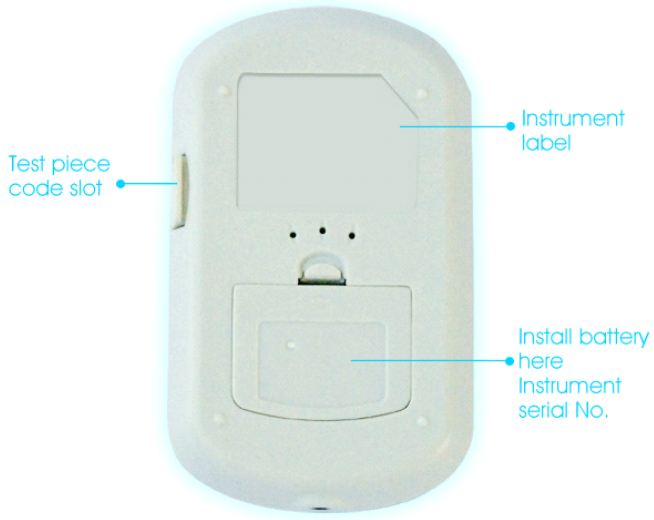
For the first purchase, please check whether all of the following components are included in the package of your Blood Glucometer; if any components are missing, please replace directly in the store where you purchase or contact the agent.

1. Standard configuration:
   a. FED BGM – II Type Blood Glucometer 1 set
   b. Lancing pen 1 piece
   c. Manual of FED BGM – II Type Blood Glucometer 1 copy
   d. Warranty card: 1 copy
   e. Battery (3V CR2032 lithium battery) 1
   f. Pocket-case 1

2. Additional configuration:
(Not included in the standard configuration; contact the dealer or purchase in a store when necessary)
   a. Glucose test strip
   b. Lancing needle (see instruction for use of lancing needle for details)
   c. Test piece code (in the packing box of test piece)

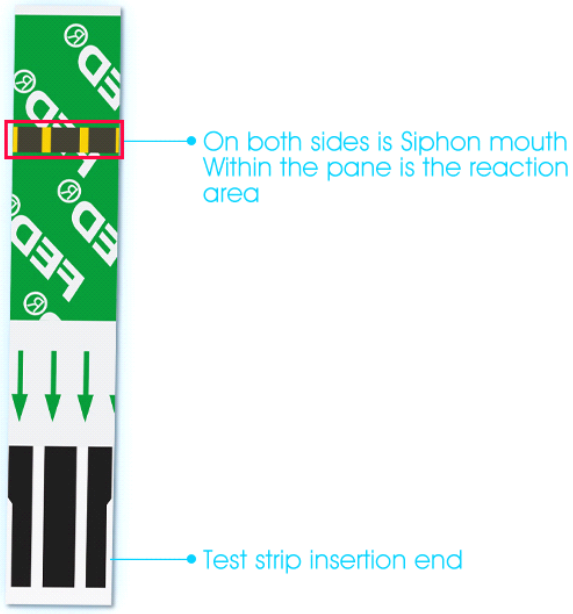
3. Explanation of front, back and side of Blood Glucometer

Front of blood glucometer



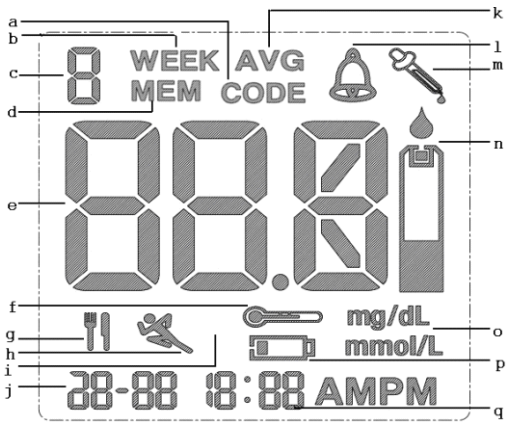
Back of Blood Glucometer

4. Blood glucose test strip (see manual of blood glucose test strip for details)
Front of test strip



5. Lancing pen (see the instruction for use of lancing pen for details)

III. LCD Symbols



a. Test piece code
b. Week
c. Display the average value of “X” weeks
d. Record
e. Display test piece code number, test result and error message
f. Temperature symbol
g. After meal
h. After sports
i. Before meal (symbol for after meal and after sports disappears)
j. Date
k. Average
l. Alarm symbol
m. Quality control test mode
n. Symbol for blood drop
o. Measurement unit: mmol/L and mg/dL
p. Low battery power
q. Time

IV. Product Specification

►Test sample: Fresh Capillary Whole Blood
►Type of sample used for calibration: Venous plasma
►Blood volume: about 3 microliters
►Measurement unit: mmol/L and mg/dL, switchable.
►Instrument calibration: automatic calibration with test piece code
►Memory capacity: 500 test results can be stored
►Calculation of average value: by 7 days, 14 days, 21 days and 28 days
►Display data and time: 12-hour system
►Working temperature: 5~42℃ (41℉~107.6℉)
►working relative humidity: not higher than 80%
►Storage temperature: -20℃~55℃ (-4℉~131℉)
►Storage relative temperature: not higher than 85%
►Instrument size: 85mm×54mm×19mm;
►Instrument weight: 50g or so
►Battery type: CR2032 (3V, lithium battery)
►Quality control solution: use key to isolate quality control value to exclude it from calculation of average value
►Alarm setting: add alarm function
►Bloodsucking symbol display: display on the LCD screen

V. Test Performance of Blood Glucometer and Blood Glucose Test Strip

1. Test time

Test time of Blood Glucometer in each case is 10 seconds.

2. Test range

Test range of Blood Glucometer is 1.1mmol/L～33.3mmol/L

3. Measurement repeatability of Blood Glucometer and Blood Glucose Test Strip

Precision of the repeated test results of Blood Glucometer and Blood Glucose Test Strip should comply with the requirements in Table 1.

Table 1 Repeatability

Test Range	Precision
＜5.5mmol/L（<100mg/dL）	Standard deviation SD＜0.42 mmol/L（<7.7 mg/dL）
≥5.5 mmol/L（≥100 mg/dL）	Coefficient of variation CV＜7.5%

4. System accuracy of Blood Glucometer and Blood Glucose Test Strip

For Blood Glucometer and Blood Glucose Test Strip, 95% of the deviation of the test results should comply with the requirements in Table 2:

Table 2 Accuracy

Test Range	Allowable deviation
≤4.2mmol / L(<75mg / dL)	Not more than ±0.83mmol / L(±15mg / dL)
＞4.2mmol / L(>75mg / dL)	Not more than ±20%

VI. Operation Procedure

1. Install the battery

The Blood Glucometer needs one 3V, CR2032 lithium battery; one battery can test for 1000 times. This device has power saving function and will be shut down automatically if no operation within 2 minutes.

Step 1. Open the battery cover.
Step 2. Put in a 3V CR2032 lithium battery; note the positive and negative electrode.
Step 3. Cover the battery cover back.

Note: 1) When the power is low, a "🔋" symbol will be displayed on the screen, in which case please replace with a new battery.

2) After replacement of battery, the time and date should be reset, for which, please refer to "setting of time and date".

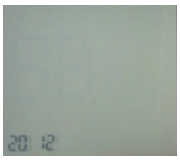
2. Set the mode:

2.1 After installing the battery, turn to the setting of year, month, date, hour, minute and test unit in succession.

Note: Setting of year, month, date, hour and minute won't influence the detection results and only provides convenience for reference.

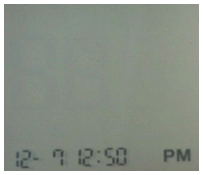
2.1.1 Setting of year:

After installation of battery, year will be displayed on the lower left part of the screen (as shown below, 2012 is displayed). Press left or right key to adjust the year (the range of year setting is 2000~2099), then press on/off key to confirm.



2.1.2 Setting of month, date, hour and minute:

Turn to setting of month, date, hour and minute (from left to right) after year is set successfully and the method is the same with that of year setting. The time follows 12-hour system. As shown below, the time is "December 7 12:50 p.m."



2.1.3 Setting of test unit conversion:

Enter setting of unit conversion after setting of minute (as shown in the following figure); press left or right key to choose the required unit (mg/dL or mmol/L), then press on/off key to confirm and the screen displays “OK”; the setting is successfully finished and the tester is automatically shut down.

2.2 Alarm setting:

2.2.1 Turning-on of alarm:

When the alarm mode is “OFF”, press and hold on/off key and there will be time flickering at the bottom of the screen including hour and minute where you can set the time required to remind you, and the setting method is the same with that of year setting. After proper setting, “OFF” flickers on the screen; press left key or right key and the screen will display “On” (flicker) and “🔔” (as shown below: the alarm time is set as: 12:00 a.m.); press on/off key again and the screen display “OK”; the setting is successfully finished and the tester is automatically shut down;

When the alarm mode is “On”, press and hold on/off key and there will be time flickering at the bottom of the screen including hour and minute where you can set the time required to remind you, and the setting method is the same with that of year setting. After proper setting, press on/off key again and the screen display “OK”; the setting is successfully finished and the tester is automatically shut down;

2.2.2 Turning-off of alarm:

When the alarm reminds you, press the on/off key once and the screen displays date and time’ press the on/off key again and the Blood Glucometer will be shut down.

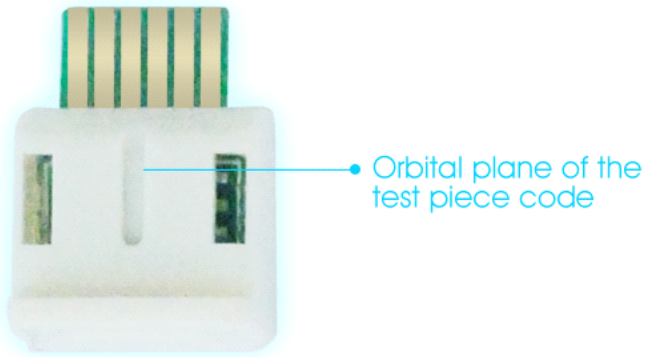
When it is required to cancel the alarm, press and hold the on/off key under shutdown state of the tester and there will be time flickering at the bottom of the screen; then press the on/off key twice in a row, “On” will be displayed on the screen and flickers; press left key or right key, “OFF” will be displayed on the screen and flickers; then press the on/off button once again and the screen displays “OK”; the setting is successfully finished and the tester is automatically shut down.

2.3 Use of test piece code

To ensure the accuracy of the detection results, please use the test piece code in the packing box or test strip bottom for calibration of instrument when replacing with a new test strip, and the specific operation procedures are as follows:

Step 1: Open the test strip package and take out the new test piece code.

Step 2: Insert the test piece code into the test piece code jack and push to the end. (Please face the orbital plane of the test piece code towards the back of the Blood Glucometer, as shown below)



Step 3: When you hear the sound of “beep”, the screen will display the test piece code (as shown below and the number of the test piece code should be consistent with the test piece code number on the test piece package).

Step 4: Press the on/off key and tester will be shut down; at this time, you can start blood glucose test.

2.4 Start the blood glucose test

After calibrating the test piece code, start the blood glucose test (if the storage temperature of Blood Glucometer has great differences with test environment temperature, the tester and test strip are required to maintain balance in the test environment for over 30min).

Step 1: remove the cap of lancing pen.

Step 2: insert a new lancing needle.

Step 3: unscrew the protective cap of the needle.

Step 4: cover the cap of lancing pen back.

Step 5: adjust the lancing depth of the lancing pen according to the thickness of skin; from 1 to 5, the pen is gradually inserted deeper and generally 3 is chosen.

Step 6: pull the lancing stopper back (don’t use excessive force in case of

damage to the lancing pen).

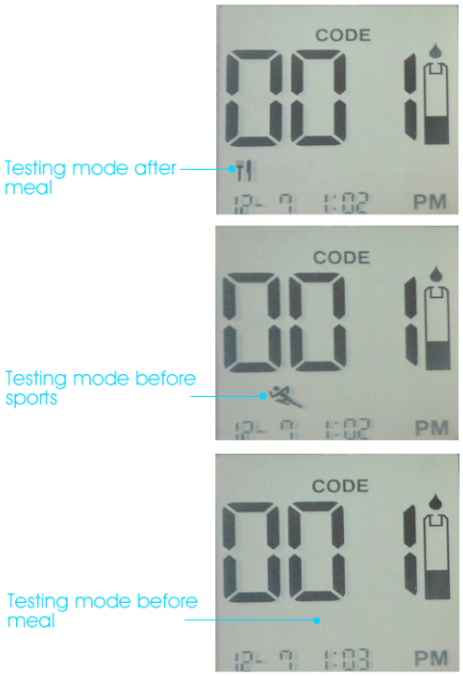
Step 7: wash hands in warm soapy water, rinse with clear water and then dry them. Afterwards, disinfect with 75%alcohol wipes, and dry fingers in the air.

Note: washing hands with warm water and massaging fingers, etc. can quicken the blood flow volume of fingers and make it easier to get correct drop of blood.
Do not use iodine-containing disinfectant.

Step 8: take out the test strip.

Note: for packaging bottle, cover the cap immediately after taking out the test strip to prevent moisture. If it is the first time to open the packaging bottle, please record the date on its label and discard it after 3 months.

Step 9: when power off, make the test strip right side up, insert its electrode tip to the test tank and then push it to end, meanwhile the instrument will give out a warning tone “beep” and display the test piece code, date, time, as well as the blood drop symbol. (By this time, you can press the left and right key to choose the test of blood glucose level before meal, after meal or after sports, and the default setting is the test of blood glucose level before meal.)



Note: 1) The test piece code displayed on the Blood Glucometer must be the consistent with that on the package, otherwise, no accurate blood glucose value will be got.

2) When inserting the test strip, please don’t use hands to touch its siphon mouth.

3) Setting test mode of blood glucose before meal, after meal or after sports has no influence on the

test results and is just for reference convenience.

Step 10: make the lancing pen close to the disinfection part, and press down its button.

Step 11: gently press the stabbed finger to form a small drop of blood and then use the siphon mouth on the side of test strip to touch the drop of blood, the blood will automatically fill the reaction area and the Blood Glucometer will give out a warning note “beep”. Afterwards, remove your finger, the screen will start countdown, display test results after 10 seconds and automatically save them.

Note: 1) Don’t press your finger hard when lancing for fear of incorrect results.

2) Don’t compress the lanced part tightly with siphon mouth.

3) Don’t suck simultaneously from both sides of the siphon mouth. The blood can only be sucked from one side (left or right).

4) If blood fails to fill the reaction area for once, please replace the test strip for retest.

Step 12: pull out the test strip, the instrument will send out a warning note “beep” and shut down automatically.

Step 13: dispose the used test strip and lancing needle as per medical wastes.

2.5 Use of memory of Blood Glucometer

This Blood Glucometer can store 500 latest blood glucose records. When the number of test results is greater than 500, the latest records will be stored and the earliest records will be deleted.

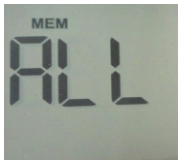
2.5.1 Steps for result query:

Step 1: when power off, shortly press the left or right key, the screen will display the total number of records (as shown in the figure below: 26 test data). Press the left or right key again, you can inquire the test records at different times. Press the on/off key for shutdown.

Step 2: when power off, press the on/off key, the screen will display characters “MEM” and “AVG”. Press the left or right key, you can inquire the average value of blood glucose of 1 to 4 weeks (if these data are not stored in the Blood Glucometer, the screen will display “---”). Press the on/off key for shutdown. As shown in the figure below: the average value of blood glucose of the last 4 weeks is 5.3mmol/L.

2.5.2 Deletion of results:

When power off, press and hold the right key, the instrument will give out a sound “beep”, and the screen will display the cyclical variation of “dEL” and “RLL” (as shown below) to prompt whether to delete the data or not. Press the left key, the screen will display “OK” and shut down automatically, which means all records stored in this instrument are deleted. Instead, press the on/off key, the screen will display “OFF” and shut down automatically, while the records will not be deleted.



Note: when the test strip is inserted to the instrument, you can’t inquire the results.

2.6 Quality control of Blood Glucometer and Test Strip (Recommended)

The blood glucose QC solution is only used to verify whether FED Series Blood Glucometer and the supporting blood glucose test strip are in normal operation. Regular QC of blood glucometer and test strip can further ensure the accuracy of test results of blood glucose.

2.6.1 When you encounter the following circumstances, it is recommended to conduct quality control to the blood glucose monitoring system:

a. When you suspect the Blood Glucometer or Test Strip can not work normally;

b. When you suspect that the test results are not accurate;

c. When the Blood Glucometer is collided violently;

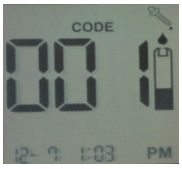
Note: blood glucose QC solution is not for sale, but is specially used to conduct quality control of FED blood glucose monitoring system. The blood glucose monitoring system has passed a strict quality control before leaving the plant. In case of the above problems, you are recommended to conduct the free quality control in the agencies of FED Blood Glucometer.

2.6.2 Quality control steps:

Step1: place the Blood Glucometer, Test Strip and QC solution under the condition of 20-25℃ for over 30min.

Step 2: after inserting the Test Strip, the screen will display the test piece code and blood drop symbol. Please ensure the test piece code is consistent with that on the package of test strip.

Step 3: press and hold the on/off key, the instrument will give out a sound "beep", and the symbol " " will appear above the blood drop symbol, which means entering the QC mode (as shown below).



Step 4: blend the QC solution with upside down, discard the first drop, and then take out one drop to a clean plastic sheet. It will be sucked in from the siphon mouth of test strip and fill the reaction area, then the instrument gives out a sound "beep". Remove the plastic sheet, the instrument will start the countdown, and display the test results after 10 seconds. The results shall be within the range of quality control. Pull out the test strip, the instrument will be shut off automatically.

Note: the quality control test results are not recorded in the Blood Glucometer; therefore, it will not affect the calculation of the average value.

VII. Precautions in Use

When you use this test system, please pay attention to the following restrictions:

1. This product is only applicable for monitoring in vitro.
2. Physiological and pathological factors disturbing the testing results:

a) Abnormal hematocrit (beyond the range of 30%~55%);

b) The following substances have no significant impacts on the test results in normal blood or normal treatment concentration, but can cause deviation of the test results when their concentration in blood are abnormally high. E.g.: uric acid, acetaminophen, ascorbic acid (vitamin C) and other reducing substances.

c) Cholesterol level is higher than 500mg/dL

d) Blood volume of peripheral blood circulation disturbance decreases, such as severe dehydration and shock.

3. Factors affecting test results due to improper operation:

a) Disinfect with disinfectant which contains "iodine";

b) After alcohol disinfection, lancing is carried out before the full volatilization of alcohol;

c) Blood volume is inadequate. Reaction area of test strip is not fully filled with blood at once or is refilled with blood again;

d) Blood sample is got by pressing fingers hard in lancing;

e) After opened, the test strip is placed in an environment with high humidity for too long;

f) The test strip is overdue;

g) This test strip is not suitable for newborn babies;

h) When the difference between the storage temperature of Blood Glucometer and the testing environment temperature is great, there is not enough time (more than 30 min) to balance the temperature.

VIII. Maintenance & Storage

1. There shouldn’t be any dirt in the jack and the interior of Blood Glucometer. If there is any dirt on the surface of the Blood Glucometer, a soft cloth can be used to gently wipe.
2. Blood Glucometer shall be stored in a well-ventilated room without corrosive gases and with the relative humidity of not higher than 85%.
3. Please remove the battery when the Blood Glucometer is not in use for a long time.

IX. Problems & Trouble-shooting

Problems	Possible causes	Suggestion
Screen shows no change when pressing keys or inserting test strip	1. Improper installation of battery. 2. Low battery. 3.Incorrect or incomplete insertion of test strip.	1. Please remove the battery with the positive electrode upwards. 2. Replace it with a new battery. 3. Please pull out the test strip with right side up and then push it down in the arrow direction.
Screen shows "Er1" after inserting test strip	Fault of Blood Glucometer	If Blood Glucometer needs repairing, please contact our agents.
Screen shows "Er2" after inserting test strip	1. Test strip is inserted before the test piece code is inserted. 2. Fault of test piece	1. Please insert the test piece code firstly, and then the test strip. 2. Please replace the test. piece code
Screen shows "Er3" after inserting test strip	Test strip becomes damp or is reused	Please start with a new test strip and test again.
Test result of blood glucose shows "Lo"	Indicating that the test result is below 1.1 mmol/L	Retest according to the correct method. In case of the same situation, please see a doctor.
Test result of blood glucose shows "HI"	Indicating that the test result is above 33.3 mmol/L	Retest according to the correct method. In case of the same situation, please see a doctor.
Discrepancy between blood glucose test results and symptoms	1. Incorrect test piece code. 2. Test strip fails to take in enough blood or test strip has been out of date and deteriorated.	1. Check whether the test piece code displayed on Blood Glucometer is consistent with that on the test strip package. 2. Please replace the test strip with a new one and retest. In case of the same situation, please see a doctor.

Screen displays "" after power on	Low battery	Please replace the battery with a new one.
Screen displays "HI/Lo+ " after power on	Ambient temperature is beyond the use range of Blood Glucometer	Please keep the Blood Glucometer in normal working environment for test
QC results are outside the normal range	1. The reaction area of test strip is not filled up. 2. Quality control solution has expired or is preserved poorly after opening.	1. Please replace the test strip with a new one and fill the reaction area for once, then retest. 2. Please replace the quality control solution that hasn't expired or correctly preserved after opening.

X. Ideal Blood Glucose Control Range

In general, the ideal blood glucose level of non-diabetic patients is:
Fasting: 3.9~6.1mmol/L (70~110mg/dL)
2 hours after meal: less than 7.8mmol/L (140mg/dL)
Blood glucose control standard of type 2 diabetes
(Made by Asian-Pacific Type 2 Diabetes Policy Group in 2002)

Project	Good	General	Poor
Fasting blood glucose	4.4~6.1mmol/L (80mg/dL~110mg/dL)	≤7.0 mmol/L (≤126mg/dL)	>7.0 mmol/L (>126mg/dL)
Non-fasting blood glucose	4.4~8.0mmol/L (80mg/dL~144mg/dL)	≤10.0 mmol/L (≤180mg/dL)	>10.0.0 mmol/L (>180mg/dL)

Note: if your test result is outside the above range, please see a doctor timely and receive treatment under the guidance of a professional doctor.

XI. Warranty

Thank you for using FED Blood Glucometer. We will provide five-year guarantee replacement and lifelong maintenance services if it is used properly. Therefore, please carefully fill out the warranty card and send the "Archive Copy" back to our company. Abnormal spoilage is not in the scope of guarantee replacement or maintenance. Thanks for your understanding!