

FUDAKANG INDUSTRIAL Co., Ltd.	Technical File	File No	TCF-004-8
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Instruction for Use

Blood Glucose Monitor and Blood Glucose Test Strip

eB-G-BT,eB-D12-BT,eB-D33-BT,eB-D34-BT,eB-D43-BT,
eB-D44-BT,eB-D45-BT,eB-D52-BT,
eB-G,eB-D11,eB-D12,eB-D21,eB-D31,
eB-D32,eB-D33,eB-D34,eB-D35,eB-D41,
eB-D42,eB-D43,eB-D51,eB-D52

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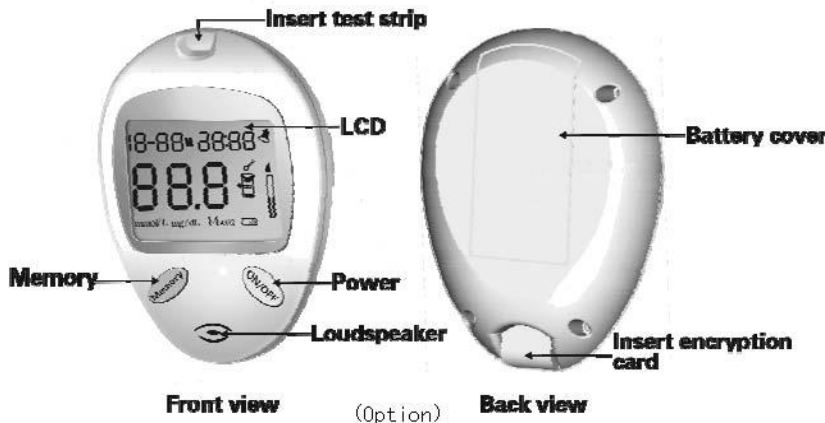
Hand-hold quick blood glucose testing system consists of the following parts.

Standard accessories:

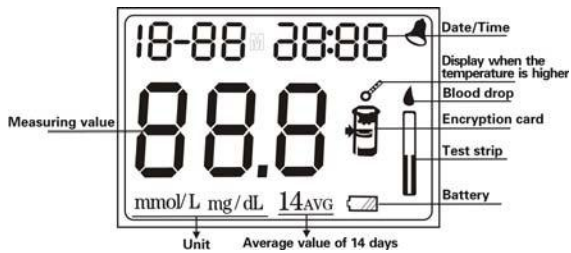
Blood glucose monitor	1 set
(eB-G-BT and suitable for all Blood Glucose monitor)	
1. Blood glucose test strip box	25 PCS
2. Lancing Device	1 PIECE
3. Disposable Lancets	25 PCS / BAG
4. Alcohol sponge	25 PCS
5. Blood glucose device	1
6. Instruction manual	1
7. Portable bag	1

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All the accessories shall be subject to the real package
Description of model no.: eB-G-BT blood glucose monitor



Description of the Display



Description of test strip

1. Introduction to the package of box

Each box have 25 pcs single package test strips to prevent each one of test strips being affected with damp. The test strips has been sure of being damped after the single package has been opened for three months and do NOT use them.

2. Introduction to the package of test strip

It should finish the test within five minutes after the test strip is opened, the test strip could be used for one time only, do NOT wrap the package and scratch the test strip; do NOT touch the reaction end; ambient temperature: 10°C-40°C(50 °F ~ 104 °F) . .

3. Introduction to the test strip



The product is designed as a disposable test strip for the blood glucose monitor, each strip comprises the following parts.

- ① Confirmation window: the user may see whether there is enough blood got into the reaction area through this window.
- ② Blood entry: the blood gets into the test strip via this entry.

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- ③ ③Electrode: insert this end into the corresponding place of the blood glucose tester to start the device, please keep the blue arrowhead side upwards in inserting.

SCOPE AND TIME OF TESTING

1. Testing scope: 2.2 mmol/L ~ 27.8mmol/L (40mg/dL ~ 500mg/dL).
2. Testing time: ≤10s.

SPECIFICATIONS

1. Model No.: eB-G-BT
(Suitable for eB-D12-BT, eB-D33-BT, eB-D34-BT, eB-D43-BT, eB-D44-BT, eB-D45-BT, eB-D52-BT, eB-G, eB-D11, eB-D12, eB-D21, eB-D31, eB-D32, eB-D33, eB-D34, eB-D35, eB-D41, eB-D42, eB-D43, eB-D51, eB-D52)
2. Parameters of blood glucose monitor:
 - (a) Power supply: DC 3.0V (two AAA alkaline batteries);
 - (b) Display mode: mmol/L or mg/dL display and testing time display;
 - (c) Times of result memory: 180 times;
 - (d) Dimensions: 80mm*58mm*23mm ;
 - (e) Weight: 46g
 - (f) Rated power: 30mW.
3. Type of test strip: Siphon type
4. Parameters of test strip
 - (a) Dimensions: 32mm*8mm*0.8mm (L*W*D)
 - (b) Nominal weight: 0.5g/piece

APPLICATION AND OPERATING ENVIRONMENT

- The product must be used together with siphon blood glucose test strip produced.
- Blood glucose monitor is applicable for out-of-body test only.
- Blood glucose monitor is applicable for the test of ending whole blood.

Ambient conditions (normal working conditions)

- (a) Ambient temperature: 10°C-40°C (50 °F ~ 104 °F);
- (b) Relative humidity: ≤80%;
- (c) Atmospheric pressure: 700hPa ~ 1060hPa;
- (d) Power supply: DC 3.0V (two AAA alkaline batteries);

OPERATING INSTRUCTIONS

1. Use the blood glucose monitor to test the blood glucose. Step

1: adjustment of time

Power On: Press Power switch for five seconds to enter the setup interface of time. Firstly the Year place shall blink, press Memory key to adjust the year and then further press Power key to enter the adjustment interface of month, use the same operation to finish the adjustment of day, hour and minute.

Step 2: Installation of pinhead

- (1) Open the protective cover of blood taking device;

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(2) Insert the new blood needle and then use one hand to hold the needle and use the other hand to open the protective cover;

(3) Put the protective cover of blood taking device on;

(4) Select the depth of taking blood (1→2→3→4→5), generally the depth of 3 is advised.

(5) Pull back the pen to start to take the blood. (Note: do NOT pull the pen by big force to avoid pulling it out).

Step 3: Clean your fingers

Please disinfect by the alcohol sponge with dry and clean fingers.

※Note: do NOT use the iodine to disinfect.

Step 4: Load the batteries (Voice function only suitable for voice model)

- (1) Press Power switch to turn on the tester and it shall give voice prompt: "Please check the Code card is correctly inserted and insert the test strip into the slot". And then please take out the Code card from the box and insert it into the device, the LCD shall display the password of the bottle/box of test strips, the password must be same with the correct mode marked on the package.

Step 5: Insert the test strip

Insert one new test strip and the electrode into the corresponding place of tester. The tester shall display the code of test strip and the blood entry icon shall blink and voice prompt shall be given: "Please get blood for testing".

Note: do NOT use your fingers to touch the reaction area and inserting end (electrode area).

Step 6: Take blood

Method: take the ending whole blood: use the disposable blood taking needle to lance the finger to take blood.

Step 7: Application of sample

- (1) Please apply the blood sample at the siphon mouth of reaction area when the LCD displays "Blood Entry".

BLUETOOTH FUNCTION

1. Press Button "Power" shortly to turn on, and 88.8 will be fully displayed.
 2. Open APK application and select "Blood Glucose Monitor", then device will be automatically searched out, then click corresponding device. After automatically match, measurement is ready to start.
 3. Insert test paper, and product is going to prompt: Please drip blood to measure.
 4. After measurement, the result will be displayed on the blood glucose monitor and cell phone at the same time.
- ※ If power off, the matched product should be connected to cell phone again.
5. If result needs to be sent, please chose the data first, and select the sending method by means of text message or email while inputting the receiver information.
 6. Bluetooth function only for Bluetooth model.

※It should make the reaction area full of blood by one time, it's NOT allowed to add the blood for many times.

Note: the blood shall be absorbed automatically by the principle of siphon.

·Do NOT press the bleeding part by the test strip;

·Do NOT use the test strip to scratch blood;

·It should finish the test within five minutes after taking out the strip.

It shall display the testing result in ten seconds after adding the blood sample,
unit: mmol/L or mg/dL.

ADDITIONAL FUNCTIONS

- (1) Memory: Press Memory key to enable the LCD to display the latest result with voice (time shall be also displayed), further press Memory key to display the second latest result (time shall be also displayed), operate by the same method till the desired value is displayed.
※Long press Memory key for five seconds to delete all values.
- (2) Calculation of average value: Power ON, press Power and Memory keys for 3 seconds to enable the LCD to

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display the average value of the latest 14 tests. (The calculation could be made only when there are 14 or more testing values)


(3) Maintenance after using: Do NOT damp the tester and wipe off any liquid at the insert and inside; it should use the soft cloth to wipe off the dirt on the surface; and the product should be stored under the normal temperature, do NOT place it in the electromagnetic environment or fall it down.

(4) Please take out the batteries if it's not being used for a long time. (5)

Unit: mmol/L or mg/dL (1mmol/L = 18mg/dL)

DESCRIPTION AND EXPLANATION OF ICONS ON LCD

1. The symbol of displayed on LCD in the measurement

- (a) "888": self-checking;
- (b) When "Bottle" displays and blinks, it's required to insert the Code card;
- (c) When "Test Strip" displays and blinks, it' required to insert the test strip;
- (d) When the symbol of "blood" displays at the top side, it's required to get the blood;
- (e) After getting the blood, it shall count down and display at the left side of LCD, the tester enters the self-testing state;
- (f) The result shall be displayed in XXX (mmol/L) or XXX (mg/dL); when the result <2.2mmol/L (40mg/dL), LCD shall display "LO", and then the result >27.8 mmol/L(500mg/dL), LCD displays "HI";
- (g) When LCD displays "Err", it means the test has error;
- (h) When the "  " symbol displays, it means the batteries is used up and should be replaced;
- (i) When the "thermometer" symbol displays at the upper side of bottle on LCD, it means the ambient temperature is higher than the normal working condition, it should use the tester in the ambient temperature of 10°C-40°C(50 °F ~ 104 °F).
- (j) When the "month", "day" and "time" symbol display, it means the date and time of the test.

TROUBLESHOOTING AND PRECAUTIONS

1. Identification of error information and measures

(1) "Err"—it means the test has error.

Possible reasons: the operating method (step) is wrong; invalid test strip is used; the blood is not enough; the blood is added repeatedly; the ambient temperature is not in the range of 10°C-40°C(50°F ~ 104 °F)the test strip is moved in testing; the tester has fault(s).

Suggestion:

- ①Please read the operating manual carefully to use the blood glucose monitor correctly and make the test once again by the correct method. ②Please contact our after-sale service department. (2) "LO"—it means the measuring value is lower than 2.2 mmol/L(40mg/dL); "HI"—it means the measuring value is higher than 27.8 mmol/L (500mg/dL).

Suggestion:

- ①Check whether the operation is correct by doing the test once again with the effective test strip, if the value is not changed.Please consult your physician.
- ②Please contact our after-sale service department.

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2. Preventive measure before using

- (1) Wash hands with clean water and soap and use the alcohol and sponge to disinfect.
- (2) Ensure that the needle is new and do NOT use the used one.

3. Measures as per the measuring result

- (1) If the result is regarded not to meet the real condition of your body, please check whether the operation is correct. And test again by the effective test strip, if the result is still same, please consult your physician in time. Do NOT make change of taking medicine in accordance with the result only.
- (2) Regularly compare with the measurement made in hospital is necessary, if you feel the symptom is not consistent with the results. Please consult your physician for further best treatment.

4. Factors of affecting the accuracy of result, applicable scope and precautions

- (1) Factors of disease affecting the result:
 - (a) The packed cell volume is smaller than 35% or bigger than 50%.
 - (b) The capacity of ending blood circulation obstruction blood is reduced, such as serious dehydration, hypotension, shock and ending blood vessel diseases.
 - (c) The level of triglyceride is higher than 57mmol/L. (2) Factors of wrong operation:
 - (a) The blood volume is not enough, the reaction is not full;
 - (b) The initial blood sample is not enough, measuring the test after adding the blood again;
 - (c) The blood sample is polluted;
 - (d) The test strip is pulled out and then inserted;
 - (e) It's stored in the low temperature (lower than 10°C (50°F)) or measuring with the deep frozen strip;
 - (f) Iodine or chlorine disinfection agent is used;
 - (g) Take blood from the wet finger after being disinfected;
 - (h) It is placed in the high temperature environment longer than 2 minutes after being unpacked.
- (3) Why the result of testing the ending blood is not consistent with the value of testing the venous blood glucose in hospital? Generally, the venous blood test in hospital it take will have 15% difference if compared to the ending blood test .

MAIN REASONS OF RESULTING IN THE ERROR

1. The blood volume is not enough which shall make the value of testing lower.
2. Pressing the bleeding area shall make a large amount of tissue fluid get into and make the thickness of blood glucose reduced.
3. The Code card is not used or the password is not consistent with the Code on bottle.
4. The test strip is out of its service life or the bottle has been opened for more than 3 months or longer; the test strip is damped or polluted;
5. When the alcohol is used for disinfection, the alcohol is not dry or the bleeding area is damped.
6. The iodine is used to make the value higher;
7. The ambient temperature is not proper (the best temperature should be in the range of 10°C-40°C (50 °F ~ 104 °F)) .
8. Other factors: the capacity of blood corpuscle is bigger than 60%, other glucides and internal substances,

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medicines (vitamin C) and uric acid.

KNOWLEDGE ON BLOOD GLUCOSE AND DIABETES

What are blood glucose and the reference standard of blood glucose value?

Blood glucose means the glucose in blood, other kinds of glucides such as fructose, disaccharide and polysaccharide, could not be called blood glucose until they are converted to glucose. The thickness of blood glucose of a normal person should be stable and balance.

Reference standard of blood glucose value

Unit conversion: 1mmol/L=18mg/dL

Limosis : 70mg/dL-110mg/dL(3.9mmol/L-6.1mmol/L)
30 minutes after dinner: 100mg/dL-180mg/dL (5.6mmol/L-10.0mmol/L)
60 minutes after dinner: 90mg/dL-170mg/dL (5.0mmol/L-9.4mmol/L)
120 minutes after dinner: 75mg/dL-135mg/dL (4.2mmol/L-7.5mmol/L)
180 minutes after dinner: 70mg/dL-110mg/dL (3.9mmol/L-6.1mmol/L)

Tip on Health

※It's better to prevent and cure the syndromes of diabetes if it could discover and cure the disease of diabetes early, please note the following risk signals of diabetes:

- ◆Thirsty and often want to drink water at night;
- ◆The urine has viscosity with foams;
- ◆The appetite is added but weight is reduced;
- ◆Often feel tired;
- ◆Pruritic, it's easy to injure the skin and get infected.
- ◆The times of emiction are frequent with much volume;
- ◆Fat body, especially big stomach;
- ◆Often feel hungry and like sweet food;
- ◆Some relatives are diabetes sufferers

- ◆Do you have any above mentioned condition (s)?
- ◆If you have one of them, you should care about that!
- ◆If you have two of them or more, you might suffer the diabetes, please go to the hospital to make examination immediately!

※Sugarless food.

Sugarless food means the food adds no extra edible sugar or uses the low energy fructose, oligosaccharide, sweet agents or food additives instead of the sugarcane sugar, glucose or fructose. These food solve the sweet of food and enhance the safety, it could meet the demands of diabetes sufferers to the sweet food. But it should note that the sugarless food have not the function of reducing the blood glucose and they also adopt rice, flour and oil as the materials, consequently the sugarless food could produce heat quantity and raise the blood glucose.

- ◆Please Note that, the sugarless food is just not to adopt the traditional sugar, the sufferers shall also take the inherent sugar, fat and protein of the food, and which should be calculated into the volume of staple food, do NOT make mistake for the word "SUGARLESS"!

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STATEMENTS AND DECLARATIONS:

- 1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
- 2) * Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
- 3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
- 4) * Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

Warning: changes or modifications not expressly approved by the party responsible for compliance could void the user' s authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

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If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Should you have any inquire, pls feel free to contact me.

Guidance and manufacture's declaration – electromagnetic emission			
The eB-G-BT is intended for use in the electromagnetic environment specified below. The customer of the user of the eB-G-BT should assure that it is used in such an environment.			
Emission test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The eB-G-BT use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emission CISPR 11	Class B	The eB-G-BT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Guidance and manufacture's declaration – electromagnetic immunity			
The eB-G-BT is intended for use in the electromagnetic environment specified below. The customer or the user of eB-G-BT should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacture's declaration – electromagnetic immunity			
The eB-G-BT is intended for use in the electromagnetic environment specified below. The customer or the user of the eB-G-BT should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V _{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the eB-G-BT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the eB-G-BT is used exceeds the applicable RF compliance level above, the eB-G-BT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the eB-G-BT.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

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Recommended separation distances between portable and mobile RF communications equipment and the eB-G-BT .			
The eB-G-BT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the eB-G-BT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the eB-G-BT as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

FCC ID: 2ADNQEBGBT

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

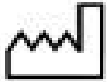
- (1) This device may not cause harmful interference, and (2) This device must accept any interference received , including interference that may cause undesired operation.

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Explanation of Symbols:



Symbol for batch code



Symbol for manufacturer



Symbol for 'CE'



Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice"



Symbol for "TYPE BF APPLIED PART"



Symbol for "Follow operating instructions"

IP22

Symbol for "the IP classification"



Symbol for " RF transmitters"



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Software Version V1.2

Manual Version: V1.0