# FEGO BLE GlucoPedo

# Pedometer and Blood Glucose Monitoring system

# **User Guide**



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# Introduction

Thank you for choosing BLE GlucoPedo. The BLE GlucoPedo system allows you to record daily steps, measure your blood glucose values, and use as a USB driver.

Please read all instructions carefully before use. To ensure you operate the BLE GlucoPedo correctly to measure the accurate blood glucose (blood sugar), read all instructions thoroughly and practice the test. Call your local agent or contact our sales representative if you have any question.

### $\triangle$ IMPORTANT SAFETY INFORMATION

- $\succ$   $\mathbf{\hat{l}}$  Please read all instructions before use and follow below precautions.
- > Use the device only for the intended use described in this manual.
- The product has measurement and record function. If the time and date are not set correctly, the data might get loss or error. Please set the current time and date correctly before use. Time setting is guided in the manual.
- > No modification is allowed on the product.
- If the electromagnetic field is too strong, it will interfere with the correct operation of BLE GlucoPedo. Do not use the product at a place close to strong electromagnetic radiation.
- To avoid the generation of static electricity, please do not use the product in a very dry environment, especially in the artificial synthetic material environment.
- Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.
- > Please discard the product properly according to the regulations of your country.
- > Do not use the device if it is not working properly, or if it has suffered any damage.

CAUTION : Please keep all small parts out of the reach of children. The bottle cap, the

test strip, and the lancets may cause a choking hazard. Please do not swallow. Go to the doctor immediately if accidentally swallowed.

Keep the user guide in case of emergency.

#### FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT

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. 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.

#### **CAUTION:**

To assure continued FCC compliance:

1. Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

FCC Label Compliance Statement:

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.

# **Getting to Know Your System**

The BLE GlucoPedo is for recording personal daily blood glucose and recording daily walking steps.

### Intended use

**IVD** The glucose test function in BLE GlucoPedo is intended for use outside of the body

self-testing (*in vitro* diagnostic use only). It should be used only for testing blood glucose (blood sugar) and only with fresh capillary whole blood samples. The system should not be used for the diagnosis of diabetes or for the testing of newborns. It can use in the home and in clinical settings.

This pedometer function in BLE GlucoPedo counts and stores the number of steps (0~100000 steps), the covered distance (distance measurements 0~9999.99 KM) and the calories burnt (0~9999.99 KCAL) hereby. This product is not suitable for commercial, industrial or medical use.

### Meter



#### Description of the buttons

#### MENU Button

**Power on/off:** Turn on / off the pedometer by pressing and hold the button for 3 seconds.

**Standby mode**—Short press to switch the figures display sequentially in Step→ Calorie→ Distance→ Blood Glucose→ Date.

**Setting mode**—the button is the enter function. Set year $\rightarrow$  month $\rightarrow$  date $\rightarrow$ 12/24 hours  $\rightarrow$  hour  $\rightarrow$  minute $\rightarrow$  second sequentially.

#### $\rightarrow$ $\square$ + $\square$ : UP/DOWN Button

Press UP + DOWN buttons together for 5 seconds to enter setting mode to set date and time.

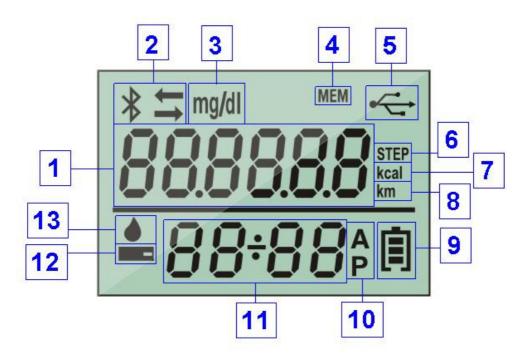
#### $\succ \Delta$ : UP button

**Memory mode**: Press to navigate between the blood glucose test records. **Setting mode**: Short press to increase value and long press for rapidly increase value.

#### **DOWN Button**

Memory mode: Press to navigate between the blood glucose test records. Setting mode: Short press to decrease value and long press for rapidly decrease value.

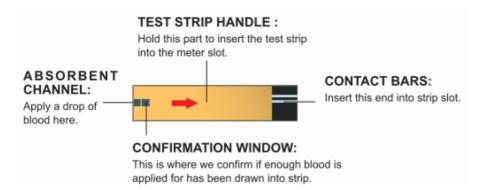
### LCD Screen Display



- (1) Main window : Shows glucose/temperature/steps/calories/distance/date/error message.
- (2) Bluetooth status: the left symbol flashes indicates no connection with the phone, constant light for the connection, and turns off the Bluetooth function is turned off; arrow symbol constant light indicates data is being transmitted.

- (3) mg/dL : Unit of measure for blood glucose. Displays with blood glucose test results.
- (4) Memory icon : Displays when the meter is in blood glucose memory mode.
- (5) USB symbol: When connected to a computer or other USB charging device for displaying the main window displays the date.
- (6) STEP : Unit of measure for step counter. Displays when the meter is showing the step counter.
- (7) KCAL : Unit of measure for calories (kilocalorie). Displays when the meter is showing the value of consumed calories.
- (8) KM : Unit of measure for distance (kilometer). Displays when the meter is showing the value of consumed calories.
- (9) Battery icon : Displays when the meter power is low. Charge the battery immediately by connecting the meter to a computer with its USB connector. The charging is complete when the icon stops flashing (while connecting to a computer).
- (10) 12-hour display: When the time is set to 12-hour display.
- (11) Time display window : The window displays time. In memory mode, it alternately shows date and time of the glucose test result.
- (12) Test strip icon : Displays when a test strip is inserted to the meter.
- (13) Blood icon : Flashes when the test strip is ready for blood sample to be applied. Do not apply blood until this icon shows up.

### **Blood Glucose Test Strip**



### Battery

Charge the battery before your first use of the BLE GlucoPedo meter by plugging the USB connector to a computer or other USB charger. Charge for at least 2.5 hours or until the

battery icon 🔋 displays all the time without flashing.

- ➤ Charge the battery when the low battery icon □ displays.
- > Please keep away from high temperature when charging.
- > Please contact the agent or sales representative if the battery icon is still flashing after 3

hours charging.

> The battery of this product is not intended to be changed.

# **Setting Your Meter**

Before using the BLE GlucoPedo for the first time, please set the correct date and time to keep correct records of daily steps and blood glucose values.

To enter setting mode, turn on the meter first by pressing MENU Button  $\square$  for 3 seconds, and press  $\square+\square$  buttons together for 5 seconds.

press ++ buttons together for 5 sec	
123step 12:00	<ul> <li>Turn on the meter</li> <li>Turn on the meter first by pressing MENU</li> <li>button for 3 seconds, and the meter is now in</li> <li>standby mode.</li> </ul>
<u>140 10 1</u> 12:00	<ul> <li>Enter setting mode</li> <li>Press + buttons together for 5 seconds until</li> <li>the number of the year is flashing.</li> </ul>
140 10 1 12:00 12:00	<ul> <li>Set the year</li> <li>Press or to navigate the value, and press</li> <li>to confirm and move on to the next setting.</li> </ul>
140 10 1 12:00 12:00	<ul> <li>Set the month</li> <li>Press or to navigate to the current year.</li> <li>Press to confirm and move on to the next setting.</li> </ul>
<u>- ', 140 10 1 140 - ', -</u> 12:00 12:00	<ul> <li>Set the date</li> <li>Press or to navigate to the current</li> <li>month. Press to confirm and move on to the</li> <li>next setting.</li> </ul>
140 10 1 12 hr 24 hr	<ul> <li>Set the hour format</li> <li>Press or to navigate to your preferred</li> <li>hour format (24 hr/12 hr). Press to confirm</li> <li>and move on to the next setting.</li> </ul>
140 10 1 12:00 7 1 300	<ul> <li>Set the hour</li> <li>Press or to navigate to the current hour.</li> <li>Press to confirm and move on to the next setting.</li> </ul>
<u>140 10 1</u> 12:00 140 10 1 12:7, -	<ul> <li>Set the minute</li> <li>Press or to navigate to the current</li> <li>minute. Press to confirm and move on to the</li> <li>next setting.</li> </ul>



#### 1. Set the second

Press  $\square$  or  $\square$  to navigate to the current second. Press  $\square$  to confirm and return to standby mode.

# **Step Counter**

### **Before Using the Step Counter**

The step counter automatically returns to zero every day. Make sure you have set the meter date and time to keep a correct record of your daily steps; refer to *Setting Your Meter* chapter for details.

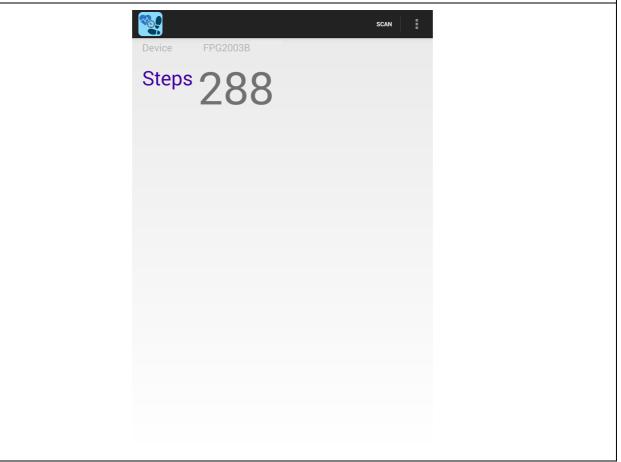
BLE GlucoPedo use triaxial accelerometer sensor which detects changes in acceleration. The number of steps walked are measured based on the vertical movement. Take care to affix the device securely near your waist line into a suitable location such as a pocket or belt pouches etc.

## **Step Counting Mode**

123step 12:00	1. Turn the meter on by pressing MENU Button <b>I</b> for 3 seconds, and the meter is in standby mode, showing the number of steps today.
13 I STEP 12:00	2. After consecutive walks (8 steps), the meter starts the pedometer function.
<u>58.7</u> kcat 12:00	3. Press 🖬 button to switch the display data to calories.
<u>0.89</u> 12:00	4. Press 🔳 button to switch the display data to distance.
mg/dl  - 12:00	5. Press <b>I</b> button to switch to blood glucose value display. <i>For details of blood glucose measuring, refer to Blood Glucose Test chapter.</i>
13:00	6. Press 🖬 button to switch to date display.

# Receive your pedometer test data from the phone APP

To receive a pedometer, please open the following FEGO BLE Communication Protocol compatible mobile phone or tablet terminal APP, pedometer data will be transmitted via a fixed time BLE to the phone side.



# **Blood Glucose Test**

### **Before Using the Blood Glucose Meter**

Before using the product to test your blood glucose value, read all instructions thoroughly and practice the test by using the control solution. Do all quality control checks as directed. Make sure you have set the correct date and time for the meter; refer to *Setting Your Meter* chapter for details.

# $\angle$ CAUTION : To measure the accurate glucose value, please do not use test strips and control solutions which are not supplied by the manufacturer.

# 

- The measured blood glucose is for reference only. It is not to be used for the diagnosis of diabetes. The user should not take any decision of medical relevance by the meter. Please consult the doctor or medical practitioner for further instructions.
- If you experience symptoms that are not consistent with your blood glucose test result, please repeat the test. If the second test result is still inconsistent, please call your doctor immediately.
- If the blood contains high concentrations of vitamin C, uric acid or other reducing substances, it may cause inaccurate measurement result. Please consult a physician before testing.
- ➤ High attitudes above than 3,402 meter (11,161ft) may affect the test result.
- Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test results. Do not test beyond of temperature range.

#### $\triangle$ Important health information

- Apply only capillary whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.
- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Test results below 60 mg/dL (3.3 mmol/L)\*1 indicates low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)\*2 indicates high blood glucose (hyperglycemia).If your results are below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately.
- Inaccurate results may occur in severely hypertensive 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.
- > Abnormal red blood cell counts (hematocrit level below 20% or above 60%) may cause false

results. Please consult your healthcare professional if you do not know your hematocrit level.

 Interference : Reducing substances occurring in the blood naturally (say, uric acid) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect BLE
 GlucoPedo test results. However, elevated concentrations of these substances may affect test results. The compounds listed in the table were found to have no affect at the concentration indicated

Compounds	Highest concentrations tested at which no interference occurred
Acetaminophen	$\leq 8.0 \text{ mg/dL} (0.53 \text{ mmol/L})$
Ascorbic Acid	$\leq 5.0 \text{ mg/dL} (0.28 \text{ mmol/L})$
Aspirin	$\leq$ 60 mg/dL (3.33 mmol/L)
Bilirubin	$\leq$ 90 mg/dL (1.54 mmol/L)
Cholesterol	$\leq$ 500 mg/dL (12.9 mmol/L)
Creatinine	$\leq$ 5.0 mg/dL (0.44 mmol/L)
Dopamine	$\leq 2.0 \text{ mg/dL} (0.11 \text{ mmol/L})$
EDTA	$\leq$ 360 mg/dL (12.3 mmol/L)
Galactose	$\leq$ 900 mg/dL (50 mmol/L)
Gentisic Acid	$\leq$ 5.0 mg/dL (0.32 mmol/L)
Glutathione	$\leq$ 53 mg/dL (1.72 mmol/L)
Haemoglobin	$\leq$ 500 mg/dL (0.08 mmol/L)
Heparin	$\leq$ 8,000 U/dL
Hydroxyurea	$\leq$ 3.0 mg/dL (0.39 mmol/L)
Ibuprofen	$\leq 50 \text{ mg/dL} (2.42 \text{ mmol/L})$
Icodextrin	$\leq$ 13 mg/dL (0.01 mmol/L)
L-dopa	$\leq 10 \text{ mg/dL} (0.51 \text{ mmol/L})$
Maltose	$\leq$ 900 mg/dL (26.3 mmol/L)
Methyldopa	$\leq$ 3.0 mg/dL (0.13 mmol/L)
Pralidoxime	$\leq 25 \text{ mg/dL} (0.94 \text{ mmol/L})$
Salicylate	$\leq 60 \text{ mg/dL} (4.34 \text{ mmol/L})$
Tolazamide	$\leq$ 100 mg/dL (3.21 mmol/L)
Tolbutamide	$\leq$ 400 mg/dL (14.8 mmol/L)
Triglycerides	$\leq$ 2,000 mg/dL (22.6 mmol/L)
Uric Acid	$\leq 8.0 \text{ mg/dL} (0.48 \text{ mmol/L})$
Xylose	$\leq$ 100 mg/dL (6.66 mmol/L)

Please read test strip instruction carefully.

Reference 1 : Jabbour, Serge, Elizabeth A. Stephens, Irl Bennett Hirsch. Type 1 Diabetes in Adults. USA : CRC Press, 2007.

Reference 2 : Unger, Jeff. Diabetes Management in Primary Care. USA : Lippincott Williams & Wilkins, 2006.

### **Principle of Blood Glucose Measurement**

Blood glucose is measured by an electrical current that is produced when a blood sample mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The BLE GlucoPedo measures the strength of the electrical current, calculates your blood glucose level and then displays your result in

milligrams of glucose per deciliter (mg/dL).

### Performance Characteristics for Blood Glucose Test

The BLE GlucoPedo adopts state-of-the-art technology to measure blood sugar easily and comfortably. The required amount of blood is less than 0.7  $\mu$ L. It tests and displays the glucose value in 6 seconds.

ACCURACY : 95 % of the measured glucose values were within either ±15 mg/dL (± 0.83 mmol/L) of the average measured values of the reference measurement procedure at glucose concentrations <100 mg/dL (< 5.55 mmol/L) or within ± 15 % at glucose concentrations  $\geq$  100 mg/dL ( $\geq$  5.55 mmol/L).

PRECISION: CVs (%) of intermediate precision and repeatability were less than 5%.

## About Alternative Site for Blood Glucose Testing (AST)

There are important limitations for doing AST. Please consult your healthcare professional before you perform AST.

#### What is AST?

Alternative Site Testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. The BLE GlucoPedo meter allows you to test your palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing.

#### What is the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, nerve endings are not so

numerous and you will not feel as much pain as you will experience at the fingertip.

#### When to use AST?

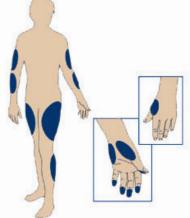
Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore, if you are testing blood glucose level during or immediately after meal, physical exercise or stressful event, take the blood sample from your fingertip only.

#### Use AST only:

In a pre-meal or fasting state (more than 2 hours since the last meal).

- Two hours or more after taking insulin.
- Two hours or more after exercise.
- During steady state blood glucose conditions.

#### Do NOT use AST if:



- You have reason to believe you have hypoglycemia or hyperglycemia.
- Your routine glucose results are often fluctuating.
- You are pregnant.

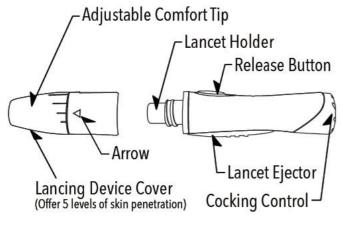
#### How to increase the accuracy?

- Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained.
- Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the fingertip. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

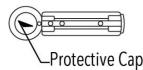
Important: To increase the accuracy when using AST, rub the puncture site more than 20 seconds before extracting blood.

### **Prepare For Blood Sampling**

Your lancing device and lancets are used for obtaining blood samples from the puncture site. • **Lancing Device** 



Lancet



/!>Important Lancing Device and Lancets Information

 $\succ$  Lancet is for single use only  $\circ$ 

- > Keep lancing device and lancets clean •
- Use caution when removing the used lancet from the device and when disposing the used lancet.
- > The meter and lancing device are for single patient use.
- > Do NOT share them with anyone including other family members.

#### > Do NOT use on multiple patients.

#### Prepare For Blood Sampling

riepuier of Blook Sump	5
	<b>STEP 1:</b> Remove the cap of the lancing device by twisting it off.
	Insert a sterile lancet into the lancet holder of the lancing device and
L) R	push down firmly until the lancet is fully seated. Do not twist the
	lancet.
C	STEP 2 :
	Remove the protective cap from the lancet by twisting it and then
	save it for later use.
	STEP 3 :
	Replace the lancing device cap and set the puncture depth to the
ET .	desired number. To select the best depth:
A C	1-2: For soft or thin skin
	3: For averag skin
	4-5: For thick or callused skin
	STEP 4 :
-5-	Pull back the cocking control until it makes a click, and then release.
Dr Ha	If it does not click, the device may have been cocked when the lancet
AEL	was inserted.

# **Performing Blood Test**

Contraction of the second seco	Wash Your Hands and the Puncture Site Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow °
	<b>Pull Out the Rubber Plug</b> The strip slot is protected by the rubber plug. Pull out the rubber plug before inserting a test strip.

	Insert Test Strip
123= A	Remove a new test strip from vial. Be sure to tightly
12:00 ▼	replace vial cap after removing test strips. Insert a test
	strip with the contact bar end entering into the test
	strip slot first. Push the test strip as far as it will go
	without bending it. The meter turns on automatically.
	Detecting Temperature
and or loca or	After the meter is turned on by inserting the test strip,
	the meter detects ambient temperature and displays
<b>_</b> 8:00 <b>_</b> 8:00	for 0.5 seconds, it enters scenario selection mode.
	Select the Measuring Scenario
00 00 1	Press $\square$ or $\square$ button to navigate to your current
	status.
<b>_</b> 8:00 <b>_</b> 8:00	AC: Before meal (default)
	PC-1: 2hr after breakfast
06-2 06-2	PC-2: 2hr after lunch
	PC-3: 2hr after dinner
<b>_</b> 8:00 <b>_</b> 8:00	Press <b>b</b> utton to confirm the selection.
mg/dl	Ready for Blood Sample
	When the blood icon $\blacklozenge$ is flashing, the meter is ready
<b>≜</b> 8:00	to test your blood.
	Select and Lance a Puncture Site
	* For Fingertip
	Hold the lancing device firmly against the side of your
10	finger. Press the release button. You will hear a click,
	indicating that the puncture is complete.
	* For AST
	Please refer to the "About Alternative Site Testing
	(AST)" section. Please consult your healthcare
	professional before obtaining blood from site other
	than your fingertip.
	Obtain a Blood Sample
	Gently massage your finger or puncture site to obtain
	the required blood volume. To perform the test, you
	I need only (1'/ up of blood comple De not among the
	need only 0.7 $\mu$ L of blood sample. Do not smear the
	blood sample. To obtain best accurate result, wipe off

Apply Blood Sample
Apply the blood sample to the opening of absorbent channel of test strip until the confirmation window is fully covered with blood. Blood will be drawn into the test strip. If the test strip confirmation window is full, you will hear a beep, and the meter starts to count down from 6 to 1.
<b>Read Your Result</b> After 6 seconds, the meter displays your blood glucose test result.
<b>Remove the Used Test Strip</b> Your blood glucose result is automatically stored in the meter memory. Leave the Blood Glucose Mode by removing the test strip. Discard the used strip and lancet safely in a puncture resistant container.
<b>Remove the Used Lancet</b> Remove the Lancing Device Cap. Push the Lancet Protective Cap back onto the exposed needle of the lancet. Direct the lancing device away from you and slide the Lancet Ejector in a forward motion, disposing the lancet in an approved container.

### **Blood Glucose Memory Recall**

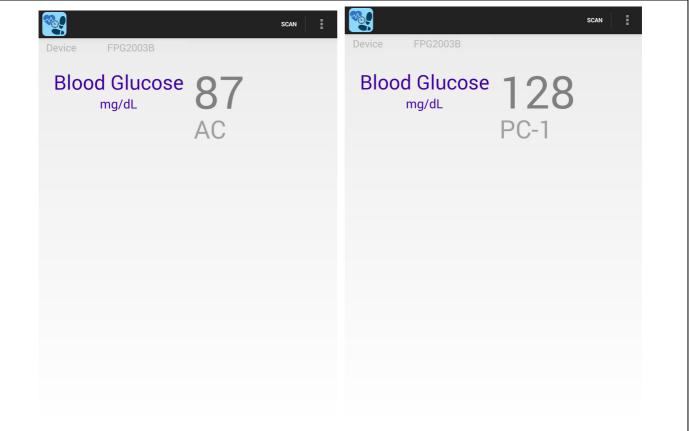
The BLE GlucoPedo meter automatically stores 99 test results, letting you review them in order from the most recent to the oldest.

You can either view your individual blood glucose test results on the meter or on a computer. **View Your Blood Glucose Test Results on the Meter** 

100 100 100 100 100 100 100 100 100 100	While the meter is turned on, press <b>b</b> button shortly and repeatedly to navigate to memory mode. The meter shows the memory record number / test result / time and measuring scenario / date alternately.
IO:00         P[-;	Press $\square$ or $\blacksquare$ to navigate the blood glucose test results.

# **Receive your Blood Glucose Measurement test data from the phone APP**

To receive information on blood glucose measurements, turn follows FEGO BLE Communication Protocol compatible mobile terminal APP, blood glucose data will be measured after the completion of the transfer to the phone side by BLE.



### **Understanding Your Blood Glucose Levels**

The normal blood glucose range is below 100 mg/dL (5.6 mmol/L) for a fasting, nondiabetic adult, but less than 140 mg/dL (7.8 mmol/L) two hours after meals.\* Consult your healthcare professional to find out your target blood glucose value.

If your blood glucose result seems unusually high or low, or inconsistent with your previous results, check the following:

- 1. Was the blood sample applied immediately to the test strip after removing it from the vial?
- 2. Was the volume of the blood sample sufficient?
- 3. Was the test strip vial cap tightly sealed?
- 4. Was the test strip used before the expiration date?
- 5. Were the test strips stored away from extreme temperatures in very cold or hot weather or from areas of high humidity?

Then run a control test with control solution. If the control test result is within the acceptable range, review testing procedure and repeat your blood glucose test with a new test strip. If your blood glucose value is still inconsistent with your previous results, glucose trend, or how you feel, contact your doctor immediately for help.

Reference:

\* American Diabetes Association Website (<u>http://www.diabetes.org</u>)

### **Control Solution Test**

*If your FEGO control solution did not come with a FEGO Control Solution Insert, the following information shall take the place of the insert.* 

#### Intended Use :

The FEGO Control solution is a liquid containing a measured amount of glucose which reacts with the FEGO test strip and meter. Only for use with FEGO BLE GlucoPedo meter and test strips as a quality control measure to verify the accuracy of the blood glucose test results. The FEGO Control solution is for in vitro diagnostic use.

#### **Important Information :**

- Use only FEGO control solutions with your FEGO BLE GlucoPedo meter.
- Check the expiration date on the bottle. Do not use if expired.
- Use within a period of 90 days from the date that you first open it. Record the discard date on the control solution bottle when you first open it to serve as a reminder to discard after 90 days.
- The control solution ranges are located on the back of the FEGO test strip vial. They are not recommended target ranges for your blood glucose.
- For in vitro diagnostic use.
- Do not add any liquid to the FEGO Control Solution.
- Do not take internally or inject.

#### Why Perform a Control Solution Test :

- To ensure that your meter and test strips are working properly together.
- To allow you to practice testing without using your own blood.

#### When to Use :

- Once a week (to ensure that you continue to have accurate results).
- When you begin using a new vial of test strips
- When test strips have been exposed to extreme environmental conditions.
- If you drop the meter.

#### Storage and Handling:

- Store the control solution tightly closed at temperatures between 4°C (39°F) and 30°C (86°F).
- Do not refrigerate, freeze, heat or expose to direct sunlight.
- Recap the bottle after use.

#### Performing a Control Solution Test

Control Solution Test	
Contraction of the second seco	Wash Your Hands and the Puncture Site Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow °
	<b>Pull Out the Rubber Plug</b> The strip slot is protected by the rubber plug. Pull out the rubber plug before inserting a test strip.
	<b>Insert Test Strip</b> Remove a new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert a test strip with the contact bar end entering into the test strip slot first. Push the test strip as far as it will go without bending it. The meter turns on automatically.
0[ <u>26</u> ] <u>26</u> ] 00:8	<b>Detecting Temperature</b> After the meter is turned on by inserting the test strip, the meter detects ambient temperature and displays for 0.5 seconds, it enters scenario selection mode.
8:00     mg/dl       ■ 8:00     8:00	Select the Measuring Scenario Press

	Apply Control Solution
	Check the expiration and discard dates on your control solution and test strip vials. Shake the control solution bottle well, then remove cap. Squeeze the bottle and discard the first drop then wipe the dispenser tip with clean tissue paper or cotton. Squeeze the bottle again to get a second drop onto a clean, non-absorbent surface or on your clean fingertip.
	Bring the tip of the test strip to touch the drop of solution until the meter beeps. $\triangle$ Caution:             To avoid contaminating the control solution with the content of the test strip, DO NOT DIRECTLY APPLY            CONTROL SOLUTION ONTO THE TEST STRIP.
Low 45-75 mg/dL High 200-300 mg/dL	Check if the Test Result is in Range. After six (6) seconds, the control solution test result appears on the display. Compare the test result with the range printed on the test strip vial. Each vial of FEGO Test Strips may have a different control solution range. The result should fall within the printed range on the test strip vial.

## Caring for Your Meter and Test Strip

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

#### Cleaning

Your meter does not require special maintenance. As long as no blood or control solution comes in direct contact with the meter, there is no special cleaning required. To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water. Do not use organic solvents to clean the meter. Your meter is a precision instrument. Please handle it with care.

#### Storage

#### ⊙Meter (BLE GlucoPedo)

- \* Storage condition :  $-20^{\circ}$ C $-50^{\circ}$ C ( $-4^{\circ}$ F $-122^{\circ}$ F), below 90% relative humidity.
- \* Avoid dropping and strong impact.
- \* Avoid direct sunlight and humidity.

OTest Strip

- \* Storage condition : 4°C~40°C (39°F~104°F), and 10~85% relative humidity. Do not refrigerate.
- \* Store your test strips in their original vial only. Do not transfer to other container.
- \* Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- \* After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- \* You may touch the test strip anywhere with clean, dry hands when removing it from the vial or inserting it into the meter.
- \* Use each test strip immediately after removing it from the vial.
- \* Do not bend, cut, or alter a test strip in any way.
- \* Keep the strip vial away from children since the cap and the test strip can be a potential choking hazard. If swallowed, please seek medical assistance immediately.

Ocontrol solution

- \* Storage condition : Store the control solution tightly closed at temperatures  $4^{\circ}C(39^{\circ}F) \sim 30^{\circ}C$  (86°F).
- \* Do not refrigerate.

# **Bluetooth 4.0 BLE function**

1.Power OFF state under BLE disabled.

Under 2.Power ON state, BLE enabled.

3. APP may end through FEGO BLE Communication Protocol compatible phone or tablet, receive information pedometer and blood glucose measurement data.

4. Through FEGO BLE Communication Protocol compatible phone or tablet terminal APP, set the timer on and time off BLE function.

1588ster 1588 ster 1588 自	BLE function turned off, the pattern is not displayed.
* 1588step 8:30 (1)	BLE feature enabled, the display * represents the connection with your phone or tablet, the pattern * blinking feature turned wait connection.
* ≒ 1588 step 8:30 €	When the function is activated and BLE connection, said information being transferred to the phone or tablet.

# **Display Messages**

The following is a summary of the display messages and symbols of Fego BLE GlucoPedo Meter.

These messages help to identify certain problems but do not appear in all cases when a problem has occurred.

Improper use may cause an inaccurate result without producing an error message.

In the event of a problem, refer to information under "ACTION TO TAKE".

DISPLAY	DESCRIPTION	ACTION TO TAKE
	All LCD segment on for display checking.	All LCD segment on for display checking every time the test strip is inserted. If some parts of the display are not working. Contact your local distributor for help.
<u>26.7 °C</u> - 8:00	Display Temperature	Move BLE GlucoPedo to a place with temperature between 10° C - 40° C. Wait for 30 minutes before performing the test. If the display keeps staying in this mode, please contact local distributor for help.
<u>R[</u> = 8:00 <u>P[-;</u> = 8:00 <u>P[-2</u> = 8:00 <u>P[-3</u> = 8:00	Scenario Selection	Select the scenario before the test : AC: Before meal PC-1: 2hr after breakfast PC-2: 2hr after lunch PC-3: 2hr after dinner
mg/dl	Blinking Blood Drop Icon	The meter is ready for blood sample applying into the test strip

<u>d-FULL</u> 8:00	Data full	Please connect the phone or tablet were immediately upload data through the BLE.	
- 8:00	Test result is higher than 600 mg/dL (33.3 mmol/L)	If this is not confirmed by the way you feel, review proper testing procedure and	
mg/dl - 8:00	Test result is lower than 20 mg/dL (1.1 mmol/L)	perform a control test. Repeat blood test, if the display still appears, please call medical assistance immediately.	
mg/dl MEM 80 ; 8:00	Display the last record	Toggle Display 1. Record Counts / Blood Glucose Value /	
805-01		Time 2. Scenario / Date	
<u> </u>	The ambient temperature is higher than the allowed operating temperature range.	The meter is not working. Move to an area with temperature between 10°C to 40°C	
<u>Lo °[</u> = 8:00	The ambient temperature is lower than the allowed operating temperature range.	(50ºF - 104ºF) and wait at least 30 minutes. Do not artificially heat or cool the meter.	
<u>USEd</u> = 8:00	<ul> <li>Possible Reason :</li> <li>1. The test strip has been used or the test strip is wed.</li> <li>2. The meter is defective.</li> </ul>	<ul><li>Please</li><li>1. Insert a new test strip.</li><li>2. Please contact local distributors or customer services for help.</li></ul>	
1588 step 8:30 D	Battery is weak.	Please charge the BLE GlucoPedo meter as soon as possible by connecting it to a computer	

<u>ε-ь</u> - 8:00 п	Battery is dead.	Please charge the BLE GlucoPedo meter as soon as possible by connecting it to a computer
<u>953-3</u> - 8:00	Memory (EEPROM) is defective.	Please contact local distributors or customer services for help.
<u>- 8:00</u>	System Error	Please contact local distributors or customer services for help.
BLE GlucoPedo meter has no response after the test strip is inserted	Possible Reason : 1. Wrong strip is inserted. 3. Meter is defective	<ul><li>Please</li><li>2. Insert FEGO test strip provided by us.</li><li>3. Contact local distributors or customer services for help.</li></ul>
BLE GlucoPedo meter does not perform blood glucose test after the blood sample is applied to the test strip	<ul> <li>Possible Reason :</li> <li>1. The volume of the blood sample is not adequate.</li> <li>2. BLE GlucoPedo meter is defective.</li> </ul>	<ul><li>Please</li><li>1. Insert a new test strip and test again by applying enough blood.</li><li>2. Contact local distributors or customer services for help.</li></ul>
Nothing shown on LCD	Possible Reason 1. Run out of battery. 2. Power is off. 3. Meter is defective.	<ul> <li>Please</li> <li>1. Charge the device.</li> <li>2. Press and hold  to turn on the meter.</li> <li>3. Contact local distributors or customer services for help.</li> </ul>
No calorie or distance value	Possible Reason 1. No step is counted 2. meter is defective	<ol> <li>Step counting function will be activated after 8 consecutive steps are detected.</li> <li>If after 8 to 10 steps, the meter is still inactive. Please contact local distributors or customer services for help.</li> </ol>

# **System Specifications**

	▲	FEGO BLE Pedometer and Blood Glucose Monitoring
General Information	Model Name	System
	Model Number	FPG2003B
	Display Content	Blood Glucose / Step Counts / Distance / Calories / Time / Date/ BLE connection status
ma	USB indicator	Orange LED Blinking : accessing data Green LED : accessing data done
tio	A seen Mathad	
ň	Assay Method	Electrochemical biosensor
		1. 3G Sensor
	Wakeup Method	2. Any Button
		3. Insert The Test Strip
	Entering Sleep Mode	No activity for 10 seconds
	Power Supply	DC 3.7V(Maximum battery voltage of 4.2V rechargeable lithium
		battery x 1)
		3.7V rechargeable lithium battery
	Battery Life	Full charged state is enough for 500blood glucose tests or
		10,000 steps per day.
	Low Battery Indicator	3.7V
		1. 128KB EEPROM : Keep step counts and raw data for 1~2
		weeks if walk 10,000 steps daily (suggest to connect BLE
	Memory Capacity	GlucoPedo to computer to upload data to computer to
		release the memory on BLE GlucoPedo)
	LCD Size	32(L)x21mm(W)
	Dimensions	66.4 mm (L) x 31 mm (W) x 14.5 mm (H)
	Weight	27g
	Material	PC/ABS
	Operating Condition for	4°C~+40°C → Humidity 10- 85%RH,
	Blood Glucose Testing	Altitude $\leq$ 3,402 m (11,161 ft) above the sea level.
	Storage/ Transportation	
	Condition for Blood	$4^{\circ}$ C ~+ $40^{\circ}$ C $$ Humidity 10- 85%RH (with strip included)
	Glucose Testing	
	Manufacturer Warranty	1 Year
ОB	Test Sample	Capillary whole blood
Blood Glucose	Test Result Calibration	Referenced to plasma glucose value
cog	Sample Size	0.7µL
je	Measuring Time	6 seconds
	measuring mile	

	M · D	
	Measuring Range	20~600 mg/dL(1.1~33.3 mmol/L)
	Memory	99 test memories
	Acceptable Hematocrit	20, (00)
	Range	20~60%
St	Pedometer sensor	3G sensor
Steps	Steps Range	0~100000 steps
N	Distance Range	0.0~9999.99 Km
	Calories Range	0.0~9999.99 Kcal
BLE		1.e-Signal SMD8105-A07-00A(AMICCOM A8105)Module 。
H	BLE Bluetooth function	2.Frequency Range: 2400 ~ 2483.5 MHz ISM (channel spacing is
		1MHz).
		3.Modulate mode: GFSK.
		4.Support the application of data rate from 4Kbps to 2Mbps.
		5.Using AES-128 CCM encryption algorithm.
		6.All packets are using the 24-bit CRC checksum.
		7. Automatically adapt to the fast frequency hopping.
		8.Bluetooth 4.0 BLE SMART.
		9. The state of motion and instant connection with the phone APP
		pedometer data transfer.
		10.Glucose measurements done automatically transfer data.

# **Symbol Description**

IVD	For <i>in vitro</i> diagnostic use
i	Please consult instructions for use
● ← →	USB Connection
	This product fulfils the requirements of
<b>C €</b> 0123	Directive CE and IEC/EN 60601-1-2 standard
	in vitro diagnostic medical device.
$\bigwedge$	Caution, consult accompanying document
LOT	Lot number
	Manufacturer
2	Do not reuse
1	Temperature limitation / Store at
	Use by / Expiry date

# **Dealer / Manufacturer Information**

Dealer : Fego Precision Industrial Co., Ltd Dealer Address : 947 Lin-Sen Rd. Wu-Fong Tai-Chung 413 Taiwan ROC Dealer Phone : +886-4-23391802



Pharmacist/Manufacture : OK Biotech Co., Ltd. Address : No. 91, Sec. 2, Gongdao 5th Rd., 30070 Hsinchu, TAIWAN



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