



eBwell eB-W01

Blood Glucose Monitoring System

User's Manual

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Welcome

Thank you for selecting the eBwell blood glucose monitoring system.

The eBwell 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 eBwell blood glucose monitoring system. Please read it carefully.

[Test principle]

The technology used for the eBwell 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 eBwell test strip and the current change is proportional to the amount of glucose in the blood.

[Accuracy (method comparison)]

The eBwell blood glucose monitoring system is calibrated by means of glucose oxidase method to display plasma equivalent results, which is traceable to an NIST standard SRM917c. The whole blood was used for calibration.

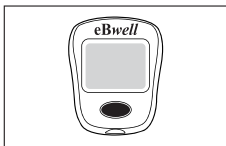
1. eBwell blood glucose monitoring system

1.1. The eBwell system

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

1.2. Equipments in package

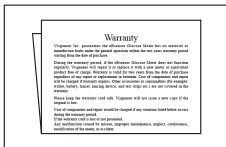
Please check the kit package for the eBwell blood glucose monitoring system which includes the following items. If not, please contact the local agents or exchange at the original purchased store.



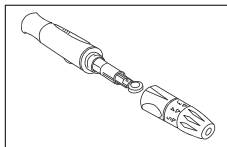
Meter



User's manual



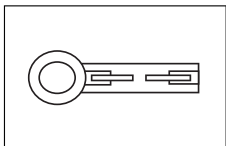
Warranty



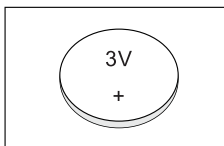
Lancing device

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

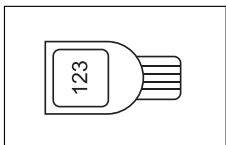
- eBwell blood glucose test strips 50 pcs/vial.
- Control solution. (Two different concentrations of eB-series control solutions are used, ie. 100 and 300 mg/dL)



Lancet



Lithium battery



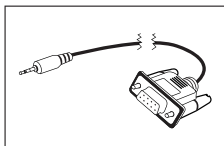
Code card



Blood glucose test strips



Control solution



RS232/USB PC
Interface

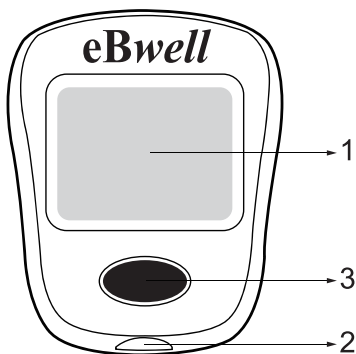
1.3. Product specification

Strip series		eBwell
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 (interchangeable)
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	12 H
10	Operating temperature range	10~ 40°C
11	Relative storage condition	Below 90 %
12	Meter storage condition	0~ 50 °C
13	Meter storage humidity range	Below 95 %
14	Dimension	84 x 66 x 16 mm
15	Weight	≤ 50 g
16	Power supply	3-volt CR2032 lithium battery
17	Data output	RS232/USB PC Interface
18	Control solution test display	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 display	°C and °F (Interchangeable)

Note:

Please read all the instructions carefully in this booklet before you start using the System. If you are under 18 years old, testing should be demonstrated by parents/seniors.

2. About eBwell blood glucose monitoring system



The front side of the meter

1. Screen

Show blood glucose result, messages and blood glucose results stored in memory.

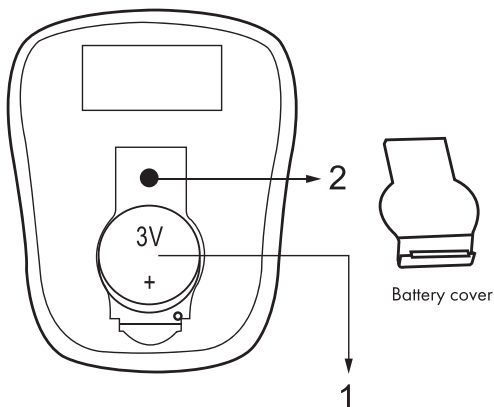
2. Test slot

Insert test strip and code card.

3. M button

Use to recall stored test results or to change the values in the setting mode (time and date).

The back side of the meter



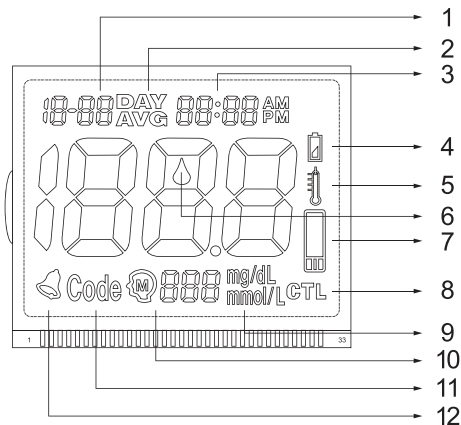
1. Battery slots

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

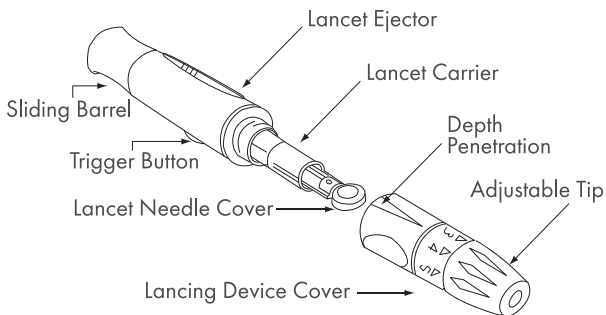
Face these contacts up and insert into the meter.

3. Indication slot

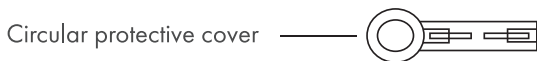
To indicate if blood has been applied enough to fill the reaction area.

The lancing set

Lancing Set



Lancet



3. Operating methods

3.1. Before testing

3.1.1. Installing the batteries

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.

Step 4. The cover is secured when the tab is pressed in and you hear a "click" sound.

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 shown 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 shown 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:
At the upper left corner, when the alarm clock is "OFF", 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 (when provided).

3.1.3. Coding the meter (when provided)

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 on the screen and the meter will detect automatically. 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 eBwell blood glucose test strip and remove the code card (Figure 1) from the box.

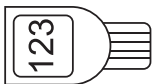


Figure 1. code card

Step 2 : Insert the code card into the test slot as shown in Figure 2.

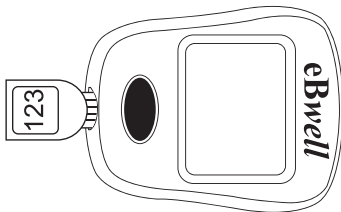


Figure 2. Insert the code card

Step 3 : You will 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 "E01" is displayed (refer to Figure 4 below), the meter is not functioning properly. Please contact local agent.



Figure 4. E01 shown on the screen

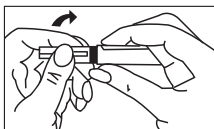
Step 4 : Check the code number on the screen with the number on the vial of test strips. These two numbers have to be the same. If not, please stop testing and contact your local agent.

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

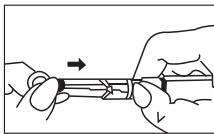
3.2 Start testing

After checking the code number, you may now start testing blood glucose. eBwell can be used anywhere.

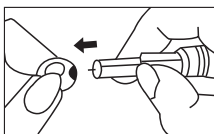
Step 1: Remove the cap from the lancing device.



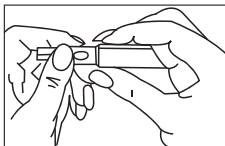
Step 2 : Insert a lancet into the lancing holder and push it down until it is fully seated.



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

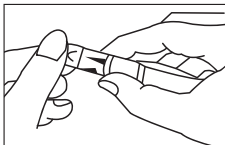


Step 4 : Put the cap back onto the lancing device.

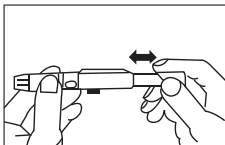


Step 5 : You have to adjust the depth setting of lancing device before using. There are 5 levels of depth you can choose. Level 1 is for people with very thin skin. Level 5 is for people with very thick skin.

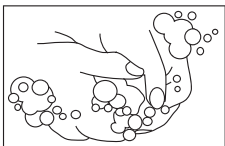
Step 6 : Choose a desired skin penetration depth for yourself by rotating the depth selector until the depth selection window displays your desired depth setting.



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



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



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

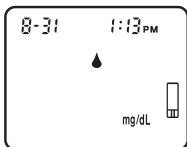
Step 10 : Make sure the triangle sign on the test strip is facing up and insert the electrical contact fully into the test slot.



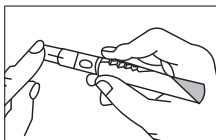
Insert the test strip into test slot. The symbol "CH" will appear on the screen, then the meter will automatically detect the followings :

1. Test strip type detect : You will hear a "beep" sound upon inserting the 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°C or above 42°C, "E-t" will appear on the screen and the meter will automatically turn off.
5. When "auto-detection" is complete, the blood drop symbol will flash on the screen, and the current code will appear on the screen for 5 seconds.

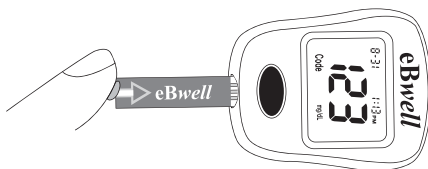
Step 11 : After inserting the test strip, the code number will be shown on the screen. The blood drop sign will flash. Please apply blood within 2 minutes or the meter will turn off automatically.



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

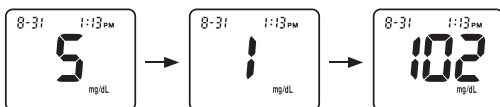


Step 13 : To obtain a drop of blood, squeeze your finger gently to form a small drop of blood. Apply the blood onto the semicircle-shaped cutout on the top edge of the test strip.



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

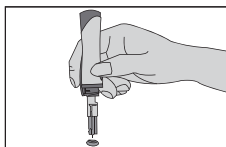
Step 15 : When the meter beeps, it starts counting down from 5 to 1. After counting down to 1, your test result will appear on the screen.



Step 16 : The meter will turn off automatically by removing the test strip. Dispose the used test strip in a sealed container.



Step 17 : Remove the cap from the lancing device. Put the protective cover onto the lancet.



Step 18 : Push the ejector forward and dispose the lancet to a sealed container.



4. Using the meter memory

Your eBwell 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. Steps of reviewing the stored results in memory

Step 1 : Press **M** button for 2 seconds to start up the eBwell.

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

eBwell 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 eBwell are required for data transmission from eBwell to PC.

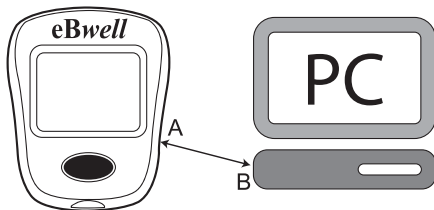
Note:

- * Users must use software and RS232/USB cable specifically designed for eBwell 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. Step 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 eBwell and port B to your PC (see sketch below) when eBwell is in OFF mode. When connected 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 eBwell, 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 eBwell blood 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 auto detection. When auto-detection is complete, the meter will show the current environment temperature, 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 you can begin the control solution test.
- Step 3. Apply a drop of control solution onto the test strip.
- Step 4. Always write down the opening date on the bottle.
- Step 5. Hold the bottle and gently squeeze the bottle to form a small drop of control solution at the tip of the bottle.

Note: Always shake the bottle gently, discard the first drop before applying the control solution.

- Step 6. After counting down from 5 to 1, your test result appears on the screen.
- Step 7. 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.

* Compare the result with the expected range printed on the vial of the test strips. The result should be within the range.

* 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

Blood glucose monitoring system will give accurate results when the following limitations are observed:





- The test strips should not be used for the testing of neonate.
- The test strips are for single use only. **DO NOT** reuse.
- Handle the meter with care. **DO NOT** drop the meter or apply a strong force to the meter.
- **DO NOT** disassemble the meter.
- **DO NOT** use code card from other glucose meter system.
- **DO NOT** operate the meter when placed on hot or cold surface.
- Always store the meter in the carrying case when not in use.
- 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 the strip while the measurement is in processing.
- The test strips are used only with fresh capillary whole blood from finger. **DO NOT** use serum or plasma.
- Hematocrit values less than 20 % may cause falsely high test results; hematocrit values higher than 60 % may cause falsely low test results (consult your healthcare 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 eBwell 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 into contact are considered biohazards and should be handled as if capable of transmitting infection.
- The meter has to be used in an environment with humidity less than 90 %.
- The meter has to be used in an environment with temperature between 10– 40 °C (50–104 °F).
- 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 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 problem. 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 local distributors.
	No battery power. The meter will turn 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°C~ 40°C (50°F~104°F).

	<p>When the temperature goes above 42°C (107.6°F), or below 4°F (39.2°F) the meter will turn off automatically.</p>	<p>Repeat the test in a place between 10°C~40°C (50°F~ 104°F).</p>
	<p>Your blood glucose level is higher than 600 mg/dl (33.3 mmol/L).</p>	<p>Re-check your blood glucose level. If “HI” is displayed again, please call your doctor immediately.</p>
	<p>Your blood glucose level is lower than 20 mg/dl (1.1 mmol/L).</p>	<p>Re-check your blood glucose level. If “LO” is displayed again, please call your doctor immediately.</p>
	<p>The test strip is used or damp.</p>	<p>Please use a new test strip.</p>

Labeling and information



Do not re-use



Consult operating instructions



Keep dry



Caution, consult accompanying documents



In-Vitro diagnostic



Operating temperature limitation



Store temperature limitation



Use-by date



Keep away from sunlight



Batch number



Serial number



Authorized representative in
the European Community/ European Union



Manufacturer



Paper recycling



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



Please do not dispose this meter with other household or
municipal waste. Please follow regulation to dispose the
meter at designated recycling facility, or return it back to
your original purchasing site.

 Lancet **CE 0197** and Lancing Device **CE**
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