VivaChek™ Eco BLE

Blood Glucose Monitoring System

User's Manual

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CE 0197

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VivaChek™ Eco BLE

Blood Glucose Monitoring System

Dear VivaChek™ Eco BLE System User,

Thank you for choosing the VivaChek™ Eco BLE Blood Glucose Monitoring System! VivaChek™ Eco BLE Blood Glucose Monitoring System is designed for easy test of blood glucose and helps you keep blood glucose under control.

Read this User's Manual carefully before you use your meter system. This manual will help you to get comfortable using the VivaChek™ Eco BLE Blood Glucose Monitoring System and get reliable test results. Please keep your User's Manual in a safe place; you may want to refer it in the future.

Thank you again for choosing the VivaChek™ Eco BLE Blood Glucose Monitoring System.

Principle and Intended Use

The VivaChek™ Eco BLE Blood Glucose Monitoring System (Meter Model: VGM34) is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The VivaChek™ Eco BLE Blood Glucose Monitoring System is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose enzyme and the mediator. Electrons are generated, producing a current that is positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed. The meter is calibrated to display plasma-like concentration results.

The VivaChek™ Eco BLE Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and health care professionals in clinical setting, as an aid to monitor the effectiveness of diabetes control. The system should not be used for diagnosis of diabetes.

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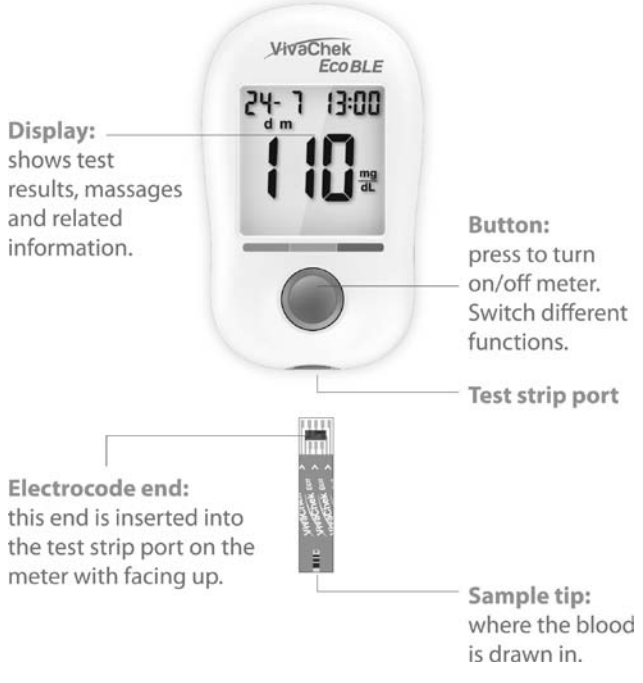
CHARPTER 1: UNDERSTANDING YOUR TESTING TOOLS

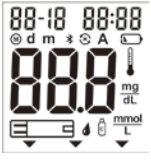
Your Meter System Overview

The VivaChek™ Eco BLE Blood Glucose Meter and Test Strip



Your Meter Display

The picture below shows all the symbols that appear on your meter display.



Icon	What it Means
88-18	Top left area on the screen indicates date.
88:88	Top right area on the screen presenting year or time.
d m	Date, month.
A	Indicates average value.
	Indicates low battery and that replacement is necessary.
88.8	Center area on the display that shows test results or error codes.
	Indicates the system is ready to test.
	Control test result.
mg/dL mmol/L	Test results are displayed as mg/dL or mmol/L according to local government regulation.
	Indicates the temperature is not suitable for testing.
	Bluetooth
	The meter failed to sync with the Smartphone.
	Memory

Notes:

Your VivaChek™ Eco BLE Blood Glucose meter is pre-set with beep sound function, the meter will beep when:

- *set the date and time.*
- *turn on the meter.*
- *the test strip is inserted and ready to apply blood or control solution.*
- *sufficient blood or control solution is pulled into the test strip.*
- *the test is complete.*
- *if any error occurs during operation.*

Meter Use and Precautions

- The meter is pre-set to display blood glucose concentration in either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on which unit of measure is standard in your country. This unit of measure cannot be adjusted.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extremes in temperature or humidity. Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Quality Control Test** on page 14 for instructions.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to the **Caring for Your Meter** section on page 19 for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.

All Glucose systems preventive warnings with regard to EMC

1. This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2.However, use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.
2. This instrument complies with the emission and immunity requirements described in EN61326-1 and EN61326-2-6.Do not use this instrument in close proximity to sources of strong electromagnetic radiation. It may interfere with

proper operation of the meter.

3. For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

Important Safety Information

- Always keep the test strips in the original vial. Tightly close the vial immediately after you have removed the test strip.
- Do not use the meter if it is dropping into water or splashing water on to it.
- Wash and dry your hands well before and after testing.
- Test strips and lancets are for single use only.
- Do not drop blood directly on the flat surface of the test strip.
- Check the expiration dates and discard dates on your test strips vial label and control solution bottle label.
- Use only VivaChek™ Eco Blood Glucose Test Strip with your VivaChek™ Eco BLE Blood Glucose Meter.
- Use only VivaChek™ Eco Control Solution with your VivaChek™ Eco BLE Blood Glucose Monitoring System.
- For self-testers, consult your physician or diabetes health care professional before making any adjustments to your medication, diet or activity routines.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.

Potential Biohazard

Healthcare professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects, which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.

CHAPTER 2: SETTING UP YOUR SYSTEM

Before you first time using your meter or if you change your meter battery, you should check and update your meter settings.

Set the Date and Time

1. Enter the Setting Mode and Set the Date

When the meter is off, press and hold ◎ until the meter beeps to enter the set up mode with the number in the year position will now flash on the display. Press ◎ to adjust it then press and hold ◎ until the meter beeps to set. Then it will shift to next digit for setting. Repeat the above action until the year setting is completed.

The month will now flash. Press ◎ to adjust the month, press and hold ◎ until the meter beeps to set.

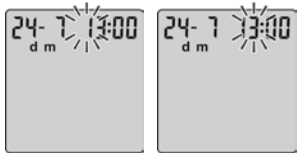
The date will now flash. Press ◎ to adjust the date, press and hold ◎ until the meter beeps to set. Then it will shift to next digit for setting. Repeat the above action until the year setting is completed.

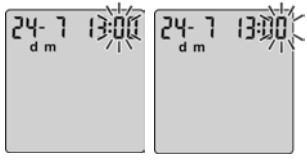
Note:

Before you first time use your meter system for testing, please adjust the meter settings to set the correct date and time, ensuring that results stored in the memory are shown with the correct date and time.

2. Set the Time

The hour will now flashing. Press ◎ to adjust the current hour, press and hold ◎ until the meter beeps to set. Then it will shift to next digit for setting. Repeat the above action until the year setting is completed.





The minute will now flash. Press ◎ to adjust the minute, press and hold ◎ to set. You will hear a long beep.

Now you have completed your meter set up. A symbol of a test strip appears letting you know the meter is ready to test.

Pairing your meter with the Smartphone

Pairing prepares your VivaChek™ Eco BLE Meter and Smartphone to communicate with each other. The devices must be within 5 meters of each other to pair and sync. Download the GlucoWell™ app before pairing your meter and Smartphone.

Note: *it is compatible with Android 4.3 or above, and iOS 8.0 or above.*

WARNING

DO NOT pair another person's meter with your Smartphone.

To pair the Smartphone with your meter, turn your meter on and follow these steps:

1. When you turn on your meter, Bluetooth will automatically turn on.
2. To turn on Bluetooth® on your Smartphone tap the Settings icon on the home screen.
3. Next select Bluetooth and set Bluetooth to ON. Your devices are now searching for each other.
4. Look for a device named BLE- VivaChek. This is your meter.
5. Tap on the entry that represents your VivaChek™ Eco BLE meter.
6. Enter your meter passcode using the keypad. The passcode is the last 5 digits from the Serial Number on the back of your meter.
7. Tap Pair
8. Wait for the Smartphone status to say "Connected". Congratulations! Your meter and Smartphone are now paired. Before testing, you must now initially sync the meter with the app.

NOTE: After successful pairing, the symbol will appear on the meter.

Initial syncing of the meter and app

You must initially sync the meter and app before you start testing your blood glucose. The first time you sync, the Smartphone will set the clock in the meter. However, you will not see the date and time on the meter display until after your first test.

The Smartphone checks and updates the date and time in your meter each time you sync. Check the date and time on your Smartphone often to be sure they are correct. For instructions on setting the date and time on your Smartphone, see the user manual for your Smartphone.

NOTE: It is important to sync the meter and app before testing for the first time. This will ensure that the correct date and time are attached to your test results. Any glucose results from tests taken before your initial Sync will not be assigned a date or time, and will never be sent to the app.

1. Open the GlucoWell™ app on the Smartphone

2. Turn your meter on
3. “Syncing Data” will appear on the app to notify you that the meter is communicating with the app

NOTE: The first time you sync, the app will display a Meter Time Difference message. Tap Yes to set the clock in your meter. The date and time will appear on your meter after your first test.

NOTE: If you tap No or do not act on the message, the clock in the meter will not be set. Any glucose results from tests taken before the meter clock is set will not be assigned a date or time, and will never be sent to the app. With your meter off, repeat steps 2-4 on page 7 to initially sync and set the meter clock.
When complete, the date and time of the initial Sync will appear under Last Sync on the app summary screen. When you begin testing, the date and time of your test will appear on the meter.

NOTE: We recommend personalising the app in your Smartphone after initial syncing and before you begin testing your blood glucose. Refer to the GlucoWell™ App Owner’s Booklet or the Help file in the app.

Syncing to send results wirelessly to the app

After pairing the meter with your Smartphone and initially syncing with the app, you are ready to begin testing. Sync often to send test results wirelessly to the app.

1. Open the app on your Smartphone
2. Turn your meter on and make sure the Bluetooth® symbol ( ) is displayed
3. “Syncing Data” will appear on the Smartphone to let you know the meter is sending results to the app
4. After the Syncing, the app will display a list of any new blood glucose results sent from the meter

Using your meter without the app

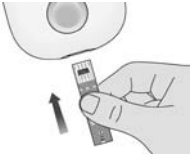
The meter can be used without a Smartphone or the app. You can still test your blood glucose and review your results on the meter screen.
Your meter automatically stores up to 500 results with the time and date. Test results are stored from the newest to the oldest. If there are already 500 records in memory, the oldest record will be erased to make room for a new one.

CHAPTER 3: TAKING A TEST

Set up your meter correctly and have all the materials you will need ready before you begin testing, including your VivaChek™ Eco BLE Blood Glucose Meter, VivaChek™ Eco Blood Glucose Test Strips and VivaChek™ Lancing Device with VivaChek™ Lancets. VivaChek™ recommend to use VivaChek™ Lancing Device (CE) and VivaChek™ Lancets (CE0197) for blood glucose testing.

Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial or foil pouch. Tightly close the vial cap immediately after you have removed the test strip.



3. Insert the test strip into the meter in the direction of the arrows. Meter turns on after a beep.

4. A symbol with a test strip with a flashing blood will appear letting you know the meter is ready to test.

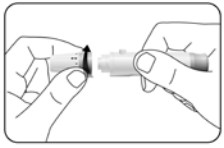
Note:

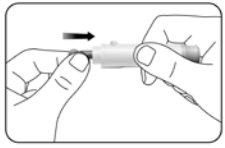
Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month format. 2017-01 indicates January, 2017. Your VivaChek™ Eco Blood Glucose Test Strips have 6 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water wash hands to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.

Preparing the Lancing Device

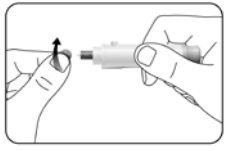
For fingertip sampling, adjust the depth penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.

1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the VivaChek™ Lancing Device and push it until the lancet comes to a complete stop in the lancing device.

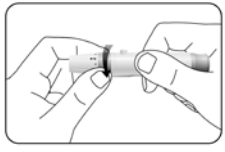




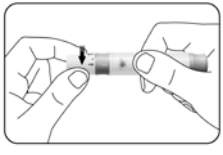
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for disposing used lancet.

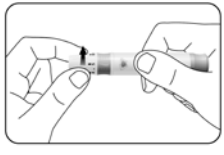


3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.



4. Adjust the puncture depth by rotating the lancing device cover. There are a total of 5 puncture depth settings. To reduce the discomfort, use the lowest setting that still produces an adequate drop of blood.





Adjustment:

0 and 1 for delicate skin
2 and 3 for normal skin

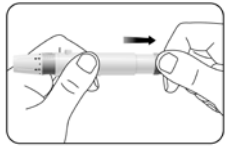
4 and 5 for calloused or thick skin

Note:

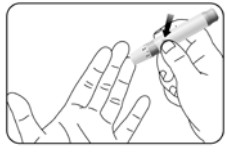
Greater pressure of the lancing device against the finger will also increase thepuncture depth.

Getting a Blood Drop and Testing

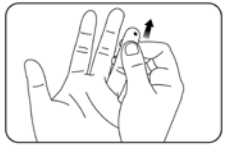
1. Pull the cocking barrel back to set the lancing device. You may hear a click; while the release button changes to orange color to indicate the lancing device is now loaded and ready for obtaining a drop of blood.



2. Press the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates.



3. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood. For the greatest reduction in pain, lance on the sides of the fingertips. Test immediately after a good blood drop has formed.

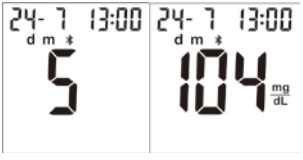


4. Immediately touch the tip of the test strip to the drop of blood. The blood pulled into the test strip through the tip. Make sure that the blood sample has been fully filled the check window on the strip tip. Hold the tip of the test strip in the blood drop until the meter beeps.

Note:

If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

5. The meter counts down from 5 to 1, then your result appears on the display after a beep. The test result will automatically be stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.



Note:

Remove the used strip meter will turn off automatically. See "Discard used test strip" instruction below. Meter shuts off automatically 2 minutes after inactivity.

Discard the Used Test Strip

You can discard the used test strip to the direction of arrow. Meter turns off automatically after a beep.

Potential Biohazard

Dispose of the used test strips as medical waste.

Expected Diabetes Control Goal:

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or exercise. Ideally, to control the glucose level as close to a normal (non-diabetic) blood glucose level as you safely can.

The American Diabetes Association suggests the following targets for most non-pregnant adults with diabetes. More or less stringent glycemic goals may be appropriate for each individual. In real life, consult your health care professional for the target value that is appropriate for you.

Expected blood glucose levels for most non-pregnant adults with diabetes:[1]

Time	Range, mg/dL	Range, mmol/L
Before a meal	70 – 130	3.9 – 7.2
1-2 hours after beginning of the meal	Less than 180	Less than 10

Reference:
1. ADA Clinical Practice Recommendations, 2014.

Warning:

- *If your blood glucose reading is under 50 mg/dL (2.8 mmol/L) or you see LO (less than 10 mg/dL (0.6 mmol/L)) on the meter display, contact your health care professional as soon as possible.*
- *If your test result is above 250 mg/dL (13.9 mmol/L) or you see HI (greater than 600 mg/dL (33.3 mmol/L)) on the meter display, contact your health care professional as soon as possible.*
- *Do not change your medication therapy based on VivaChek™ Eco BLE test result before consult your health care provider.*

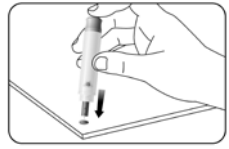
Questionable or Inconsistent Results:
If your blood glucose result does not match how you feel, please:

- Check the expiration date and the discard date of the test strip. Make sure that the test strip vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is between 5 and 45°C (41-113°F).
- Make sure that the test strip vial has been tightly capped.
- Make sure the test strip has been stored in cool, dry place.
- Make sure the test strip was used immediately after removing from the test strip vial or foil pouch.
- Make sure that you followed the test procedure correctly.
- Perform a control solution test (See Performing a Control Test on page13 for instructions).

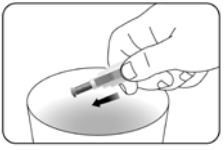
After checking all of the conditions listed above, repeat the test with a new test strip. If you are still unsure of the problem, please contact your local dealer.

Removing the Used Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.



Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.



Potential Biohazard

Always dispose of the used lancet properly to prevent injury or contamination to others.

Caution:

- *Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.*
- *Do not use the lancet if the needle is bent.*
- *Be cautious whenever the lancet needle is exposed.*
- *Never share lancets or the lancing device with other people to prevent possible infections.*
- *In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.*
- *Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.*

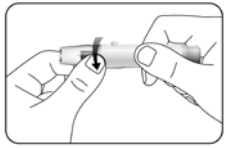
Alternative Site Testing

Blood samples for glucose testing may be taken from sites other than your fingertips. Alternative site testing using blood from the forearm or palm may give glucose results that significantly differ from fingertip blood. Differences occur when blood glucose levels are changing rapidly, such as after a meal, after insulin, during or after exercise.

The forearm and palm areas have less nerve endings than the fingertip. You may find that obtaining blood from these sites are less painful than from the fingertip. The procedure for forearm and palm sampling is different. You need a clear cap to draw blood from these sites. The clear cap is not adjustable for puncture depth.

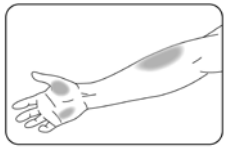
The clear cap may not be included in the VivaChek™Eco Blood Glucose Monitoring System package; it isavailable for separate purchase from local dealer.

Follow Step 1 and 2 of “Preparing the Lancing Device” to insert the lancet and load the lancing device.

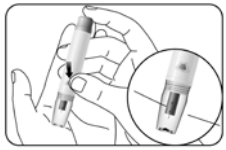


3. Screw the clear cap onto the lancing device.

4. Choose a puncture site on the forearm or palm. Select a soft and fleshy area of the forearm and palm that is clean and dry, away from bone, and free of visible veins and hair. To bring fresh blood to the surface of the puncture site, massage the puncture site vigorously for a few seconds until you feel it getting warm.



5. Place the lancing device against the puncture site. Press and hold the clear cap against the puncture site for a few seconds. Press the release button of the lancing device, but do not immediately lift the lancing device from the puncture site. Continue to hold the lancing device against the puncture site until you can confirm a sufficient blood sample has formed.



Notes:

- *Consult your health care professional to determine if alternative site testing is right for you.*
- *Alternative site testing is not recommended if you have hypoglycemic unawareness (you do not recognize the symptoms of or cannot tell when you have low blood glucose). Please consult with your health care professional if you have low blood glucose level.*
- *Select a soft, fleshy area of skin that is free from hair, moles and visible veins for alternative site testing. Wash the site with soap and warm water, then rinse and dry thoroughly.*
- *Use alternative site testing for blood glucose tests only when it is more than 2 hours after:*

·· A meal · Taking medication · Exercise

Testing with Control Solution

Why Perform Control Tests

Performing a control test lets you know that your meter and test strips are working properly to give reliable test results. You should perform a control test when:

- At least once a week
- You open a new box of test strip
- You want to check the meter and test strips
- Your test strips were stored in extreme temperature or humidity
- After cleaning your meter
- You dropped the meter
- Your test result does not match with how you feel

About the Control Solutions

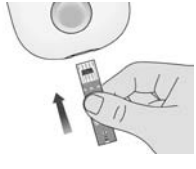
- Only use VivaChek™ Eco Control Solutions (Low, Normal or High) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not included in the average value calculation.
- All expiration dates are printed in Year-Month format. 2017-01 indicates January, 2017.
- Do not use control solution that is past the expiry date or discard date (the control solution will expire 6 months after the bottle is opened for the first time).
- Shake the bottle well before use.
- Close the bottle tightly after use.

Performing a Control Test

1. Remove a test strip from the test strip vial or foil pouch. Tightly close the vial cap immediately after you have removed the test strip.

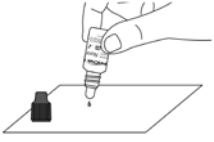
Note: *Check the expiration and discard dates of the test strips. Do not use the expiredtest strip.*

2. Insert a test strip into the meter in the direction of the arrows.



3. The meter turns on after a beep. An image of a test strip with a flashing blood drop will appear letting you know the meter is ready to test.

4. Shake the control solution bottle thoroughly. Squeeze the control solution bottle gently and discard the first drop. Squeeze out a second small drop on a clean nonabsorbent surface.

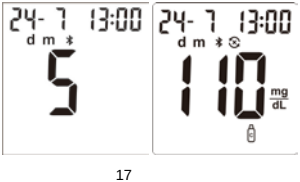


Note:
Do not apply control solution to the test strip directly from the bottle.

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is pulled into the test strip through the strip tip.

Note:
If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

6. Hold it in the drop until the meter beeps, and then you see the meter count down on the screen and followed with your control test result after a beep.



Note: *The meter will automatically recognize and mark the control result for you. Control results are not included in the 7, 14 and 30 day average calculation.*

Understand Your Control Test Result

Compare your control test result with the ranges printed on the test strip vial label or on the foil pouch.

Notes:

If your control test result is out of range:

- *Check the expiration dates and discard dates of the test strip and control solution. Make sure that the test strip vial has not been opened for more than 6 months and the control solution bottle has not been opened for more than 6 months. Discard any expired test strips or control solution.*
- *Confirm the temperature in which you are testing is between 10 and 40°C (50-104°F).*
- *Make sure that the test strip vial and the control solution bottle have been tightly capped.*
- *Make sure the test strip was used immediately after removing from the test strip vial or foil pouch.*
- *Make sure the control solution was mixed well.*
- *Confirm that you are using VivaChek™ brand control solution.*
- *Make sure that you followed the test procedure correctly.*

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip vial label or on the foil pouch, your meter or test strips may not be working properly. **DO NOT** use the system to test blood. Contact your dealer for help.

To turn your meter off, just remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will be not included in your blood glucose averages.

Using the Meter Memory

Your meter automatically stores up to 500 results with the time and date. Test results are stored from the newest to the oldest. The meter will also calculate the average values of records from the last 7, 14 and 30 days.

Notes:

- *If there are already 500 records in memory, the oldest record will be erased to make room for a new one.*
- *It is very important to set the correct time and date in the meter, please make sure*

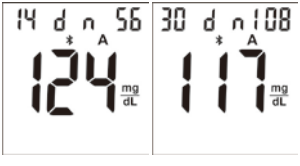
the time and date are correct after you change your battery.

- *Control results are not included in the 7, 14 and 30 day average calculation.*

Viewing Your Test Results

When your meter is off, press ◎ to turn meter on after a beep, a symbol of strip flashes on the display, press ◎ again, the 7 day average will appear in the center of the display with the number of results shown at the top of the display. If you want to review the memory after you immediately performed a test, with the test result on the display, press ◎ to see the 7 day average.

Press ◎ to view the 14 day average. Press ◎ again to review the 30 day average.



Continue to press ◎ to review previous results in order. Results will be shown starting with the most recent. Eachresult will show the date and time the test was taken.

When END appears on the display, you have viewed all of the results in the memory.

CHARTER 4：MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended for best results.

Changing the Battery

Battery should be replaced when the meter continually displays , or the meter shows then turns off.

1. Turn off your meter before changing battery.

2. Press firmly on the battery cover and slide in the direction of the arrow.

Note:

After you change battery, your meter prompts you to confirm the meter's time and date settings. All test results are saved in memory.

If you take out the battery when your meter is turned off, date and time setting will be saved for one minute, insert the new battery immediately, you do not need to reset the meter.

3. Remove the old battery by lift old battery.

4. Place new battery under the prongs and into the battery compartment with the “+” side up (Use one 3-volt CR 2032 lithium battery).

5. Slid the battery cover back into place, lining up with the open slots, and close firmly.

Warning:

Keep battery away from children. Lithium batteryis poisonous. If swallowed, immediately contact your doctor or poison control center. Discard battery according to your local environmental regulations.

Caring for Your Glucose Monitoring System

Blood Glucose Meter

Your VivaChek™ Eco BLE Blood Glucose Meter does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip or data port. It is recommended that you store the meter in the carrying case after each use.
The VivaChek™ Eco BLE Blood Glucose Meter is a precision electronic instrument. Please handle it with care.

Lancing Device

Clean the lancing device using a soft cloth with mild soap and warm water as required. Use 70% Isopropyl Alcohol to disinfect the lancing device. Carefully dry the lancing device. Do not immerse the lancing device in liquid.

Troubleshooting Guide

What You See	What It Means	What You Should Do
	Blood or control solution was applied to the test strip before the flashing drop appeared on the display	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.

	The meter is sensing a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a VivaChek™ Eco Blood Glucose Test Strip from VivaChek Laboratories, Inc..
	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and VivaChek™ Eco Control Solution can be used for the test.
	Temperature out of range.	Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20minutes before performing a test.
	Potential software or hardware issue.	Take out battery and restart the meter. If the problem continues, contact your local dealer.

	Not enough blood or control solution was applied.	Discard test strip and repeat the test with a new test strip.
	Test result is below 10 mg/dL (0.6 mmol/L).	Repeat the test using a new test strip. If your result still flashes LO, contact your health care professional as soon as possible.
	Test result is above 600 mg/dL (33.3 mmol/L).	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.
	The meter failed to sync with the Smartphone.	Turn on the meter, Smartphone's Bluetooth and the app, and try to pair again. If the problem continues, contact your local distributor.

Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association, some of the most common symptoms are:

Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- irritability
- seizure
- extreme hunger
- dizziness

High blood glucose (Hyperglycemia):

- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

Ketones (ketoacidosis):

- shortness of breath
- nausea or vomiting
- very dry mouth

CHAPTER 5: TECHNICAL INFORMATION

System Specifications：

Feature	Specification
Measurement range	10 to 600 mg/dL (0.6-33.3 mmol/L)
Result calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample volume:	About 0.5 μL
Test time	About 5 seconds
Power source	One (1) CR 2032 3.0 V coin cell battery
Battery life	12 months or approximately 1,000 tests
Glucose units of measure	The meter is pre-set to either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country
Memory	Up to 500 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	79 mm × 48 mm × 18 mm
Display size	30 mm × 31 mm
Weight	Approximately 39g (with battery installed)
Operating temperature	5-45°C
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%
Bluetooth	Version 4.1

Limitations

The VivaChek™ Eco BLE Blood Glucose Meter, Test Strips and Control Solution are been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.

- Fresh capillary blood may be collected into test tubes containing sodium heparin, lithium heparin if the blood is used within 10 minutes. Do not use sodium fluoride/oxalate or other anticoagulants or preservatives.
- Use only with whole blood. Do not use with serum or plasma samples.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your health care professional to find out your hematocrit level.
- Abnormally high levels of vitamin C and other reducing substances will produce false high blood glucose measurements.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 10 to 600 mg/dL (0.6-33.3 mmol/L).
- Fatty substances (triglycerides up to 3,000 mg/dL (166.7 mmol/L) or cholesterol up to 500 mg/dL (27.7 mmol/L)) have no major effect on blood glucose test results.
- The VivaChek™ Eco BLE Blood Glucose Monitoring System has been tested and shown to work properly up to 10,000ft (3,048 meters).
- Severely ill persons should not run the glucose test with the VivaChek™ Eco BLE Blood Glucose Monitoring System.
- Patient who is taking oxygen therapy is not recommended for testing with VivaChek™ Eco BLE Blood Glucose Monitoring System.
- Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with VivaChek™ Eco BLE Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of materials.

Index of Symbols

These symbols may appear on the packaging and in the instructions for the VivaChek™ Eco BLE Blood Glucose Monitoring System.

Symbols	Explanation
	Consult instructions for use
IVD	For *in vitro* diagnostic use only
	Manufacturer
	Temperature limitations
	Contains sufficient for <n> tests
	Use by
LOT	Lot Number
EC REP	Authorized Representative
STERILE R	Sterilized using irradiation
CTRL	Control range
REF	Catalog number
Model	Model number
SN	Serial Number
	Do not re-use
	Caution, consult accompanying documents

	Dispose items according to local relevant laws regarding disposal and recycle
	Keep away from sunlight and heat
	Use by 6 months from the opening

Warranty

Please complete the warranty card that came with this product and mail it to your dealer to register your purchase.

If the meter fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new meter free of charge. For your records, also write the purchase date of your product here.

Date of purchase: _____

***Note*:**

This warranty applies only to the meter in the original purchase, and does not apply to the battery supplied with the meter.

Warranty Card

Please complete this warranty card to validate your warranty. Mail it within 30 days of purchase to the local dealer address labeled on the Starter Kit box to process the validation.

If the meter does not work for any reason other than obvious abuse in the first 5 years after purchase, we will replace it with a new or equivalent meter free of charge.

Date of purchase _____/_____/_____

Meter serial number（e.g.101A0000001）

Where purchased

Date of birth _____/_____/_____Gender □M □F

Telephone number

Email address

Year/Age of Diabetes Diagnosis _____/_____

How many times a week do you test your blood glucose?

What type of diabetes you have:

□Type 1 □Type 2 □Pre-diabetes □ Gestational

Suggestion/Comments

VivaChek™
VivaChek Biotech (Hangzhou) Co.,Ltd.
www.vivachek.com

FCC Regulations

（15C）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.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

(15B)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.
- This device complies with FCC RF radiation exposure limits set forth for an uncontrolled enviroment.
- The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter and must be installed to provide a separation distance of at least 20cm from all persons