

VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System

User Manual



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VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System

Dear User,

Thank you for choosing the VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System. This system is designed for easy tests of blood glucose and β -ketone and helps you keep blood glucose and β -ketone under control.

Read this User Manual carefully before using your system. This manual will help you to get comfortable using this system and get reliable test results. Please keep your User Manual in a safe place. You may want to refer it in the future.

Once you firstly receive the meter, it is recommended to download the VivaChek GK Indexer App from App Store or Google Play Store on your cell phone and to create app user account and register the meter with serial number. The risks associated with not creating your account and registering your meter may include unauthorized registration and historical testing results viewing by malicious individual using your meter serial number. Therefore, one method to safely secure access to your testing results would be to create your user account and register your meter once you receive the meter to prevent potential unauthorized access and protect your testing results.

The VivaChek GK Indexer App is a feature of the system. This app is designed such that the meter serial number only be used in one account. After creating your account and registering your meter, you can view your historical glucose and β -ketone results on the app. Use of the app to view the historical glucose and β -ketone results from your meter is solely at your discretion.

Intended Use

VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System is comprised of VivaChek Blood Glucose and β -Ketone Dual BLE Meter and VivaChek Blood Glucose and β -Ketone Dual Test Strips. The VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System is intended to quantitatively measure the glucose concentration and β -ketone (β -hydroxybutyrate) concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use) and should only be used by a single person and should not be shared.

Principle of Operation

VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System is designed to quantitatively measure the glucose concentration and β -ketone (β -hydroxybutyrate) concentration in fresh capillary whole blood from the fingertips. The glucose measurement and β -ketone measurement are achieved by using the amperometric detection method. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose dehydrogenase and the mediator. β -ketone (β -hydroxybutyrate) in the sample reacts with β -hydroxybutyrate dehydrogenase and the mediator. Electrons are

generated, producing currents that are positive correlation to the glucose concentration and to the β -ketone concentration in the sample respectively. After the reaction time, the glucose concentration value and β -ketone concentration value are reported in plasma equivalents and are displayed on meter screen.

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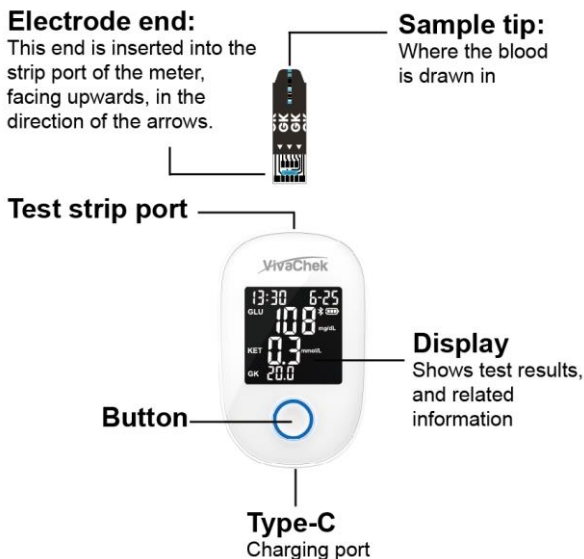
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CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

Your System Overview

1. The VivaChek Blood Glucose and β -Ketone Dual BLE Meter



2. VivaChek Blood Glucose and β -Ketone Dual Test Strips

- ① Sample Tip
Where the blood is drawn in.
- ② Electrode End
This end is inserted into the test strip port of meter.

3. VivaChek Lancing Device & Lancets



VivaChek Lancing Device



VivaChek Lancets

4. VivaChek Glucose and β -Ketone Dual Control Solutions



Control Solutions

SN	Proprietary Name	Common Name	Included in the Kit Box?
1	VivaChek Blood Glucose and β -Ketone Dual BLE Meter	Blood Glucose and β -ketone Dual BLE Meter	Yes
2	Type C USB Cable	USB Cable	Yes
3	VivaChek Blood Glucose and β -Ketone Dual Test Strips	Blood Glucose and β -Ketone Dual Test Strips	Yes
4	VivaChek Lancing Device	Lancing Device	Yes
5	VivaChek Lancets	Lancet for single patient use only	Yes
6	VivaChek Glucose and β -Ketone Dual Control Solution	Control Solution	No and should be purchased separately

Notes: Only charge the meter with the provided cable to avoid the potential risk of fire. VivaChek Glucose and β -Ketone Dual Control Solution is not included in the kit box, but is necessary for use. Please contact 24/7 Customer Support at 888-860-3894 for purchase.

Your Meter Display

The picture below shows all the symbols that may be displayed on your meter. Please make sure the display works properly before testing. When the meter is off, press and hold button to see the complete display. All display segments will appear. If you need more time to check the display, repeat the above operation. All display segments should be clear and exactly like the picture below. If not, contact 24/7 Customer Support 888-860-3894 for help.



Icon	What it Means
00:00	Top left area on the screen indicates the time.
AM PM	The top middle area on the screen indicates morning or afternoon time.
10-00	Top right area on the screen indicates the date.
GLU	It represents blood glucose.
KET	It represents blood β -ketone.
Hypo	Indicates that low glucose test result may cause hypoglycemia.
Bluetooth icon	When the icon flashes, it indicates it's trying to connect. Solid icon means successful Bluetooth communication.
Battery icon	Indicates the battery level.
mg/dL	Blood glucose measurement unit.
mmol/L	Blood β -ketone measurement unit.
GLU 000	Indicates glucose testing result.
KET 0.0	Indicates β -ketone testing result.

GK	Glucose testing result divides β -ketone testing result using the unit mmol/L.
	Control testing result.
M	Indicates memory (historical testing results in the memory).
	The testing result was transmitted successfully.
	The testing result was not transmitted.
	When the test strip is inserted, an icon of drop of blood will flash, and it indicates the system is ready to test.

Meter Use and Precautions

- The meter displays glucose concentration in milligrams per deciliter only. The meter displays β -ketone concentration in millimoles per liter only.
- Meter will enter into sleep mode after 2 minutes of no operation.
- Refer to the section Cleaning and Disinfection to keep the entire meter clean.
- Keep your meter in 45-113°F and 10-90% relative humidity.
- Do not leave the meter in your car.
- Do not drop the meter or get it wet. If you drop the meter or get it wet, check the meter by running a quality control test. Refer to Testing with Control Solution for instructions.
- Do not use the meter if it drops into liquids or splashes water into it.
- You should use the meter as described in the user manual, and any use of the meter beyond the scope of instructions may impair normal operation of the meter and battery.
- Do not transfer the test strips to a new vial or any other container.
- Do not drop blood on the test strip. The blood is pulled into the tip of the test strip through capillary action.
- Check the expiration date and discard date on your test strips vial label and control solution vial label.
- Use only VivaChek Blood Glucose and β -Ketone Dual Test Strip with your VivaChek Blood Glucose and β -Ketone Dual BLE Meter.
- Use only VivaChek Glucose and β -Ketone Dual Control Solution with your VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System.
- Keep the meter and all associated parts out of reach of children.
- Wash and dry your hands well before and after testing.

Important Safety Information

- The meter and lancing device are for single patient use. Do not share them with anyone, including other family members. Do not use it on multiple patients.
- All parts of the kit are considered biohazardous, and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Do not alter your blood glucose and β -ketone management or treatment without first consulting your healthcare professional.
- Refer to the Cleaning and Disinfection section for details on cleaning and disinfecting the meter.
- Follow proper precautions and local regulations when disposing of the meter.
- For more safety information, please refer to the table below:

Name of Safety Information Reference	Link
Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication	https://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
Considerations for Blood Glucose Monitoring and Insulin Administration	https://www.cdc.gov/injection-safety/hcp/infection-control/?CDC_AAref_Val=https://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Limitations

- Do not test your blood glucose during or soon after a xylose absorption test. Xylose in the blood can give inaccurate results with this meter.
- Not for neonatal use.
- Not for screening or diagnosis of diabetes mellitus.
- Not for Alternative Site Testing (AST).
- Do not use the system above 10413 ft (3174 meters) in altitude.
- This meter is not intended for use in healthcare or assisted-use settings, such as hospitals, physician offices, or long-term care facilities. It has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus, Hepatitis C Virus, Hepatitis B Virus, or other bloodborne pathogens.
- Not for use on the specific patients listed in table below:

Critically ill patients
Patients in shock
Patients in a hyperglycemic- hyperosmolar state with or without ketosis
Patients with severe dehydration
Patients with severe hypotension

CHAPTER 2: SETTING YOUR SYSTEM

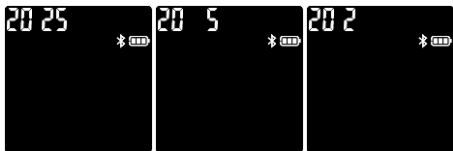
Before using your meter for the first time, you should check and update your meter settings.

Set the Date and Time

1. Enter the setting mode and set the date

When the meter is in sleep mode, long press the button for 2 seconds at least, the meter will beep, then all display segments will appear on the meter.

The numbers of year will now flash. Press the button to adjust it then press and hold the button until the meter beeps, then it will shift to the next digit for setting. Repeat the above actions until the year's setting is completed.



The numbers of month will flash. Press the button to adjust the month, press and hold until the meter beeps, then it will shift to the next digit for setting. Repeat the above operation until the month setting is completed.

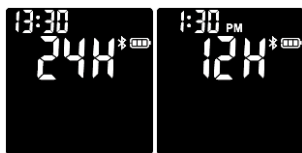


The numbers of date will flash. Press the button to adjust the date, press and hold the button until the meter beeps, then it will shift to the next digit for setting. Repeat the above action until the date setting is completed.



2. Set the time format

12h or 24h time format: you have two options for the time format 12h or 24h. Press button to adjust it then press and hold the button to save your set-up.



3. Set the time

The numbers of hour will flash. Press the button to adjust the current hour, press and hold the button complete the set-up, then it will shift to the next digit for setting. Repeat the above action until the hour setting is completed.



The numbers of minute will flash. Press the button to adjust the minute, press and hold the button to complete the set-up, then it will shift to the next digit for setting. Repeat the above action until the minute setting is completed.



Note:

Before your first use of the meter 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.

Set the Audio Feature

After setting the time, the word "beep" will now flash. Press the button to select "On" or "OFF". Press and hold the button to set.



Set the Hypoglycemia (Hypo) Warning

After setting the audio feature, you can set the hypo alarm, which indicates that low glucose test result may cause hypoglycemia.

The icon "Hypo" flashes on the meter screen along with an "On". Press the button to turn the Hypo alarm function on or off, then press and hold the button to set. If you select the hypo alarm to be "on", then the screen shows 70 mg/dL with the symbol of "GLU", press the button again.



Notes: Talk to your healthcare professional to help you decide the hypo level that suits your health condition.

Now you have completed your meter set-up. Press the button, and a symbol of a test strip appears, which lets you know the meter is ready to test.



Once all the settings are completed, if you want to change the setting, please press and hold the button for 3 seconds when the meter is powered off and then enter to the setting mode.

Create User Account Using Your Meter on App

Your cell phone should be a smartphone which can download the app from your App Store or Google Play Store.

The distance between your meter and cell phone for connection should be within five (5) meters.

Make sure that the symbol "⌘" is displayed on meter screen, and the Bluetooth in your cell phone is turned on.

Download the VivaChek GK Indexer App from the App Store for iPhone or Google Play Store for Android phones.

Recommend creating a user account and registering your meter with serial number on the app once you receive the meter.

You can view the historical testing results on the app as well if you have performed tests on meter and connected with the meter.

Please follow detailed instructions in VivaChek GK Indexer App Operation Guide regarding creating user account and connecting with meter.

Note: *The VivaChek GK Indexer App should be run on cell phone with Android version 12.0 or higher, or iOS version 15.6 or higher.*

Using Your Meter without the App

The meter can be used without running the app. You can still test your blood glucose and β -ketone and view your results on the meter screen.

Your meter automatically stores up to 300 testing results with the time and date.

Testing results are stored from the newest to the oldest. If there are already 300 records in memory, the oldest record will be erased to make room for a new one.

CHAPTER 3: PERFORMING A TEST

Set your meter correctly and have all materials you will need ready before testing. This includes your VivaChek Blood Glucose and β -Ketone Dual BLE Meter, VivaChek Blood Glucose and β -Ketone Dual Test Strips, VivaChek Lancing Device and VivaChek Lancets.

Preparing Test Strips

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial. 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. The meter turns on automatically.



4. A symbol of a test strip and a blood drop will appear on meter screen. This lets you know the meter is ready for testing.



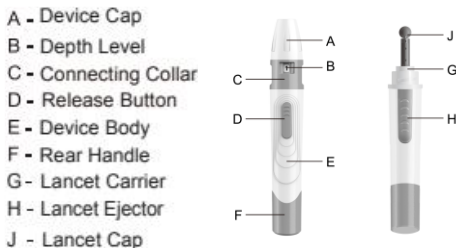
Note:

Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month-Day format. 2025-02-01 means February 01, 2025. Your 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, clean the test site with an alcohol swab or soapy water. Use warm water to 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.

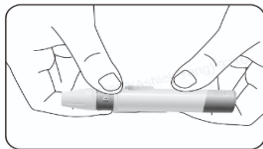
Preparing Lancing Device

The lancing instructions in this user manual are for reference. You should follow the labeling provided by the lancing device for complete instructions. The main structure of lancing device is shown as below.



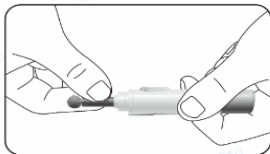
For fingertip sampling, adjust the depth penetration to reduce the discomfort. You do not need a clear cap for fingertip sampling.

1. Remove the device cap together with connecting collar.

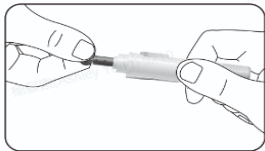


Note: The **VivaChek** lancing device uses **ONLY VivaChek** sterile lancets.

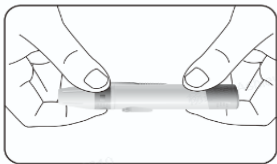
2. Insert the lancet into the lancet carrier and push down firmly until it is fully inserted.



3. Twist off the lancet cap and save it for lancet disposal.



4. Put the lancing device cap and the connecting collar back on the device and make sure they are fully seated.



5. Adjust to the proper level, usually mid-level (e.g., level 2, 3, 4 as shown below).



Adjustment:

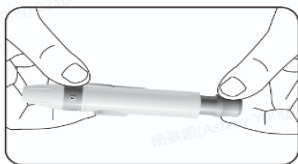
1 for delicate skin

2 and 3 for normal skin

4 and 5 for calloused or thick skin

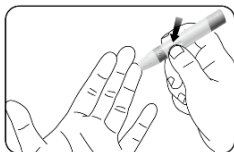
Note: Greater pressure of the lancing device against the puncture site will also increase the puncture depth.

6. Pull back the device's rear handle.

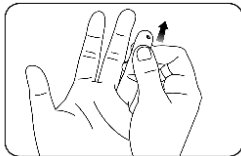
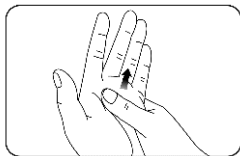


Getting a Blood Drop for Testing

1. Hold the lancing device firmly and vertically against the blood sampling site, then press the release button.



2. Remove the first drop of blood with a clean paper towel to ensure a more accurate result. 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 side of the fingertip. Test immediately after a good blood drop has formed.



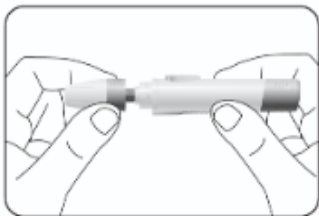
3. Immediately touch the tip of test strip to the drop of blood. The blood is drawn into the test strip through the tip. Make sure that the blood sample has been fully filled in sample channel on the strip tip. Hold the tip of test strip in blood drop until the meter beeps.



Note:

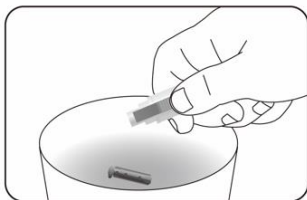
If the blood sample does not fill the sample channel, please do not add a second drop. Discard the test strip and start over with a new test strip.

4. The meter counts down 12 seconds and your testing results and GK value appear on the screen after a beep. The test results will be automatically stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.
5. Remove the device cap and the connecting collar, and stick the lancet tip into the lancet cap.



Discarding the Used Test Strip

Push the lancet ejector and discard the used lancet in an appropriate container.

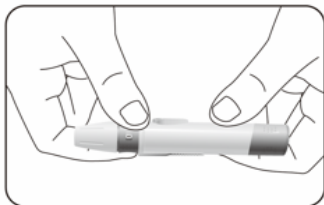


**Potential Biohazard**

Dispose of the used test strips as potential medical waste.

Removing the Used Lancet

Put the device cap and connecting collar back on the lancing device.



Please wash hands thoroughly with soap and water after handling the meter, lancing device, and test strip.

**Potential Biohazard**

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

**Caution:**

- Refer to the VivaChek lancing device labeling for additional instructions.
- Check and do not use the VivaChek lancet if the safety tab is missing or loose when you take the lancet out from the package.
- Do not use the contaminated or dropped VivaChek lancet that safety tab has been removed or damaged.
- Be cautious when the VivaChek lancet needle is exposed.
- Do not reuse VivaChek lancet. Do not share VivaChek lancet with anyone including family members.

Questionable or Inconsistent Results:**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 and β -ketone. 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

Warning:

If you are experiencing any of these symptoms, test your blood glucose and β -ketone. If your test result is under 50 mg/dL or above 250 mg/dL, contact your healthcare professional immediately.

If your blood glucose or β -ketone 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 45-113°F (7-45°C).*
- *Make sure that the test strip vial has been tightly capped.*
- *Make sure test strips are stored in 36-86°F, 10-90% relative humidity.*
- *Make sure test strip is used immediately after taking it from test strip vial.*
- *Make sure that you have followed the test procedure correctly.*
- *Perform a control solution test (See **Testing with Control Solution** for instructions).*
- *Perform a control solution test to verify whether the system works properly.*
- *After checking all the conditions listed above, repeat the test with a new test strip. Please contact 24/7 Customer Support at 888-860-3894 for technical support or questions.*
- *If the test result does not match how you feel, please do not change your medication or food regimen before contacting your healthcare professional.*

Precision and Accuracy

Linearity Results for Glucose:

Lot	Linearity	R ²
Lot 1		
Lot 2		
Lot 3		

Combined Lots		
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Linearity Results for β -Ketone:

Lot	Linearity	R ²
Lot 1		
Lot 2		
Lot 3		
Combined Lots		

The results support the claimed measurement range 20~600 mg/dL for glucose and 0.1~8.0 mmol/L for β -ketone.

Within-Run Precision and Intermediate Precision

VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System was tested for within-run precision and intermediate precision. See tables below for results.

Within-Run Precision:

Within-Run Precision - Whole Blood			
Interval	Glucose Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1			
2			
3			
4			
5			

Within-Run Precision - Whole Blood			
Interval	β -Ketone Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1			
2			
3			
4			
5			

Intermediate Precision:

Intermediate Precision - Control Solution			
Interval	Glucose Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1			
2			
3			
4			
5			

Intermediate Precision - Control Solution			
Interval	β -Ketone Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1			
2			
3			
4			
5			

User Evaluation:

The VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System was tested by 351 lay users using capillary blood samples. The results were compared to the YSI 2900C Biochemistry Analyzer and Randox RX Imola Chemistry Analyzer. See the tables below with accuracy results. It shows the System achieved 99.8% of results within $\pm 15\%$ of the laboratory instrument. The results shown here are intended to inform you about your meter, how much results are consistent from your actual blood glucose and β -ketone values.

Table 1 - Linear Regression Results for Glucose

Slope	XX mg/dL
Intercept	
Correlation Coefficient (R)	
Number of Samples	

Table 2 - Linear Regression Results for β -Ketone

Slope	XX mmol/L
Intercept	
Correlation Coefficient (R)	
Number of Samples	

Table 3 - Consumers Glucose Accuracy Results

Accuracy for Home Use by Lay-Users VivaChek Blood Glucose and β-Ketone Dual BLE Meter results may vary slightly from your actual blood glucose values. This may be due to slight differences in technique and the natural variation in test technology. The chart below shows the results of a study where 351 typical users used meters to test their blood glucose level. In this study, the meters gave results within $\pm XX\%$ of their true blood glucose level XXX out of XXX times.				
Difference range between the true blood glucose level and meter results.	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
The percentage (and number) of meter results that matches true blood glucose level within x%.	XX% (XX/XX)	XX% (XX/XX)	XX% (XX/XX)	XX% (XX/XX)

Table 4- Consumers β -Ketone Accuracy Results

Accuracy for Home Use by Lay-Users VivaChek Blood Glucose and β-Ketone Dual BLE Meter result may vary slightly from your actual β-ketone value. This may be due to slight differences in technique and the natural variation in test technology. The chart below shows the results of a study where 351 typical users used meters to test their β-ketone level. In this study, the meters gave results within $\pm XX\%$ of their true blood β-ketone level XXX out of XXX times.				
Difference range between the true β -ketone levels and meter results.	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
The percentage (and number) of meter results that matches true blood β -ketone levels within x%.	XX% (XX/XX)	XX% (XX/XX)	XX% (XX/XX)	XX% (XX/XX)

Comparing Meter and Laboratory Results

Before you go to the lab:

- Perform a control test to make sure the meter is working properly.
- If your healthcare professional requested you go fasting, then this would be a good time to do this comparison.
- Bring your meter and test strips.

While you stay at the lab:

- Wash your hands before obtaining a blood sample.
- Obtain and test the blood samples immediately.
- Follow User Manual for performing blood glucose and β -ketone tests.

Note: Users should periodically review their technique. For example, compare a result obtained with the meter against a laboratory method. Or a well-maintained and monitored system used by your healthcare professional.

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:

- Once a week.
- When using or when opening a new vial of test strips.
- When you suspect that meter and test strips are not working together properly.
- After cleaning and disinfecting your meter.
- You dropped the meter.
- Perform a quality control test if you suspect your results are inaccurate or do not match how you feel.

About the Control Solutions

- Only use VivaChek Glucose and β -Ketone Dual Control Solutions (1, 2 or 3) on the system.
- Your meter can recognize the control solution.
- Control solution results are not included in the calculation of average values in the meter.
- Store the control solution within 36-86°F, 10-90% relative humidity.
- All expiration dates are printed in a Year-Month-Day format. 2025-02-01 means February 01, 2025.
- Do not use control solution that is out of the expiration date or discard date. The control solution will expire 6 months after the vial is opened for the first time.
- Shake the vial well before use.
- Close the vial tightly after use.

Performing a Control Test

1. Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have taken out the test strip.

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

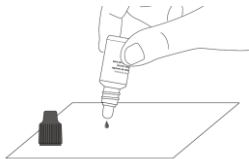
2. Insert a test strip into the meter in the direction of the arrows.



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 non-absorbent surface.



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

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



Note: If the control solution sample does not fill the sample channel, 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 you see the meter beeps, and then you can see the meter count down on the screen, followed by your control test results.



7. Please wash hands thoroughly with soap and water after handling the meter, test strip and control solution.

Understanding Control Test Results

Compare your control test result with the ranges printed on the test strip box or label.

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 test strip vial and control solution vial have 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 59-104°F.
- Make sure you store test strips and control solution at 36-86°F and 10-90% relative humidity.
- Make sure that test strip vial and control solution vial have been tightly capped.
- Make sure the test strip is used immediately after removing it from test strip vial.
- Make sure the control solution was mixed well.
- Confirm that you use VivaChek brand glucose and β -ketone dual control

solution.

- *Make sure that you followed the test procedure correctly.*

After checking all 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, your meter or test strips may not work properly. DO NOT use the system to test blood. Contact 24/7 Customer Support at 888-860-3894. Please contact your healthcare professional if you need 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.

Using Meter Memory

View your historical glucose and β -ketone testing results in your meter. Your blood glucose and β -ketone dual BLE meter can store at most 300 testing results. Test results are stored from the newest to the oldest.

Notes:

- *If there are already 300 records in memory, the oldest record will be erased to make room for a new one.*
- *It is important to set the correct time and date in the meter, please make sure the time and date are correct.*
- *Control solution results are included in the memory.*

Viewing Your Test Results

When the meter is in sleep mode, press the button to turn the meter on. After a beep, a symbol of a test strip flashes on the display. Continue to press the button to review previous results in order. Results will be shown starting with the most recent. Each result will show the date and time the test was taken. When END appears on the display, you have viewed all the results in the memory.



CHAPTER 4: MAINTENANCE AND TROUBLESHOOTING

Requirements for Charging Battery:

The meter battery shall be charged using one of the following options:

- Connect the supplied USB cable with computer USB-A port when the computer is turned on and not in standby mode.
- Connect the supplied USB cable with an AC adapter for wall charging.
- AC adapter is not supplied with the meter. It is important to purchase and use an AC adapter with USB-A port and that meets the following specifications: Input: 100-240V~, 50/60Hz, 0.2A (200mA) Max. Output: 5.0V  , 1.0A (1000mA).

Use only "the supplied USB cable" and "the specified AC adapter" for charging battery. Otherwise, overheating, smoking, or catching fire of meter battery may occur.

Warnings for Charging Battery:

- *Do not disassemble the meter and take battery out for charging.*
- *Do not use the USB cable, AC adapter or meter if it is damaged, discolored or deformed.*
- *Do not insert a test strip when charging. The meter is designed that blood glucose testing can't be performed during meter charging.*
- *Do not put the meter on the thermally insulating materials such as clothing, carpet, blanket, or plastic surface for charging. Otherwise, this may potentially pose a risk of overheating, smoking or catching fire.*
- *Do not recharge the meter outdoors, sunlight, a wet area or a heating area. Otherwise, this may potentially pose a risk of overheating, smoking, catching fire or impairing normal operation of the meter.*
- *Do not charge the meter in environmental temperature above 104°F. The meter can be safely recharged at normal indoor temperatures.*
- *Do not allow unsupervised children to charge the meter battery.*

Recommended Procedures for Charging Battery:

Step 1): Select a charging method from the options below:

Option A: Using the supplied USB cable and connecting to computer. The computer should be turned on during charging.

Option B: Using the supplied USB cable and connecting the AC adapter. The AC adapter should meet the specifications in the section "Requirements for Charging Battery" in the user manual to prevent potential overcharging.

Step 2): Check and ensure the contents in the section "Recommendations for Charging Battery" are followed.

Step 3): Check and ensure that the applicable contents in the section "Warnings for Charging Battery" are followed.

Step 4): Check that the meter displays the battery icon and repeats the charging status from  through , , .

Step 5): Check whether the meter displays battery icon . This means that the battery is fully charged. If not, please continue to charge.

Step 6): Recommend charging the meter for not more than three hours.

Step 7): Remove the USB cable from the meter after charging.

Step 8): Your meter is now ready to use.



Warning:

Please note that the battery is not removable. If the battery requires sorting and discarding due to scrap of the product, please keep it away from children. A lithium battery is poisonous. If swallowed, immediately contact your doctor or poison control center. Discard battery according to your local environmental regulations.

Caring for Your Glucose and β -Ketone Dual BLE Monitoring System

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water and other contaminants.
- The meter is a precision electronic instrument. Please handle it with care.
- Avoid exposing meter, test strips and control solution to excessive humidity, heat, cold, dust, or dirt. The operating conditions for meter and test strips are 45-113°F, relative humidity 10-90%. The operating conditions for control solution are 59-104°F, relative humidity 10-90%. Avoid heat and direct sunlight.

Cleaning and Disinfection

The purpose of cleaning step is to remove the potential dirt and dust particles and make a clean surface for the next disinfection step. The purpose of disinfection step is to kill the microorganism on whole surface of meter.

Use only Clorox™ Healthcare Bleach Germicidal Wipes. It has been proven to be safe to use with the meter. The wipes are available by visiting and purchasing at <http://www.walmart.com>, <http://www.staples.com/>, or <https://www.amazon.com/>. The meter should be cleaned and disinfected at a minimum of once per week. The process has been validated for 608 cycles, which is equivalent cleaning and disinfecting your meter every 3 days for 5 years. This is to ensure that your meter will operate properly over the 5-year life.

Warning: If the meter is being operated by a second person who is providing testing assistance to you, the meter should be cleaned and disinfected prior to use by the second person.

Notes:

- Do not use alcohol or any other solvent. These have not been proved to be safe and effective for use with the meter.
- Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the type-C USB port.
- Do not squeeze the wipe or gauze into test strip port.
- Do not spray the cleaning solution on the meter.
- Do not immerse the meter in any liquid.
- Please refer to the safety instruction in the labeling of Clorox™ Healthcare Bleach Germicidal Wipes before using wipes.

Cleaning Your Meter

Step 1: Take one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) from the container.

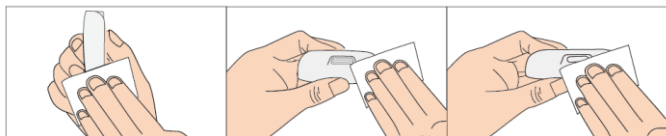
Step 2: Clean the entire surface of the meter. It includes the front, back, left, right, top and bottom sides of the meter, test strip port, button, material seams and USB port for one minute. This cleaning is to prepare a clean surface for a disinfection process.



Front side

Back side

Right side



Left side

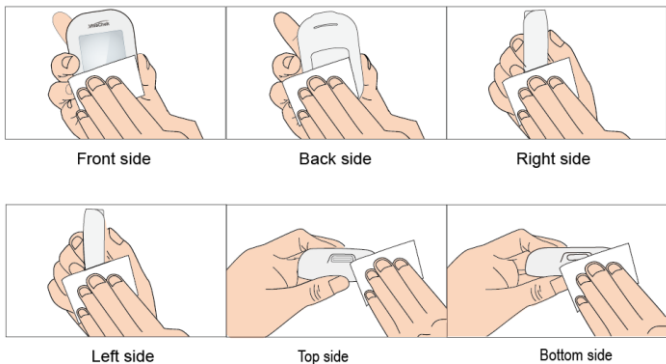
Top side

Bottom side

Disinfecting Your Meter

Step 1: After cleaning your meter, take out another new piece of Clorox™ Healthcare Bleach Germicidal Wipes.

Step 2: Wipe the entire surface of the meter. The parts of meter that are particularly susceptible to blood contamination should be wiped. These include the front housing, buttons, test strip port, display screen, material seams and charging port. Keep the meter wet for one minute.



Step 3: Please do not touch the meter. And wait for one minute at least to make the meter's surface to be dry after performing the step 2 above.

Step 4: Please wash hands thoroughly with soap and water after completing the disinfection procedure.

Notes:

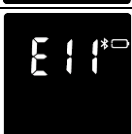
Although it has not been observed, some alterations may appear on your meter due to the cleaning and disinfection procedure. Such as cloudy display window, plastic housing cracking, meter's button does not function, partial display on screen, unable to execute the meter's initial set up.

If you notice any of these, please stop using the meter and contact 24/7 Customer Support at 888-860-3894 for help.

If you have questions about cleaning or disinfection, contact 24/7 Customer Support at 888-860-3894.

Troubleshooting Guide

What You See	What It Means	What You Should Do
	Add blood sample or control solution before the flashing of a blood drop appears.	Discard the test strip and repeat the test with a new test strip. Add blood sample or control solution after you see the flashing of a blood drop on the screen.
	The meter is sensing the use of 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 of a blood drop on the screen 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 Blood Glucose and β -Ketone Dual Test Strips.
	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a blood sample or VivaChek Glucose and β -Ketone Dual Control Solution.
	Temperature is out of range.	Move to an area that is within the operating temperature for the meter. Let the meter adjust to this temperature for 30 minutes before performing a test.
 	Potential hardware issue.	Restart the meter. If the problem continues, contact your local distributor.

	A test strip was inserted while the meter was connected to a computer or wall outlet for recharging.	When the recharging is completed (generally it requires about 2 hours y), remove the Type-C USB cable from the meter, and then take a test.
	Insufficient sample.	Repeat test and apply enough sample to fill check window of the test strip.
	Low battery indicator	Charge immediately and check year/date/time settings.
	Blood glucose test result is above 600 mg/dL, and blood β-ketone test result is above 8.0 mmol/L.	Wash and dry your hands, then repeat the test using a new test strip. If your result still shows HI, contact your healthcare professional as soon as possible.
	Blood glucose test result is below 20 mg/dL, and blood β-ketone test result is below 0.1 mmol/L.	Wash and dry your hands, then repeat the test using a new test strip. If your result still shows LO, contact your healthcare professional as soon as possible.

Expected Glucose Range for People without Diabetes:

Time	Normal Plasma Glucose Range for Adults without Diabetes (mg/dL)
Before Breakfast (Fasting)	< 100
2 Hours after a Meal	< 140

Reference: American Diabetes Association. Standards of Care in Diabetes - 2023 Abridged for Primary Care Providers. Clin Diabetes 2 January 2023; 41 (1): 4–31.

Note: Please work with your healthcare professional to determine a glucose target range that works best for you.

CHAPTER 5: TECHNICAL INFORMATION

System Specifications:

Feature	Specification
Measurement Range	Blood glucose: 20-600 mg/dL Blood β -ketone: 0.1-8.0 mmol/L
Measurement Result	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample Volume:	1.6 μ L
Test Time	Blood glucose: 5 seconds Blood β -ketone: 7seconds
Power Source	Rechargeable, 3.7 Volt Lithium Ion battery
Charging Current	100mAh,  Direct current
Battery Type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Units of Measurement	Blood glucose: mg/dL Blood β -ketone: mmol/L
Memory	300 records with date and time
Automatic Shutoff	2 minutes after last action
Dimensions	83 mm $\times$ 52 mm $\times$ 18.7 mm
Display Size	32 mm $\times$ 32 mm
Weight	Approximately 50 g
Operating Temperature	45°F - 113°F (7°C - 45°C)
Operating Relative Humidity	10 - 90% (non-condensing)
Hematocrit Range	20 - 65%
Charging Port	USB Type-C
Bluetooth	Bluetooth Low Energy (BLE)

BLE Specifications (This is a draft only)

Item Name	Design Specification
Transmit Frequencies	2400~2484 MHz.
Data Integrity	Data shall be transmitted correctly and completely.
Precision Location	AoA/AoD enables indoor navigation, AR applications, and real-time asset tracking.
Efficiency	GATT caching reduces connection time and saving power
Scalability	Sync transfer supports dense IoT deployments

A List for Interface regarding Glucose and β -Ketone Testing Results:

Interface Name	Functionality	Incoming, Outgoing, or Both	Destination End-point
Application Programming Interface	Request glucose and β -ketone testing results from meter	Incoming	Meter (The API is sent to meter from app)

Warranty

Please complete the warranty card that comes with this product and mail it to:

VivaChek Biotech (Hangzhou) Co., Ltd.
No.17 Wuzhou Road,
Donghu Street, Linping District,
Hangzhou, 311100, Zhejiang, China.

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, write the purchase date of your product here.

Date of purchase: _____

Note: This warranty applies only to the meter in the original purchase. It does not apply to the battery supplied with the meter.

Electromagnetic Compatibility Instructions (The content below is draft only):

The device is intended for home use. Classified as CISPR 11 Group 1, Class B.

Use of accessories, transducer, and cable other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and may result in improper operation.

Portable RF communications equipment such as antenna should be used no closer than 30 cm (12 inches) to any part of this device.

Although the device is intended for home use only, we still remind that please do not expose your device to unique medical emitters such as electrocautery, MRI, electrosurgical units, diathermy devices.

Please try to increase distance between the device and source of the interference if it is suspected that function or performance may be affected by electromagnetic interference.

Please follow all instructions in the user manual for maintaining the device's basic safety and essential performance regarding electromagnetic disturbances. You can contact the distributor for technical support using the contact information listed in the user manual or outer box.

It is recommended that the user should not use the device and then check above items if the functions or performance of the device may be lost or degraded due to electromagnetic disturbances.

FCC Requirement

Test Frequency:

Test Mode	Nominal Bandwidth (MHz)	RF Channel		
		Low (L)	Middle (M)	High (H)
		MHz	MHz	MHz

This meter has been tested and found to comply with the standards below:

47 CFR Part 15, Subpart B

47 CFR Part 15, Subpart C 15.247

FCC Rules 47 CFR §2.1093

KDB 447498 D04 interim General RF Exposure Guidance v01

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.