

# VivaChek

Blood Glucose and  $\beta$ -Ketone Monitoring System

## User's Manual



**VivaChek**<sup>™</sup>

VivaChek Biotech (Hangzhou) Co., Ltd.  
1/2/3 F, Building 1, 16 East Zhenxing Rd.,  
Yuhang Economy Development Zone, Yuhang,  
Hangzhou, 311100, Zhejiang, China

[www.vivachek.com](http://www.vivachek.com)

©2019 VivaChek Laboratories, Inc.

Part Number: 1205091101  
Effective date: 2019-08

For Self-Testing



颜色：CMYK

VivaChek <sup>™</sup>			
<b>Description</b>	VivaChek GLU & KET User's manual Cover(En)	<b>Code No.</b>	1205091101
<b>Material</b>	200g双铜纸+水性上光/70g轻涂纸	<b>Size</b>	160x110mm
<b>Deigned by</b>	Celine	<b>Checked by</b>	
<b>Approved by</b>		<b>Effective Date</b>	



## Blood Glucose and $\beta$ -Ketone Monitoring System

Dear VivaChek™ System User,

Thank you for choosing the VivaChek™ Blood Glucose and  $\beta$ -Ketone Monitoring System! VivaChek™ Blood Glucose and  $\beta$ -Ketone Monitoring System is designed for easy test of blood glucose/ $\beta$ -ketone and helps you keep them under control.

Read this User's Manual carefully before you use your system. 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™ System.

### Intended Use and Principle

VivaChek™ Blood Glucose and  $\beta$ -Ketone Monitoring System is comprised of the VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter (VGM200), the VivaChek™ Blood Glucose Test Strips (VGS01) and the VivaChek™ Blood  $\beta$ -Ketone Test Strips (VKS01). Glucose measurement is based on electrochemical biosensor technology using the enzyme Glucose Dehydrogenase to catalyze the formation of gluconolactone from the oxidation of glucose whereby two electrons are produced. The electrical current resulting from this enzymatic reaction is proportional to the concentration of glucose in the sample and is measured by the meter. The meter is calibrated to display the equivalent of plasma glucose values. Using the same technology,  $\beta$ -ketone is converted by  $\beta$ -hydroxybutyrate dehydrogenase and the magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of  $\beta$ -hydroxybutyrate present in the sample.

The System is intended to quantitatively measure the glucose and  $\beta$ -ketone concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for self-testing outside the body (*in vitro* diagnostic use) by people 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 to be used by a single person and should not be shared.

The System is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings. Use of this system on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

## TABLE OF CONTENTS

<b>1. Understanding Your Testing Tools.....</b>	<b>1</b>
Your Meter System Overview.....	1
Your Meter Display.....	2
Important Safety Information.....	4
Limitations.....	5
<b>2. Setting Up Your System.....</b>	<b>6</b>
Set the Time and Date.....	6
Set the Audio Feature.....	8
Set the Test Alarm.....	8
Set the Meal Marker.....	9
Set the Hypoglycemia (Hypo) Alarm.....	9
Set the Ketone Warning.....	10
Pairing Your Meter with the Smart Phone.....	10
Using Your Meter without the App.....	11
<b>3. Taking a Test.....</b>	<b>12</b>
Preparing the Test Strip.....	12
Getting a Blood Drop and Testing.....	12
Discard the Used Test Strip.....	14
Expected Blood Glucose/ $\beta$ -Ketone Control Goal.....	14
Taking a GKI Testing.....	16
Questionable or Inconsistent Results.....	18
Testing with Control Solution.....	18
Using the Meter Memory.....	21
<b>4. Maintenance and Troubleshooting.....</b>	<b>23</b>
Replace the Battery.....	23
Caring for Your Monitoring System.....	24
Cleaning and Disinfection.....	24
Troubleshooting Guide.....	26
Symptoms of High/Low Blood Glucose and Ketoacidosis.....	27
<b>5. Technical Information.....</b>	<b>28</b>
System Specifications.....	28
Warranty.....	31

## CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

### Your Meter System Overview

The VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter and Test Strips










## Your Meter Display

The picture below shows all the symbols that appear on your meter display. Please make sure the display is working properly before testing. When the meter is off, press and hold **power 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 of the segments should be clear and exactly like the picture below. If not, contact VivaChek Customer Support at 888-969-6928 (7 days a week, 9 a.m.-5 p.m. Eastern Time) for help. Please contact your healthcare professional if you need help outside of these hours.



Icon	What it Means
88/88	The top left area on the screen indicates the date.
88:88	The top right area on the screen indicates the time.
AM PM	The top middle area on the screen indicates morning or afternoon time.
d/m/d	Indicates the display form of date and month have been set.
*	Indicates success Bluetooth communication.
⊗	Indicates failure Bluetooth communication.
🕒	Indicates the alarms have been set.

<b>GLU</b>	Blood glucose test mode.
<b>KET</b>	Blood $\beta$ -ketone test mode.
<b>GKI</b>	Glucose ketone index (GKI) test mode.
	Indicates a low battery or it needs to be replaced.
<b>A</b>	Indicates average value.
<b>MEM</b>	Indicates test result history.
	Center area on the display that shows test results or error codes.
	Indicates the system is ready to test.
	Control test result.
	Pre-meal marker.
	Post-meal marker.
<b>mg/dL mmol/L</b>	Blood glucose test results are displayed as mg/dL and blood $\beta$ -ketone test results are displayed as mmol/L.
	Indicates the temperature is not suitable for testing.
<b>Ketone?</b>	Ketone warning.
<b>Hypo</b>	Indicates that a low test result may cause hypoglycaemia.

**Notes:**

Your VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter is pre-set with beep sound function, the meter will beep when:

- turn on the meter.
- set the date and time.
- set the test mode.
- 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.
- it is time to perform a test if you set the test alarms.
- if any error occurs during operation.

## Meter Use and Precautions

- The meter is preset to display blood glucose concentration in milligrams per deciliter (mg/dL) by default. And meter is preset to display blood  $\beta$ -ketone concentration in millimoles per liter (mmol/L) by default. The 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 extreme temperatures 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** for instructions.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to the **Caring for Your Meter** section 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.

## Important Safety Information

- The meter is single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- 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 safety 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 (or on the foil pouch) and control solution bottle label.
- Use only VivaChek™ Blood Glucose/ $\beta$ -Ketone Test Strip with your VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter.
- Use only VivaChek™ Blood Glucose/ $\beta$ -Ketone Control Solution with your VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter and VivaChek™ Blood Glucose/ $\beta$ -Ketone Test Strip.
- Please contact your physician or diabetes healthcare professional if you determine to make a change on your current medical therapy or diet activity based on test results.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.



### Potential Biohazard

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

**Note:**

1. The meter is for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
2. All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Please follow proper precautions when handling your meter.
3. For more information, please refer to the FDA Public Health Notification: “Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010) at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>. You may also refer to the CDC Clinical Reminder: “Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) at <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>.

**Limitations**

- For single-patient use only.
- The system is tested to accurately read the measurement of glucose in fresh capillary whole blood within the range of 20 to 600 mg/dL and  $\beta$ -ketone in fresh capillary whole blood within the range of 0.1 to 8.0 mmol/L.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results for blood glucose testing, and very high (above 65%) and very low (below 20%) hematocrit levels can cause false results for blood  $\beta$ -ketone testing. Talk to your healthcare professional to find out your hematocrit level.
- Patients undergoing oxygen therapy may cause false results.
- Severe dehydration (excessive water loss) may cause inaccurate results.
- Not for neonatal use.
- Not for use on patients with critical illness.
- Not for use in severely hypotensive individuals or on patients in shock or in a hyperosmolar state.
- Not for screening or diagnosis of diabetes.
- Do not use the system at altitudes above 13123ft (4000 meters) above sea level for blood glucose testing and 8700 ft (2651 meters) above sea level for blood  $\beta$ -ketone testing.
- Do not use when humidity is higher than 90% and lower than 10%, as extremes in humidity may affect results.
- For *in vitro* diagnosis use only.
- The system is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings.



## CHAPTER 2: SETTING UP YOUR SYSTEM

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

### Set the Date and Time

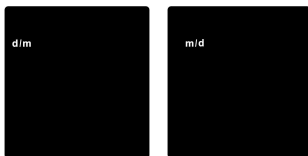
#### 1. Enter the setting mode and set the clock

When the meter is off, press and hold the **power button** for more than 2 seconds until the meter beeps to enter the set up mode. Press the **side button** to adjust the set of clock for 12 or 24 hour mode, then press the **power button** to save your choice. Start setting the display form of date.



#### 2. Set the date display form

The date icon will now flash, press the **side button** to adjust the set of date display form for d/m or m/d mode, then press the **power button** to save your choice. Start setting the date.



#### 3. Set the date

The year will now flash. Press the **side button** to adjust it and press **power button**. Then it will shift to next digit for setting. Repeat the above action until the year setting is completed, then press the **power button** until the meter beeps to set.



The month will now flash. Press the **side button** to adjust it and press **power button**. Then it will shift to next digit for setting. Repeat the above action until the month setting is completed, then press the **power button** until the meter beeps to set.



The date will now flash. Press the **side button** to adjust it and press **power button**. Then it will shift to next digit for setting. Repeat the above action until the date setting is completed, then press the **power button** until the meter beeps to set.

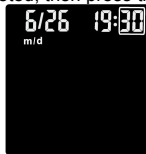


#### 4. Set the Time

The hour will now flash. Press **side button** to adjust the current hour and press **power button**. Then it will shift to next digit for setting. Repeat the above action until the hour setting is completed, then press the **power button** until the meter beeps to set.



The minute will now flash. Press **side button** to adjust the minute and press **power button**. Then it will shift to next digit for setting. Repeat the above action until the minute setting is completed, then press the **power button** to set.



**Note:**

*Before you first time use your meter system for testing, please adjust the meter settings to set the 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 date and time, press the **power button** until the meter beeps to set, the beep will now flash. Press the **side button** to set ON or OFF, press the **power button** to save the audio setting.

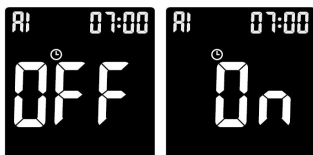



## Set the Test Alarm

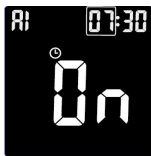
After the audio setting is completed, the meter will enter the test alarm setting mode, the reminder function reminds users to take a measurement. Your meter is pre-set with the test alarm function to "OFF", you can set up to 5 reminders per day. If you turn 5 test alarms on (A1, A2, A3, A4 and A5), your meter is pre-set with the following times for your convenience, you can adjust each time to suit your needs.

A1 7:00 A2 9:00 A3 14:00 A4 18:00 A5 22:00

Before you set the time, the  and the word "OFF" will be displayed, symbol "A1" flashes. Press **side button** to turn the alarm function on or off, and press **power button** to save.



If you select "On", the hour flashes, "A1" and the  remain on the display. Press **side button** to select the hour. Press **power button** to set.



The minute flashes, press **side button** to select 00, 15, 30, or 45. These are the only choices. Press **power button** to set minutes.



The next alarm "A2" flashes on the display with and "OFF".



You can either set a second alarm by press **side button** to turn on the second alarm. Do the same procedures to set the rest alarms.

**Note:** *If the meter is on at the test reminder time, the test alarm does not occur.*

### Set the Meal Marker

After setting the test alarm functions, the symbols of 🍎🍷 will now flash, along with word "On" on the display. Press **side button** to turn the meal marker function on or off, press power button to set.



### Set the Hypoglycemia (Hypo) Alarm

After setting the meal marker, you can set the hypo alarm, which indicates a possible hypoglycemic condition (blood glucose level is too low).

Before you set the hypo alarm, the **Hypo** flashes along with "On" on the display. Press **side button** to turn the Hypo alarm function on or off, press **power button** to set. If you select the hypo alarm "on", the display shows 70 mg/dL (as default). Press **power button** to set.

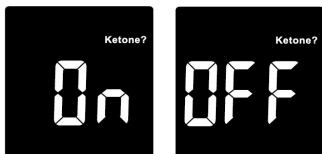


**Note:**

- Talk to your healthcare professional to help you decide the hypo level that suit for your situation.
- For healthcare professionals, the hypoglycemic level may vary from person to person. It is recommended to turn the hypo alarm function OFF when using the meter in a professional facility.

### Set the Ketone Warning

After the hypo alarm setting is completed, the **Ketone?** symbol will now flash, along with word “On” on the display. Press **side button** to turn the Ketone Warning on or off, press **power button** to set.



After setting Ketone Warning, the screen will show all symbols which you have set before. Press **power button** and the meter will turn off.



Once all the settings are completed, if you want to change the setting, please press and hold the **power button** when the VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter is off and then return to the setting mode.

### Pairing Your Meter with the Smart Phone

Pairing prepares your VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter and Smart Phone to communicate with each other. The distance between the meter and smart phone should be within 5 meters. Download the XXXXX App before pairing your

meter with smart phone.



**Note:** XXXXX App is compatible with Android 4.1 above, and iOS 8.0 above operating system.



## **WARNING**

**DO NOT** pair another person's meter with your Smart Phone.

To pair the Smart Phone with your meter, start with your meter on and follow these steps:

1. Turn on your meter.
2. Turn on Bluetooth® on your Smart Phone.
3. Open the APP on your Smart Phone.
4. Select searching my device on the APP.
5. Look for a meter named VivaChek.
6. Tap on the meter named VivaChek.
7. Enter your meter pass code using the keypad. The pass code is the last 5 digits from the Serial Number on the back of your meter.
8. Tap Pair
9. Wait for the Smart Phone status to say "√". Congratulations! Your meter and Smart Phone are now paired.
10. After pairing the meter with your Smart Phone, the Smart Phone will Sync date and time on your meter.
11. The "Syncing Data" will appear on the App with the symbol  to notify you that the meter is communicating with the app. Tap the symbol , and then the meter will send test results to the Smart Phone.
12. After syncing data between meter and the Smart Phone, the App will display all data of test result from meter.

## **Using Your Meter without the App**

The meter can be used without a Smart Phone or the App. You can still test your blood glucose/β-ketone and review your test results on the meter screen.

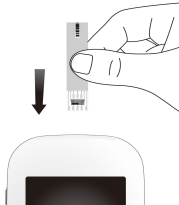
Your meter automatically stores up to 1000 results with the time and date. Test results are stored from the newest to the oldest. If there are already 1000 records in memory, the oldest record will be erased to make room for a new one.

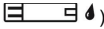
## CHAPTER 3: TAKING A TEST

Set up your meter correctly and have all the materials you will need ready before you begin testing. This including your VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter, VivaChek™ Blood Glucose Test Strips, VivaChek™ Blood  $\beta$ -Ketone Test Strips and VivaChek™ Safety Lancets.

### Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial (or the 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.



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

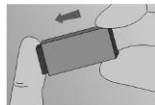
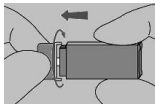
#### **Note:**

*Check the expiration and discard dates on the test strip vial (or the foil pouch). All expiration dates are printed in Year-Month format. 2021/01 indicates January, 2021. Make sure the test strip does not appear damaged. Prior to testing, wipe and dry the test site with an alcohol swab or soapy water. Make sure there is no cream or lotion on the test site.*

### Getting a Blood Drop and Testing

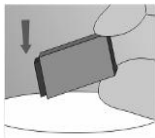
Here is an example of how to use a VivaChek™ Safety Lancet for fingertip blood sampling. If you use a different single-use auto-disabling safety lancet or lancing device, please follow the manufacturer's instructions.

1. Carefully rotate and pull off the protective cap. Avoid placing your thumb or fingers over the uncapped end of the safety lancet.
2. Hold the safety lancet against the puncture site. **Note** Before using a **single-use auto-disabling safety lancet** for blood sampling, wash both hands with soap and warm water and disinfect the puncture site

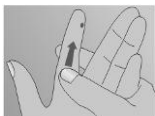


with a topical skin antiseptic such as an alcohol swab.

3. Gently press the safety lancet against the puncture site to lance the skin. Listen for an audible click. This indicates that the safety feature of the device has been activated. Dispose of the lancet in an appropriate biohazard sharps container. Please see the **Caution Statement**.

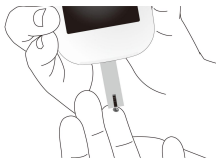


4. Gently massage from the surrounding area toward the puncture site to collect the required blood volume. For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make fingers sore and callused.



#### **Caution Statement**

- Do not use the single-use auto-disabling safety lancet if the cap is missing or loose.
  - Always use a new, sterile single-use auto-disabling safety lancet. Do not reuse the single-use auto-disabling safety lancet.
  - Avoid getting the single-use auto-disabling safety lancet dirty with hand lotion, oil, dirt or debris.
  - Single-use auto-disabling safety lancets appropriate biohazard sharps container. If a biohazard sharps container is not available use a heavy duty plastic container such as a laundry detergent bottle. Ensure the container is leak-resistant and has a hard puncture proof lid. Do not place loose sharps into the trash and do not flush down the toilet. Do not place sharps into the recycle bin as they are not recyclable.
5. 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:**

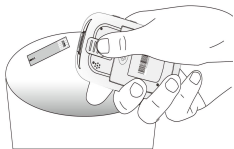
*If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.*



6. For blood glucose testing, the meter counts down from 5 to 1, and for blood  $\beta$ -ketone testing, the meter counts down from 9 to 1. And then the result appears on the display. 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.

## Discard the Used Test Strip

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



### Potential Biohazard

Dispose of the used test strips as medical waste.

#### Note:

1. *The meter is for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!*
2. *All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Please follow proper precautions when handling your meter.*

## Expected Blood Glucose/ $\beta$ -Ketone Control Goal

### 1. Blood Glucose Reference Ranges

Expected blood glucose values for people without diabetes:<sup>1</sup>

Time of Day	Glucose Range
Fasting and before Meals	<100 mg/dL
2 hours after meals	<140 mg/dL

#### Warning:

- *If your blood glucose result is below 50 mg/dL or above 250 mg/dL, it may indicate a potential serious medical condition, please contact your healthcare*

*professional as soon as possible.*

- *Please contact your physician if you determine to make a change on your current medical therapy based on test result.*

## **2. Blood $\beta$ -Ketone Reference Ranges**

The blood  $\beta$ -ketone test measures beta-hydroxybutyrate, an important ketone body in the blood.<sup>2</sup> Normally, levels of beta-hydroxybutyrate are expected to be less than 0.6 mmol/L.<sup>3</sup>

Beta-hydroxybutyrate may increase if a person fasts, exercises vigorously or has diabetes and becomes ill.<sup>2,4</sup> If your blood  $\beta$ -ketone result is lower than 0.1 mmol/L and your blood glucose result is 300.0 mg/dL or higher, repeat both the  $\beta$ -ketone and glucose tests with new test strips. If the same result appears again or the result does not match with how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication programme.

If your blood  $\beta$ -ketone result is between 0.6 and 1.5 mmol/L and your blood glucose result is 300.0 mg/dL or higher, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's advice.

If your blood  $\beta$ -ketone result is higher than 1.5 mmol/L and your blood glucose result is 300.0 mg/dL or higher, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).<sup>3-7</sup>

### **References:**

1. American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care 2018; vol.41 (supplement 1): S13-S27.
2. Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. Special Topics in Endocrinology and Metabolism 1982; 4: 1-27.
3. Wiggam MI, O'Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, Bell PM. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care 1997; 20: 1347-1352.
4. Harano Y, Kosugi K, Hyosu T, Suzuki M, Hidaka H, Kashiwagi A, Uno S, Shigeta Y. Ketone bodies as markers for Type 1 (insulin-dependent) diabetes and their value in the monitoring of diabetes control. Diabetologia 1984; 26: 343-348.
5. Ubukata E. Diurnal variation of blood beta-Ketone bodies in insulin-dependent diabetes mellitus and noninsulin-dependent diabetes mellitus patients: The relationship to serum C-Peptide immuno reactivity and free insulin. Ann Nutr Metab 1990; 34: 333-342.
6. Luzi L, Barrett EJ, Groop LC, Ferrannini E, DeFronzo RA. Metabolic effects of low-dose insulin therapy on glucose metabolism in diabetic ketoacidosis. Diabetes 1988; 37: 1470-1477.
7. Hale PJ, Crase J, Natrass M. Metabolic effects of bicarbonate in the treatment of diabetes ketoacidosis. Br Med J 1984; 289: 1035-1038.

## Taking A GKI Testing

You will know your GKI (Glucose Ketone Index) result after performing blood glucose and blood  $\beta$ -ketone test.

### 1. Enter GKI testing mode

When meter is on, press **power button** for 3s, the symbol of GKI and a test strip will both flash, then press **power button** again to confirm.



### 2. Performing Blood Glucose Testing

The symbol of "GLU", "GKI" and a test strip will appear letting you know the meter is ready to test blood glucose.



Insert the VivaChek™ blood glucose test strip into the meter, the symbol of a test strip with flashing blood will appear letting you know the meter is ready to test.



Immediately touch the tip of the test strip to the drop of blood, the meter counts down from 5 to 1, your blood glucose result appears on the display after a beep. The test result will display for 1 second and automatically be stored in the meter memory, then the meter turns to blood  $\beta$ -ketone testing.



### 3. Performing Blood $\beta$ -Ketone Testing

The symbol of “KET”, “GKI” and a test strip will appear letting you know the meter is ready to test blood  $\beta$ -ketone.



Insert the VivaChek™ blood  $\beta$ -ketone test strip into the meter, the symbol of a test strip with flashing blood will appear letting you know the meter is ready to test.



Immediately touch the tip of the test strip to the drop of blood, the meter counts down from 9 to 1, your blood  $\beta$ -ketone result appears on the display after a beep. The test result will display for 1 second and automatically be stored in the meter memory, then the meter turns to GKI testing.



### 4. Understanding your GKI Result

One second after the blood  $\beta$ -ketone result displayed on the screen, the meter will display GKI result permanently, and store it in memory.



**Note:**

- The interval time between blood glucose and blood  $\beta$ -ketone testing is 3 minutes. If pass 3minutes, the GKI mode will deactivate and meter will turn off.
- If you insert the wrong strips, the meter will show the error message.

**Questionable or Inconsistent Results**

If your blood glucose/blood  $\beta$ -ketone/glucose ketone index result does not match how you feel, please:

- Check the expiration date and the discard date of the test strip.
- Confirm the temperature of blood glucose in which you are testing is between 41 and 113°F, the temperature of blood  $\beta$ -ketone in which you are testing is between 45.5 and 113°F.
- Make sure the test strip has been stored at 36-86°F, 10-90% humidity..
- Make sure the test strip was used immediately after removing it from the test strip vial (or the foil pouch).
- Make sure that you followed the test procedure correctly.
- Perform a control solution test (See **Performing a Control Test** 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 VivaChek Customer Support at 888-969-6928 (7 days a week. 9 a.m.-5 p.m. Eastern Time). Please contact your healthcare professional if you need help outside of these hours.

**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
- You open a new box of test strips
- 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
- You suspect your test result. Or if your test result does not match with how you feel

## About the Control Solutions

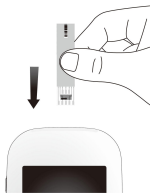
- Only use VivaChek™ Blood Glucose/ $\beta$ -Ketone Control Solutions (1, 2 or 3) to practice on the system.
- The control solution results are not including in the average value calculation.
- Store the control solution at 36-86°F, 10-90% humidity.
- All expiration dates are printed in Year-Month format. 2021/01 indicates January, 2021.
- Do not use control solution that is out of the expiration date or discard date (the VivaChek™ blood glucose/ $\beta$ -ketone 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

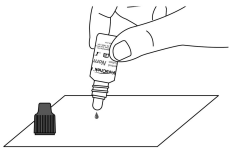
1. Remove test strip from the test strip vial (or the foil pouch). Tightly close the vial cap immediately after you have removed the test strip.

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

2. Turn on the meter and insert a test strip into the meter in the direction of the arrows.



3. The symbol 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 days 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 blood glucose/β-ketone test strip vial and control solution bottle 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 of blood glucose control solution is between 50-104°F, and testing of blood β-ketone is between 59-104°F.*
- *Make sure that you stored test strip and control solution at 36-86°F, 10-90% humidity.*
- *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 it from the test strip vial (or the foil pouch).*
- *Make sure the control solution was mixed well.*
- *Confirm that you are using VivaChek™ brand blood glucose/β-ketone test strip and 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 VivaChek Customer Support at 888-969-6928 (7 days a week. 9 a.m.-5 p.m. Eastern Time) for help. Please contact your healthcare professional if you need help outside of these hours. 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 1000 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 blood glucose records from the last 7, 14 and 30 days.

### Notes:

- *If there are already 1000 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 of blood glucose are not included in the 7, 14 and 30 days average calculation.*

## Viewing Your Test Results

When your meter is off, press **power button** to turn meter on after a beep, a symbol of strip flashes on the display, press **power button** again, the 7 day average of blood glucose will appear in the center of the display. If you want to review the memory after you immediately performed a test, with the test result on the display, press **power button** to see the 7 days of blood glucose average.



Continue to press **power button** to view the 14 days average of blood glucose, then press **power button** again to review the 30 days average of blood glucose.





Continue to press **power button** to review previous results in order (including blood glucose and blood  $\beta$ -ketone). 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 of the results in the memory.



## CHAPTER 4: MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended.

### Replace the Battery

When the meter needs to be replaced, the Battery symbol (  ) will appear.

1. Turn off your meter before changing the batteries.
2. Press firmly on the battery cover and slide.



#### **Note:**

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

3. Lift out the old batteries.
4. Place new batteries under the prongs and into the battery compartment.



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



#### **Warning:**

*Keep batteries away from children. The batteries are poisonous. If swallowed, immediately contact your doctor or poison control centre. Discard batteries according to your local environmental regulations.*

## Caring for Your Monitoring System

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands well after handling to keep the meter and test strips free of water and other contaminants.
- VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter is a precision electronic instrument. Please handle it with care.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.

## Cleaning and Disinfection

Your VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter should be cleaned and disinfected a minimum of once per week. Use only Clorox™ Healthcare Bleach Germicidal Wipes, which has been proven to be safe to use with the VivaChek™ Blood Glucose and  $\beta$ -Ketone Meter.

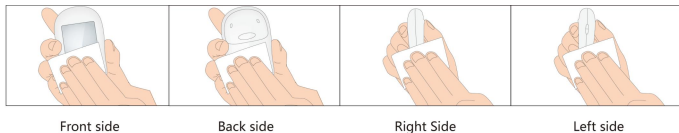
Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. After use and exposure to blood, all parts of this kit can potentially transmit infectious diseases. Disinfecting reduces the risk of transmitting infectious diseases.

*Note: 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.*

### 1. 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 meter surface including front side, back side, right side and left side.

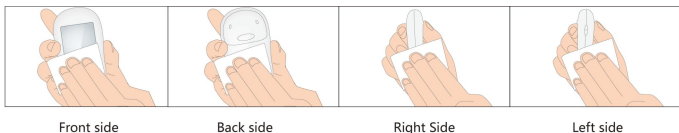


The meter should be cleaned whenever they are visibly dirty or a minimum of once per week. This cleaning is to prepare the meter surface for a disinfection process.

### 2. 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 including front side, back side, right side and left side of the meter, by a back and forth movement.



Step 3: Keep the meter surface wet for at least one minute.

Step 4: Wait for the surface of meter to be dry.

Clorox™ Healthcare Bleach Germicidal Wipes containing Sodium hypochlorite 0.55%, which has been proven to be safe to use with the VivaChek™ Blood Glucose and  $\beta$ -Ketone Monitoring System. Clorox™ Healthcare Bleach Germicidal Wipes are available by contacting Krasity Medical Supply at 800-537-1394 directly or visiting and purchasing at <http://www.walmart.com> and <http://www.staples.com/>. The meter should be disinfected a minimum of once per week. The meter disinfection process has been validated for 608 disinfection 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 of the meter.

**Notes:**

- Do not use alcohol or any other solvent.
- Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the data port.
- Do not squeeze the wipe or gauze into test strip port.
- Do not spray cleaning solution on the meter.
- Do not immerse the meter in any liquid.

**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 buttons do not function, partial display on full screen, unable to execute the meter's initial set up, etc. If you notice any of these external changes to your meter or any changes to the performance of your meter stop using the meter and please contact Customer Support for help.*

If you have questions about cleaning or disinfection, or if you see evidence of physical damage, contact VivaChek Customer Support at 888-969-6928 (available 7 days a week, 9 a.m.-5 p.m. Eastern Time). Please contact your healthcare professional if you need help outside of these hours.


## Troubleshooting Guide

What You See	What It Means	What You Should Do
<b>E1</b>	Add blood or control solution before the flashing blood drop appears.	Discard the test strip and repeat the test with a new test strip. Add blood or control solution after you see the flashing blood drop on the display.
<b>E2</b>	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.
<b>E3</b>	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using VivaChek™ Blood Glucose/β-Ketone test strip.
<b>E4</b>	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using blood sample or VivaChek™ Blood Glucose/ β-Ketone control solution.
<b>E5</b>	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 20 minutes before performing a test.
<b>E6, E7</b>	Potential hardware issue.	Take out batteries and restart the meter. If the problem continues, contact VivaChek Customer Support at 888-969-6928 (available 7 days a week, 9 a.m.-5 p.m. Eastern Time). Please contact your healthcare professional if you need help outside of these hours.
<b>E10</b>	Insufficient sample.	Repeat test and apply enough sample to fill check window of the test strip.
<b>HI</b>	Blood glucose test result is above 600 mg/dL; blood β-ketone test result is above 8.0 mmol/L.	Wash, dry your hands and the test site well, then repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.



**Caution:**

Glucose levels above 250 mg/dL may indicate a potential serious medical

condition.		
<b>LO</b>	Blood glucose test result is below 20mg/dL; blood $\beta$ -ketone test result is below 0.1 mmol/L.	Wash, dry your hands and the test site well, then repeat the test using a new test strip. If your result still flashes LO, contact your health care professional as soon as possible.
 <b>Caution:</b> Glucose levels below 50 mg/dL may indicate a potential serious medical condition.		

### Symptoms of High/Low Blood Glucose and Ketoacidosis

You can better understand your test results by being aware of the symptoms of high/low blood glucose and ketoacidosis. 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/ $\beta$ -ketone. If your test result does not match with how you feel, contact your healthcare professional immediately.*

**System Specifications**

<b>Feature</b>	<b>Specification</b>
Measurement Range	Blood glucose: 20 to 600mg/dL; Blood $\beta$ -ketone: 0.1-8.0 mmol/L
Test Measured	Blood Glucose/ $\beta$ -Ketone in fingertip capillary whole blood
Result calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample Volume	Blood glucose: 0.8 $\mu$ L; Blood $\beta$ -ketone: 0.8 $\mu$ L
Test Time	Blood glucose: 5 seconds; Blood $\beta$ -ketone: 10 seconds
Power Source	Two AAA LR03 1.5V batteries
Battery life	12 months or approximately 1,000 tests
Units of Measure	Blood glucose: pre-set to milligrams per deciliter (mg/dL) ; Blood $\beta$ -ketone: pre-set to millimoles per liter (mmol/L)
Memory	Up to 1000 records with date and time
Automatic Shutoff	2 minutes after last action
Dimensions	90.4 mm x 54.5 mm x 27.8 mm
Display Size	39 mm x 41 mm
Weight	Approximately 63g
Operating Temperature	Blood glucose: 41-113°F; Blood $\beta$ -ketone: 45.5-113°F
Operating Relative Humidity	10-90% (non-condensing)
Hematocrit Range	Blood glucose: 20-70%; Blood $\beta$ -ketone: 20-65%
Data Port	Micro USB
Bluetooth	Version 4.2

### Clinical Study for Blood Glucose

The VivaChek™ Blood Glucose and  $\beta$ -Ketone Monitoring System was tested by 352 lay persons using capillary whole blood samples and three VivaChek™ Blood Glucose test strip lots. The results were compared to the YSI Model 2300 STAT PLUS Glucose Analyzer. The tables below show how well the two methods compared.

**Table 1-Linear Regression Results**

Slope	1.0083
Y-Intercept	-1.9367 mg/dL
Correlation coefficient (R)	0.9982
Number of sample	352
Range tested	39.3 ~ 492.6 mg/dL

**Table 2-Consumers Accuracy Results**

The numbers and percentages represented in this table are the number of meter results compared to a laboratory result.

Difference range between the true blood glucose level and the VivaChek™ Blood Glucose and $\beta$ -Ketone meter result.	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
The percent (and number) of meter results that match true blood glucose level within x%	72.7% (256/352)	98.3% (346/352)	100% (352/352)	100% (352/352)

Accurate Results (Meter result is +/-15% of laboratory result)	352 out of 352 (100% of results)
More Accurate Results (Meter result is +/-10% of laboratory result)	346 out of 352 (98.3% of results)
Most Accurate Results (Meter result is +/-5% of laboratory result)	256 out of 352 (72.7% of results)

### Clinical Study for Blood $\beta$ -Ketone

The VivaChek™ Blood Glucose and  $\beta$ -Ketone monitoring system was tested by 101 lay persons using capillary blood samples and three VivaChek™ Blood  $\beta$ -Ketone test strip lots. The results were compared to the Randox RX Daytona Plus Chemistry Analyzer. The tables below show how well the two methods compared.

**Table 1-Linear Regression Results**

Slope	1.0037
Y-Intercept	0.015 mmol/L
Correlation coefficient(R)	0.9928
Number of sample	101
Range tested	0.10 ~ 5.37 mmol/L

**Table 2-Consumers Accuracy Results**

The numbers and percentages represented in this table are the number of meter results compared to a laboratory result.

For Blood $\beta$ -Ketone Concentration $\geq 1.5$ mmol/L				
Difference range between the true blood $\beta$ -ketone level and the	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$



VivaChek™ Blood Glucose and $\beta$ -Ketone meter result.				
The percent (and number) of meter results that match true blood $\beta$ -ketone level within x%	25.0% (2/8)	75.0% (6/8)	100.0% (8/8)	100.0% (8/8)
For Blood $\beta$ -Ketone Concentration <1.5 mmol/L				
Difference range between the true blood $\beta$ -ketone level and the VivaChek™ Blood Glucose and $\beta$ -Ketone meter result.	Within $\pm 0.075$ mmol/L	Within $\pm 0.150$ mmol/L	Within $\pm 0.225$ mmol/L	Within $\pm 0.300$ mmol/L
The percent (and number) of meter results that match true blood $\beta$ -ketone level within x%	64.4% (65/101)	90.1% (91/101)	98.0% (99/101)	99.0% (100/101)

Accuracy Results for Blood $\beta$ -Ketone Concentration $\geq 1.5$ mmol/L	
Accurate Results (Meter result is +/-20% of laboratory result)	8 out of 8 (100.0% of results)
More Accurate Results (Meter result is +/-15% of laboratory result)	8 out of 8 (100.0% of results)
Most Accurate Results (Meter result is +/-10% of laboratory result)	6 out of 8 (75.0% of results)
Accuracy Results for Blood $\beta$ -Ketone Concentration <1.5 mmol/L	
Accurate Results (Meter result is +/-0.300 mmol/L of laboratory result)	100 out of 101 (99.0% of results)
More Accurate Results (Meter result is +/-0.225 mmol/L of laboratory result)	99 out of 101 (98.0% of results)
Most Accurate Results (Meter result is +/-0.150 mmol/L of laboratory result)	91 out of 101 (90.1% of results)

## Warranty

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

### **VivaChek Biotech (Hangzhou) Co., Ltd.**

1/2/3 F, Building 1, 16 East Zhenxing Rd., Yuhang Economy Development Zone,  
Yuhang, 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, 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 batteries supplied with the meter.*

(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 environment.