VivaChek™ Link Plus

Blood Glucose Monitoring System

User Manual

Document Number:1205228801

Effective Date:2023--09-19

VivaChek™ Link Plus Blood Glucose Monitoring System

Dear VivaChek™ Link Plus System User,

Thank you for choosing the VivaChek™ Link Plus Blood Glucose Monitoring System. VivaChek™ Link Plus Blood Glucose Monitoring System is designed for easy test of blood glucose and helps you keep blood glucose under control.
Read this User Manual carefully before you use your meter system. This manual will help you to get comfortable using the VivaChek™ Link Plus Blood Glucose Monitoring System and get reliable test results. Please keep your User Manual in a safe place; you may want to refer it in the future.

Intended Use

VivaChek™ Link Plus Blood Glucose Monitoring System is comprised of the VivaChek™ Link Plus Blood Glucose Meter and the VivaChek™ Ino Blood Glucose Test Strips. VivaChek™ Link Plus Blood Glucose Monitoring System is intended to quantitatively measure the glucose 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™ Link Plus Blood Glucose Monitoring System is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The glucose measurement is achieved by using the amperometric detection method. The test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose oxidase and the mediator. Electrons are generated, producing a current that is positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed.

TABLE OF CONTENTS

1. Understanding Your Testing Tools..... 1

Your System Overview..... 1
Your Meter Display..... 2
Meter Use and Precautions..... 3
Important Safety Information..... 4
Limitations..... 5

2. Setting Your System..... 6

Set the Date and Time..... 6
Set the Audio Feature..... 8
Set the Meal Marker..... 8
Set the Hypoglycemia (Hypo) Warning..... 8
Set the Ketone Warning..... 9

3. Performing a Test..... 10

Preparing the Test Strip..... 10
Preparing the Lancing Device..... 11
Getting a Blood Drop for Testing..... 12
Discarding the Used Test Strip..... 14
Removing the Used Lancet..... 14
Expected Diabetes Control Goal..... 15
Questionable or Inconsistent Results..... 16
Symptoms of High or Low Blood Glucose..... 16
Precision and Accuracy..... 17
Comparing Meter and Laboratory Results..... 19
Testing with Control Solution..... 19
Understand Control Test Result..... 22
Using the Meter Memory..... 23
Viewing Your Test Results 23

4. Maintenance and Troubleshooting..... 25

Charging the Battery..... 25
Caring for Your Glucose Monitoring System..... 26
Cleaning and Disinfection..... 26
Troubleshooting Guide..... 29

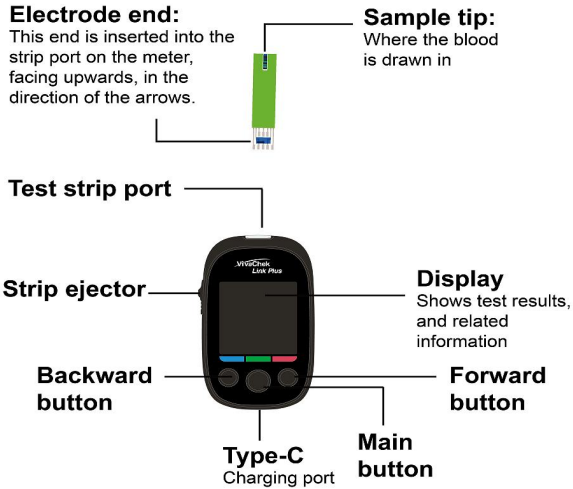
5. Technical Information..... 31

System Specifications..... 31
4G Specifications..... 32

Warranty…… 32
EMC Guidance…….. 33
FCC Requirement…… 36

CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

Your System Overview



SN	Proprietary Name	Common Name	Included in the Meter Box?
1	VivaChek™ Link Plus Blood Glucose Meter	Blood Glucose Meter	Yes
2	VivaChek™ Ino Blood Glucose Test Strip	Blood Glucose Test Strip	No and should be purchased separately
3	VivaChek™ Ino Control Solution	Glucose Solution	No and should be purchased separately
4	VivaChek™ Lancing Device	Lancing Device	No and should be purchased separately
5	VivaChek™ Lancets	Lancet for single patient use only	No and should be purchased separately

VivaChek™ Lancing Device

VivaChek™ Lancets

VivaChek™ Ino Control Solution

Note:

- The VivaChek™ Ino Blood Glucose Test Strips, VivaChek™ Ino Control Solution, VivaChek™ Lancing Device and VivaChek™ Lancets are necessary for use but not included in the meter box and should be purchased separately, please contact 24/7 VivaChek Customer Support at 888-969-6928 for purchasing.

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 Main 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 VivaChek Customer Support at 888-969-6928 for help.

Icon	What It Means
88/88	The top left area on the screen indicates date.
88:88	The top right area on the screen indicates year or time.
AM PM	The top middle area on the screen indicates morning or afternoon time.
d/m/d	Indicates the display form of day and month (d/m) or month and day (m/d).
	Data transmitted successfully.
	Data not transmitted.
M	Indicates test result history.
A	Indicates average value.
	Indicates the battery level.
Ketone?	It recommends performing a ketone measurement based on the high glucose test result (≥ 300mg/dL) obtained from this meter.
Hypo	The low glucose test result may indicate hypoglycemia.
	Signal strength.
888	Center area on the display that shows test results or error codes.
	Indicates the temperature is not suitable for testing.
mg/dL	Test results are displayed as mg/dL.
	When strip is inserted, the drop will flash, indicating the system is ready to test.

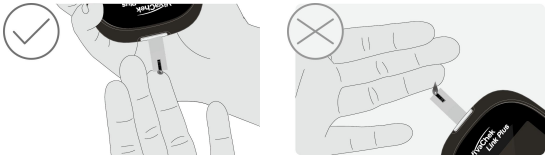
	Pre-meal marker.
	Post-meal marker.
	Control test icon.

Notes:
Your VivaChek™ Link Plus Meter is preset with beep sound function, the meter will beep when:

- *Turn on the meter.*
- *The test strip is inserted and ready to apply blood or control solution.*
- *Sufficient blood or control solution is pulled into the test strip.*
- *The test is complete.*
- *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 displays blood glucose concentration in milligrams per deciliter (mg/dL) only.
- Meter will shut off by itself after 2 minutes of inactivity.
- Refer to the Cleaning and Disinfection section to keep the entire meter clean.
- Keep your meter in the temperature range 41-113°F and relative humidity range 10-90%. 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 **Testing with Control Solution** for instructions.
- Do not use the meter if it drops into water or other liquids or splashing water on to it.
- You should use the meter as described in the user manual, and any use of the meter beyond the scope of the 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 the blood on the test strip. The blood is pulled into the tip of the test strip through capillary action:



- Check the expiration dates and discard dates on your test strips vial label and control solution vial label.
- Use only VivaChek™ Ino Blood Glucose Test Strip with your VivaChek™ Link Plus Blood Glucose Meter.
- Use only VivaChek™ Ino Control Solution with your VivaChek™ Link Plus Blood Glucose Meter and VivaChek™ Ino Blood Glucose Test Strip.
- 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 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.
- 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: https://wayback.archive-it.org/7993/20170111013014/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.
- Do not alter your blood glucose management or treatment without first consulting your doctor or 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.

Limitations

- Not for use on critically ill patients, patients in shock or in a hyperglycemic-hyperosmolar state with or without ketosis. And not for neonatal use.
- Not for use on patients who have been diagnosed by a healthcare provider with a dehydration disease requiring hospitalization.
- Not for use on patients who have been diagnosed by a healthcare provider with a hypotensive disease requiring hospitalization.
- 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 screening or diagnosis of diabetes mellitus.
- Not for Alternative Site Testing (AST).
- Do not use the system above 10413ft (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 because 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 (HIV),

Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

CHAPTER 2: SETTING YOUR SYSTEM

Before using your meter for the first time, make sure to set your meter properly.

Set the Date and Time

1. Enter the setting mode and set the clock.

When the meter is off, press and hold **Main Button** until the meter beeps to enter to the setting mode. Then set the clock for either 24- or 12-hour format. Press **Forward Button** or **Backward Button** to adjust it then press and hold **Main Button** to save your setting. Start setting the year, month and day.

2. Set the Year, Month and Date.

The year will now flash. Press **Forward button or Backward button** to adjust it, then press **Main button** to set.

The display form of day and month will now flash, press **Forward button or Backward button** to set the display form to m/d or d/m format, press and hold **Main button** until the meter beeps to set. And then the meter will prompt you to set the month.

The month will now flash, press **Forward button or Backward button** to adjust the month, press and hold **Main button** until the meter beeps.

The day will now flash. Press **Forward button or Backward button** to adjust the day, press and hold **Main button** to set.

3. Set the Time

After the date setting is completed. Press **Forward button or Backward button** to adjust the current hour, press and hold **Main button** to set, then it will shift to the next digit for setting.

The minute will now flash. Press **Forward button or Backward button** to adjust the minute, press and hold **Main button** to set the minute.

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 you set the time, press **Forward button or Backward button** to select “On” or “OFF”, and then press **Main button** to set.

Set the Meal Marker

After setting the audio feature, the symbols of will now flash, along with the word “On” or “OFF” on the display. Press **Forward button or Backward button** to turn the meal marker function on or off, press **Main button** to set.

Set the Hypoglycemia (Hypo) Warning

After you have confirmed the meal marker setting, the **Hypo** flashes on the display along with “On” or “OFF”. Press **Forward button or Backward button** to turn the Hypo alarm function on or off, then press **Main button** to set. If you select the Hypo alarm to be “On”, the display shows 70 mg/dL as default. Press **Forward button or Backward button** once to adjust blood glucose level (the level increases by 1 mg/dL). You can adjust the range from 60 to 80 mg/dL. Press and hold the **Main button** to confirm.

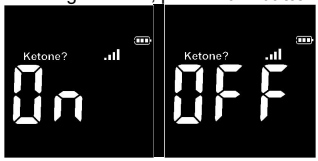
Notes:

- Hypo Alarm (Warning) is a reminder displayed on meter for user that the measured glucose level is equal or less than a settable glucose value that has been recommended by your healthcare professional.
- You can set the Hypo Alarm to let you know when your blood glucose is possibly too low. If you select the Hypo Alarm to be “On”, the “Hypo” warning will appear when your blood glucose test result is below your setting blood glucose level. Please talk to your healthcare professional to help you decide and set the blood glucose level that suits your physical condition.

Set the Ketone Warning

The icon is to provide a “high glucose” alarm that recommends performing a ketone measurement. However, the icon does not mean this meter measures ketones.

After the hypo warning setting is completed, the **Ketone?** symbol will now flash, along with word “On” or “OFF” on the display. Press **Forward button or Backward button** to turn the Ketone Warning on or off; press **Main button** to set.



Now you have completed your meter setting. Press **Main button** for 5 seconds when a symbol of a flashing strip appears letting 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 **Main button** for 5 seconds when the meter is powered off and then to return to the setting mode.

CHAPTER 3: PERFORMING A TEST

Set your meter correctly and have all the materials you will need before you begin testing. This includes your VivaChek™ Link Plus Blood Glucose Meter, VivaChek™ Ino Blood Glucose Test Strips, and VivaChek™ lancing device and lancets.

Preparing the Test Strip

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. Meter turns on after a beep.

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

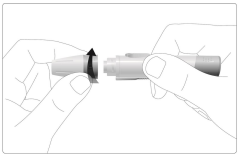
Note:

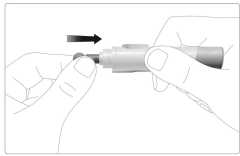
Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st January, 2023. Your VivaChek Ino test strips have 6 months' shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water 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 the Lancing Device

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

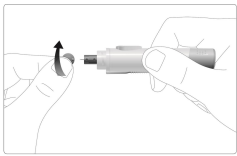
1. Unscrew the lancing device cover from the body of the lancing device. Insert a VivaChek™ sterile lancet into the lancing device and push it until the lancet comes to a complete stop in the lancing device.



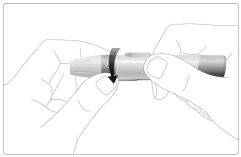


Note: *The* ***VivaChek™*** *lancing device uses* ***ONLY VivaChek™*** *sterile lancets.*

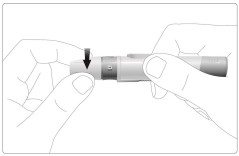
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for disposing the used lancet.

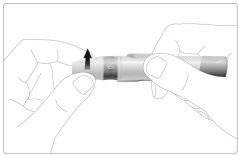


3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed lancet. Make sure the cover is fully sealed on the lancing device.



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





Adjustment:

1 for delicate skin

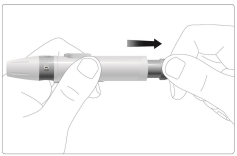
2 and 3 for normal skin

4 and 5 for calloused or thick skin

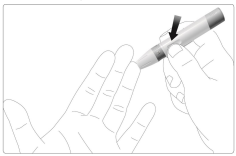
Note: *Greater pressure of the lancing device against the puncture site will also increase the puncture depth.*

Getting a Blood Drop for Testing

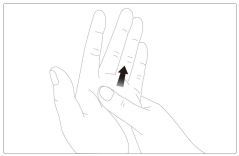
1. Pull the cocking barrel back to set the lancing device. You may hear a click to indicate the lancing device is now loaded and ready for obtaining a drop of blood.

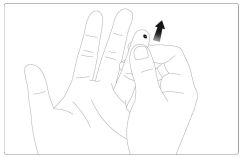


2. Press the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates.



3. 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 (half the size of a match head). 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.





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

Note:
If the blood 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.

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

6. After the testing is completed, the measurement data will be transmitted.

Note:
You could log into your VivaChek Web App to view the historical measurement data from the website: linkplus.vivachek.com

Discarding the Used Test Strip

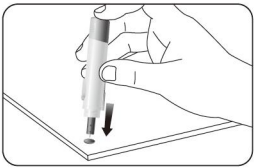
You can eject and discard the used test strip by using the strip ejector.

Potential Biohazard

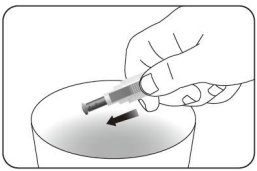
Dispose of the used test strips as potential medical waste.

Removing the Used Lancet

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



Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to release the used or contaminated lancet in an appropriate container with a potential biohazard identification. Do not use your fingers to pull the used lancet out to prevent injury from the lancet. Dispose of used lancets and follow local regulations for proper disposal to prevent injury from the lancets.



Place the lancing device cover back on the lancing device.
Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Potential Biohazard

Always dispose of the used or contaminated lancet properly to prevent potential injury or infections to others.

Caution:

- *Lancing device is intended only for a single user and should not be shared.*
- *Check and do not use the 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 lancet that safely tab has been removed.*
- *Be cautious when the lancet needle is exposed.*
- *Do not reuse lancet, and do not share lancet with anyone including family members.*

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 target range that works best for you.

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. 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

If you experience any of these symptoms, please contact your physician or diabetes healthcare professional.

If your blood glucose result does not match how you feel, please*:*

- Check the expiration date and the discard date of the test strip. Make sure that the test strip vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is between 41-113°F.
- Make sure that the test strip vial has been tightly capped.
- 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 from the test strip vial.
- Make sure that you followed the test procedure correctly.
- Perform a control solution test (See **Testing with Control Solution** for instructions).
- After checking all the conditions listed above, repeat the test with a new test strip. Please contact 24/7 Customer Support at 888-969-6928.

As glucose levels range for self-monitoring may vary from person to person, please check with your healthcare professional to determine the levels range you need to monitor, and

•Please contact your healthcare professional if your test result is below the lower limit of your level range or you see LO (less than 20 mg/dL).

•Please contact your healthcare professional If you test result is above the upper limit of your level range or you see HI (greater than 600 mg/dL).

• Please contact your healthcare professional if you obtain results that are not consistent with the way you feel, and to not change your medication or food regimen without approval from a healthcare professional.

Precision and Accuracy

Linearity Results:

Lot 1: y = ; R^2 = .
Lot 2: y = ; R^2 = .
Lot 3: y = ; R^2 =.
All 3 Strips Lots: y =; R^2 = .
The results support the claimed measurement range of 20-600 mg/dL.

The VivaChek™ Link Plus blood glucose monitoring system was tested for within-run precision (300 measurements per glucose concentration for repeatability) using venous whole blood samples and intermediate precision (30 measurements per glucose concentration a day for 10 days) using glucose controls. See tables below for results.

Within-Run Precision:

Interval	Glucose Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1			
2			
3			
4			
5			

Intermediate Precision:

Interval	Glucose Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1			
2			
3			
4			
5			

User Evaluation:

The VivaChek™ Link Plus blood glucose monitoring system was tested by 352 lay users using capillary blood samples and three VivaChek™ Ino blood glucose test strips lots. The results were compared to the YSI Model 2300 STAT PLUS Glucose Analyzer, a laboratory instrument. See the table below with accuracy performance study results that shows the VivaChek™ Link Plus blood glucose monitoring system achieved 100% of results within ±15% of the laboratory instrument. The results show here are intended to inform you about your meter, how much results are consistent from your actual blood glucose values.

Table 1- Linear Regression Results

Slope
Intercept
Correlation coefficient (R)
Number of samples

Table 2-Consumers Accuracy Results

Accuracy for Home Use by Lay-Users

VivaChek™ Link Plus Blood Glucose Meter result may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology.

The chart below shows the results of a study where 352 typical users used the VivaChek™ Link Plus Blood Glucose Meter to test their blood glucose level.

In this study, VivaChek™ Link Plus Blood Glucose Meter gave results within 15% of their true blood glucose level 352 out of 352 times.

Difference range between the true blood glucose level and VivaChek™ Link Plus Blood Glucose Meter result.				
The percent (and number) of meter results that match true blood glucose level within x%				

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 doctor 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 for your tests.
- Follow User Manual for performing a blood glucose test.

Note:

Users should periodically review their technique, and compare a result obtained with their meter to a result obtained using 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 the meter and test strips are not working together properly.
- After cleaning and disinfecting your meter.
- You dropped the meter.
- Always perform a quality control test if you suspect your results are inaccurate or do not match how you are feeling.

About the Control Solution

- Only use VivaChek™ Ino Control Solution (1, 2 or 3) to practice on the system.
- Your meter automatically recognizes the control solution.
- 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-Day format. 2023-01-01 indicates 1st January, 2023.
- 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 removed 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 vial thoroughly. Squeeze the control solution vial gently and discard the first drop. Squeeze out a second small drop on the top of the control solution vial surface.

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

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 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 the meter beeps, and then you see the meter count down on the screen, followed by your control test result.

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

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

Understand Control Test Result

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

The ranges in the picture above are only example and the ranges on the vial in use should be referenced.

Notes:

If your control test result is out of range:

- *Check the expiration dates and discard dates of the test strip and control solution. Make sure that the test strip vial and the 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 between 50-104°F.*
- *Make sure that you stored strip and control solution at 36-86°F, 10-90% humidity.*
- *Make sure that the test strip vial and the control solution vial have been tightly capped.*
- *Make sure the test strip was used immediately after removing from the test strip vial.*
- *Make sure the control solution was mixed well.*
- *Confirm that you are using VivaChek™ Ino 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 be working properly. **DO NOT** use the system to test blood. Contact 24/7 VivaChek Customer Support at 888-969-6928. 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. Control results will be not included in your blood glucose averages.

Using the Meter Memory

Your meter automatically stores up to 500 results with time, date and meal marker. 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 500 records in memory, the oldest record will be erased to make room for a new one.*
- *Control results of blood glucose are not included in the 7-day, 14-day and 30-day average calculation.*

Viewing Your Test Results

When your meter is off, press **Main button** to turn meter on. After a beep, a symbol of a test strip flashes on the display. Press **Main 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.

Continue press **Main button** for 2 seconds until the 7-day average of blood glucose appears in the center of the display. If you want to review the memory after you immediately performed a test, when the test result on the display, press **Main button** to see the 7-day average of blood glucose.

Continue to press **Main button** to view the 14-day average of blood glucose, then press **Main button** again to review the 30-day average of blood glucose.

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

CHARTER 4：MAINTENANCE AND TROUBLESHOOTING

Indications on the meter displayed for when the meter is in recharging or fully recharged:

When the meter is in charging, the meter displays the battery icon and repeats the charging status from ▭ through ▭, ▭, ▭.

When the meter is fully charged, the meter displays the battery icon ▭.

Recommendations for Recharging Battery:

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

• Micro USB cable (computer charging)

• Micro USB cable with the AC adapter (wall charging)

To optimize battery life, it is recommended to recharge the battery when the critical battery level (running out of battery ▭) appears.

When using the USB port on your computer to recharge the battery, be sure the computer is turned on and not in standby mode. If the meter is not recharged, try using another USB port on your computer.

Contact seller to confirm whether the AC adapter meets following specifications before purchasing it:

Input: 100-240V~, 50/60Hz, 0.2A Max; Output: 5.0V ⎓, 1.0A;

Standard ANSI/AAMI ES 60601-1 or IEC 60601-1.

Warnings for Recharging Battery:

- *Do not disassemble the meter and take battery out for recharging.*
- *Do not use the Micro USB cable, AC adapter or meter if it is damaged, discolored or deformed.*
- *Do not insert a test strip when the meter is connected to a computer or AC adapter with Micro USB cable since the meter is designed that blood glucose testing is not allowed during meter charging.*
- *Do not put the meter on the thermally insulating materials such as clothing, carpet, blanket, or plastic surface for recharging.*
- *Do not recharge the meter in outdoors, sunlight, a wet area or a heating area.*
- *Do not allow unsupervised children to recharge the meter battery.*

Recommended Procedures for Recharging Battery:

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

Option A: Using a micro USB cable by connecting computer, the computer should be turned on during recharging;

Option B: Using a micro USB cable by connecting AC adapter, the AC adapter should meet the specifications in the section “Recommendations for Recharging Battery” in the user manual.

Step 2): Check and ensure the contents in the section “Recommendations for Recharging Battery” are followed.

Step 3): Check and ensure that the applicable contents in the section “Warnings for Recharging Battery” are followed.

Step 4): Check that the meter displays the battery icon and repeats the recharging 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 recharge.
Step 6): Recommend recharging the meter for three hours.
Step 7): Remove the micro USB cable from the meter after recharging.
Step 8): Your meter is now ready to use.

Warning:
Please note that the battery is not removable. If the battery needs to be separated for 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 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.
- VivaChek™ Link Plus Blood Glucose 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 41-113°F, relative humidity 10-90%. The operating conditions for control solution are 50-104°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 clean surface for the next disinfection step. The purpose of disinfection step is to disinfect the microorganism on whole surface of meter.
Use only Clorox™ Healthcare Bleach Germicidal Wipes, which has been proven to be safe to use with the VivaChek™ Link Plus Blood Glucose Meter. Clorox™ Healthcare Bleach Germicidal Wipes are available by visiting and purchasing at http://www.walmart.com, http://www.staples.com/, and https://www.amazon.com/.
The meter should be cleaned and disinfected a minimum of once per week. This 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 of the meter.

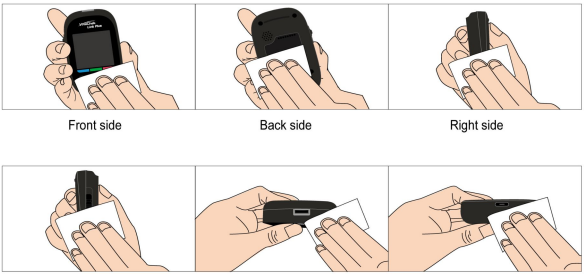
Warning: If the meter is being operated by a second person who is providing testing assistance to you, the meter should be cleaned and disinfected prior to use by the second person.

Notes:

- *Do not use alcohol or any other solvent that have not been proved to be safe and effective for use with the device.*
- *Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the USB 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.*
- *Please refer to the safety instruction in the labeling of Clorox Healthcare Bleach Germicidal Wipes before using wipes.*

Cleaning Your Meter

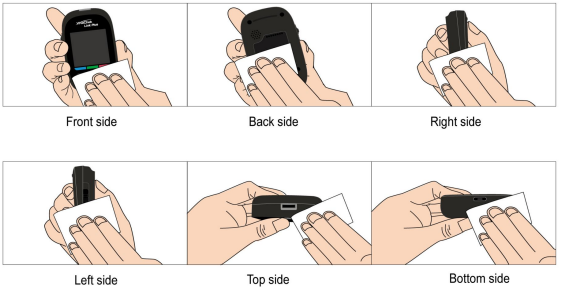
Step 1: Take one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) from the container.
Step 2: Clean the entire surface of the meter including the front, back, left, right, top and bottom sides of the meter, and specifically also including the test strip port, test strip ejector, button, material seams and USB port for one minute. This cleaning is to prepare a clean meter surface for a disinfection process.



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 by a back-and-forth movement including the front, back, left, right, top and bottom sides of the meter. The parts of the meter that are particularly susceptible to blood contamination should be wiped, which include the test strip port, test strip ejector, button, material seams, and USB port.

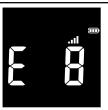
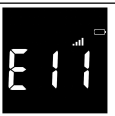


Step 3: Please do not touch the meter and wait for one minute at least to make the meter's surface to be dry after performing the step 2 above.

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

Notes: *If you have questions about cleaning or disinfection, please contact 24/7 VivaChek Customer Support at 888-969-6928.*

Troubleshooting Guide

What You See	What It Means	What You Should Do
	Blood or control solution was applied to the test strip before the flashing blood drop appeared on the display	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	The meter is sensing a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a VivaChek™ Ino test strip.
	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and VivaChek™ Ino Control Solution are used for the test.
	Temperature out of range.	Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test.
	Potential hardware error.	Restart the meter. If the problem continues, contact 24/7 VivaChek Customer Support at 888-969-6928.
	A test strip was inserted while the meter was connected to a computer or wall outlet.	When the charge is completed (about 3 hours for charging an empty battery), remove the Micro USB cable from the meter, and then take a test.
	Insufficient sample.	Repeat the test and apply enough sample to fill the test strip sample channel.
	Running out of battery.	Charge the battery.

	Data not transmitted	Please check network connection. Then discard the test strip and repeat the test with a new test strip. If the problem continues, contact 24/7 VivaChek Customer Support at 888-969-6928
	No signal	Restart the meter. If the problem continues, contact 24/7 VivaChek Customer Support at 888-969-6928.
	The test result is above 600 mg/dL.	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still shows “HI”, contact your healthcare professional as soon as possible.
	The test result is below 20 mg/dL.	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still shows “LO”, contact your healthcare professional as soon as possible.

CHAPTER 5: TECHNICAL INFORMATION

System Specifications：

Feature	Specification
Measurement Range	20 - 600 mg/dL
Measurement Result	Plasma Glucose
Sample	Fresh capillary whole blood
Sample Volume	0.8 μL
Test Time	5 seconds
Power Source	Rechargeable 3.7 Volt Lithium Ion Battery
Charging Time	≤ 3h, ⎓ Direct current
Battery Type	Rechargeable, 800 mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Unit of Measure	mg/dL
Memory	500 records
Automatic Shutoff	2 minutes after last action
Dimensions	100.9mm x 61.6mm x 23.7mm
Display Size	42 mm x 41 mm
Weight	Approximately 85g
Operating Temperature	41 - 113℉
Operating Relative Humidity	10-90% (non-condensing)
Hematocrit Range	20 - 70%
Charging Port	Micro USB
Data Transmission	4G

4G Specifications:

Item Name	Design Specification
Throughput	Downlink≥500Kbps, Uplink≥1000Kbps
Latency	≤25ms
Data Integrity	Data shall be transmitted correctly and completely
Accessibility	Accessibility is high since 4G is broadband
Signal Priority	Routine priority using 4G access standard

Warranty

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

VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd.,
Yuhang Economy Development Zone,
Hangzhou, 311100, Zhejiang, P.R. 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 battery supplied with the meter.

FCC Requirements

Frequency Requirement

Frequency Band	Transmit (MHz)	Receive (MHz)
Band 2	1850 - 1910	1930 - 1990
Band 4	1710 -1755	2110 - 2155
Band 12	699 - 716	729 - 746
Band 13	777 - 787	746 - 756

TX POWER

Frequency Band	Max Power
Band 2/4/12/13	21 dBm +1.7/-3 dB

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The portable device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission (USA). These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the extremity, with 0 mm separation.

SAR compliance for body-worn operating configurations is limited to the specific configurations tested for this filing. Body-worn operations are restricted to belt-clips, holsters or similar accessories that have no metallic component in the assembly and must provide at least 15mm separation between the device and the body of the user. End-users must be informed of the body-worn operating requirements for satisfying RF exposure compliance. The highest reported SAR for body-worn accessory use conditions is 0.24W/kg.

FCC Regulations

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.

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.

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