

VivaChek™ *Fad Sync*

Blood Glucose Monitoring System

Dear VivaChek™ Fad Sync System User,

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

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

Thank you again for choosing the VivaChek™ Fad Sync System.

Intended Use and Principle

VivaChek™ Fad Sync Blood Glucose Monitoring System is comprised of the VivaChek™ Fad Sync Blood Glucose Meter (VGM08) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01) and VivaChek™ Fad Blood Glucose Test Strips (VGS02). The VivaChek™ Fad Sync 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.

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.

TABLE OF CONTENTS

1. Understanding Your Testing Tools.....	1
Your Meter System Overview.....	1
Your Meter Display.....	2
Important Safety Information.....	3
Limitations.....	4
2. Setting Up Your System.....	6
Set the Clock.....	6
Set the Date.....	6
Set the Time.....	7
Set the Audio Feature.....	8
Pairing Your Meter with the Smartphone.....	9
Syncing to send results wirelessly to the app.....	9
Using Your Meter without App.....	9
3. Taking a Test.....	10
Preparing the Test Strip.....	10
Getting a Blood Drop and Testing.....	12
Discard the Used Test Strip.....	13
Testing with Control Solution.....	17
Using the Meter Memory.....	20
4. Maintenance and Troubleshooting.....	21
Recharging Batteries.....	21
Caring for Your Glucose Monitoring System.....	22
Cleaning and Disinfection.....	22
Troubleshooting Guide.....	24
Symptoms of High or Low Blood Glucose.....	26
5. Technical Information.....	27
System Specifications.....	27
Warranty.....	28

CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

Your Meter System Overview

The VivaChek™ Fad Sync Blood Glucose Meter and VivaChek™ Ino/Fad Strip

Electrocode end:

this end is inserted into the strip port on the meter, facing upwards, in the direction of the arrows.

Sample tip:

where the blood is drawn in



Test strip port

Display


Button



Micro USB data port








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  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 800-951-8430 (7 days a week, 9 a.m.-5 p.m. Eastern Time) for help. Please contact your health care professional if you need help outside of these hours.



Icon	What it Means
	The top right area on the screen indicates the date.
	The top left area on the screen indicates the time.
	Indicates empty battery or battery needs to be recharged
	The center area on the display, this shows the test results or error codes.
	Indicates the system is ready to test.
	Control test result.
mg/dL	Test results are displayed as mg/dL
	Bluetooth

	The meter failed to sync with the Smartphone.
M	Memory

Notes:

Your VivaChek™ Fad Sync meter is pre-set 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 is preset to display blood glucose concentration in milligrams per deciliter (mg/dL) by default.
- Meter will shut off by itself after 2 minutes of inactivity.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry. 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, check the meter by running a quality control test. Refer to **Quality Control Test** for instructions.
- Do not take the meter apart. This 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!
- Always keep the test strips in the original vial. Tightly close the vial immediately after you have removed the test strip.
- Do not use the meter if it is dropping into water or splashing water on to it.
- Wash and dry your hands well before and after testing.
- Test strips and 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™ Ino/Fad test strip with your VivaChek™ Fad Sync meter.
- Use only VivaChek™ Ino/Fad control solution with your VivaChek™ Fad Sync meter and VivaChek™ Ino/Fad 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 and lancing device are 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 and lancing device.
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 <https://www.fda.gov/medical-devices/in-vitro-diagnostics/letter-manufacturers-blood-glucose-monitoring-systems-listed-fda>. 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.
- When using with VivaChek™ Fad test strips, very high (above 70%) hematocrit levels can cause false results.
- When using with VivaChek™ Ino test strips, very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your health care professional to find out your hematocrit level.
- If you are taking vitamin C (ascorbic acid in your blood > 3 mg/dL) then your glucose results using this meter may not be reliable.
- Patients undergoing oxygen therapy may cause false result.
- Not for use on patients with critical illness.

- Not for use on patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis).
- The VivaChek™ Fad Sync Blood Glucose Monitoring System should not be used following xylose absorption procedures.
- Not for neonatal use.
- Not for screening or diagnosis of diabetes mellitus.
- Not for use in hypotensive individuals.
- Do not use at altitudes above 13123ft (4000 meters) above sea level.

Note:

- The system is tested to accurately read the measurement of glucose in whole blood within the range of 20 to 600 mg/dL.

Note:

This meter complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This meter may not cause harmful interference, and (2) this meter 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 meter.

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

This meter 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. The meter 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 meter 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.

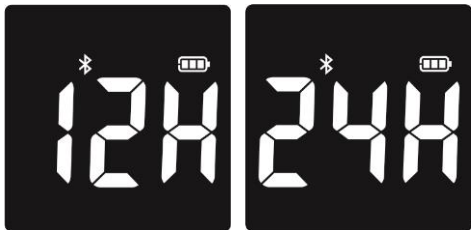
This meter complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

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.

1. Set the Clock

Set the clock for either 12 or 24 hour mode Press to adjust it then press and hold to save your choice. Start setting the year, month and date.





2. Set the Date

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



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





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





Note:

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

3. Set the Time



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



The minute will now flash. Press  to adjust the minute, press and hold  to set.



Set the Audio Feature

After you set the time, press  to select "On" or "OFF". Press and hold  to set.



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



Pairing Your Meter with the Smartphone

Pairing prepares your VivaChek™ Fad Sync Meter and Smartphone to communicate with each other. The distance between the meter and Smartphone should be within 5 meters. Download the VivaGuard™ app before pairing your meter and Smartphone.



WARNING

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

Syncing to send results wirelessly to the app

The first time you sync, the Smartphone will set the time in the meter. The Smartphone checks and updates the date and time in your meter each time you sync. Check the date and time on your Smartphone often to be sure they are correct.

NOTE: It is important to sync the meter and app before testing for the first time. This will ensure that the correct date and time are attached to your test results. Any glucose results from tests taken before your initial Sync will never be sent to the app.

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

1. When you turn on your meter, the (📶) symbol will appear to indicate Bluetooth® is on.
2. To turn on Bluetooth® on your Smartphone.
3. Open the VivaGuard™ app on the Smartphone.
4. “√” will appear on the app to notify you that the meter is communicating with the app.

After the Syncing, the app will display a list of any new blood glucose results sent from the meter.

NOTE:

- The button will continue to blink with blue light after successful pairing.
- Please install anti-virus App on the Smartphone but not install App from any unknown source.

Using Your Meter without the App

The meter can be used without an Smartphone or the app. You can still test your blood glucose and review your results on the meter screen.

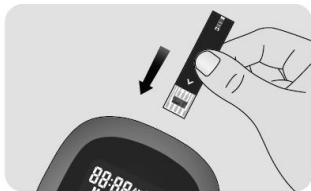
Your meter automatically stores up to 500 results with the time and date. Test results are stored from the newest to the oldest. If there are already 500 records in memory, the oldest record will be erased to make room for a new one.

CHAPTER 3: TAKING A TEST

Set up your meter correctly and have all the materials you will need ready before you begin testing. This including your VivaChek™ Fad Sync meter, the VivaChek™ Ino test strips and VivaChek™ lancing device with 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. Meter turns on after a beep.



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



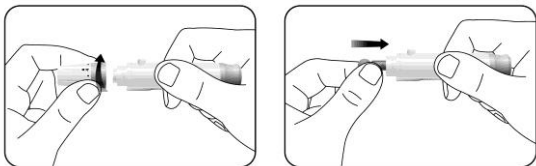
Note:

Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year/Month/Day format. 2022/01/01 indicates 1st January, 2022. Your VivaChek™ Ino/Fad test strips have 6 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water wash hands to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.

Preparing the Lancing Device

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

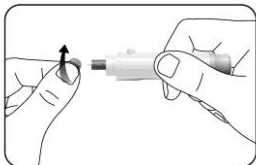
1. Unscrew the lancing device cover from the body of the lancing device. Insert a VivaChek™ sterile lancet into the VivaChek™ lancing device and push it until the lancet comes to a complete stop in the lancing device.



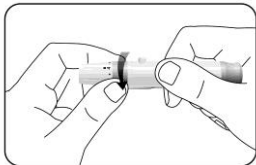
Note:

The VivaChek™ lancing device uses **ONLY** VivaChek™ sterile lancet.

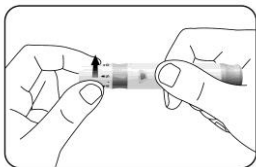
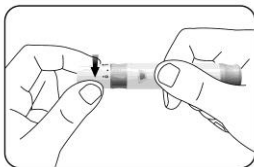
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for disposing used lancet.



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



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



Adjustment:

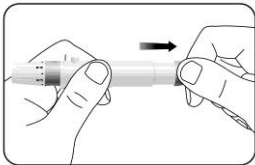
- 1 for delicate skin
- 2 and 3 for normal skin
- 4 and 5 for calloused or thick skin

Note:

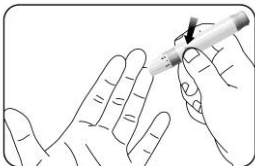
Greater pressure of the lancing device against the finger will also increase the puncture depth

Getting a Blood Drop and Testing

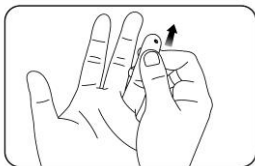
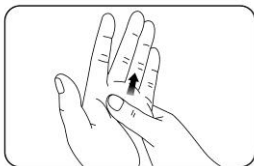
1. Pull the cocking barrel back to set the lancing device. You may hear a click; while the release button changes to orange color to indicate the lancing device is now loaded and ready for obtaining a drop of blood.



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



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



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



Discard the Used Test Strip

You can discard the used test strip by hand. The Meter turns off automatically after a beep.



Potential Biohazard

Dispose of the used test strips as medical waste.

Note:

1. 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!
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 and lancing device.

Warning:

- *If your blood glucose reading is under 50 mg/dL or you see LO (less than 20 mg/dL) on the meter display, contact your health care professional as soon as possible.*
- *If you test result is above 250 mg/dL or you see HI (greater than 600 mg/dL) on the meter display, contact your health care professional as soon as possible.*
- *Please contact your physician if you determine to make a change on your current medical therapy based on VivaChek™ Fad Sync test result.*

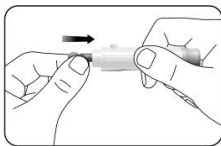
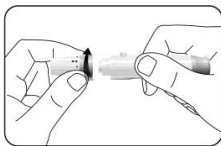
Alternative Site Testing

The forearm and palm areas have less nerve endings than the fingertip. Because of this, you may find that obtaining blood from these sites is less painful than from the fingertip. The procedure for forearm and palm sampling is different. You need the lancing device with clear cap to draw blood from these sites. The clear cap is not adjustable for puncture depth. And our starter kit is not included the lancing device, and please contact Customer Support at 800-951-8430 for information about purchasing the lancing device. Please contact your health care professional if you need help.

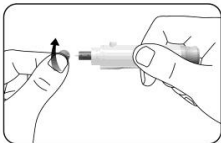
Blood samples for glucose testing may be taken from sites other than your fingertips. Alternative site testing using blood from the forearm or palm may give glucose results that significantly differ from fingertip blood. Differences occur when blood glucose levels are changing rapidly, such as after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

The lancing device with clear cap is not included in the kit. Please purchase it separately if you need. Please refer to the lancing device insert which you purchase for AST testing.

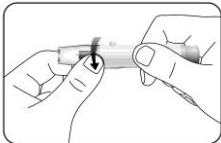
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it until the lancet is fully inserted.



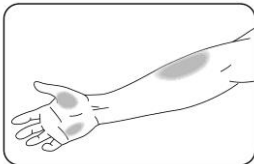
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it is loose, then pull the safety tab off the lancet. Save the safety tab for disposing of the used lancet.



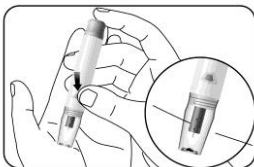
3. Screw the clear cap onto the lancing device.



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



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



Notes:

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

IMPORTANT: There are important differences among forearm, palm and fingertip samples that you should know. Important Information about forearm and palm glucose testing:

- You should consult your doctor before choosing to perform forearm or palm testing.
- When blood levels are changing rapidly, such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- You should use fingertips if testing is within 2 hours of a meal, insulin dose or exercise. You should also use fingertip testing any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

Glucose Reference Ranges:

Expected glucose values for people without diabetes:

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

Questionable or Inconsistent Results:

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

- Check the expiration date and the discard date of the test strip. Make sure that the test strip vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is between 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 (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 800-951-8430 (7 days a week. 9 a.m.-5 p.m. Eastern Time). Please contact your health care 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
- Your test result does not match with how you feel

About the Control Solutions

- Only use VivaChek™ Ino/Fad Control Solutions (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. 2022/01/01 indicates 1st, January, 2019.
- Do not use control solution that is out of the expiration date or discard date (the control solution will expire 6 months after the bottle is opened for the first time).
- Shake the bottle well before use.

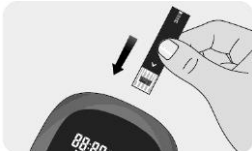
- Close the bottle tightly after use.

Performing a Control Test

1. Remove 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.

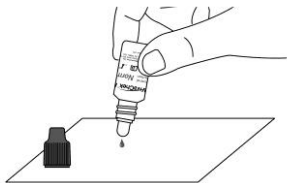
2. Insert a test strip into the meter in the direction of the arrows.



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



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



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

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

Note:

If the control solution sample does not fill the check window, do not add a second

drop. Discard the test strip and start over with a new test strip.

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

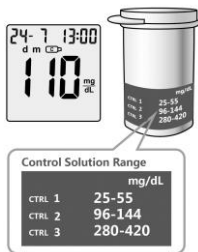


Note:

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

Understand Your Control Test Result

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



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 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 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 bottle have been tightly capped.
- Make sure the test strip was used immediately after removing from the test strip vial (or the foil pouch).

- *Make sure the control solution was mixed well.*
- *Confirm that you are using VivaChek™ Ino/Fad brand control solution.*
- *Make sure that you followed the test procedure correctly.*

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip vial label, your meter or test strips may not be working properly. **DO NOT** use the system to test blood. Contact VivaChek Customer Support at 800-951-8430 (7 days a week, 9 a.m.-5 p.m. Eastern Time) for help. Please contact your health care 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 500 results with the time and date. Test results are stored from the newest to the oldest.

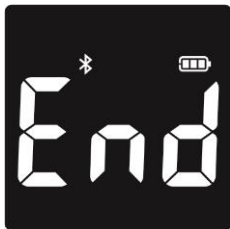
Notes:

- *If there are already 500 records in memory, the oldest record will be erased to make room for a new one.*

Viewing Your Test Results

When your meter is off, press  to turn the meter on. After a beep, a symbol of a test strip flashes on the display. Continue to press  to review previous results in order. Results will be shown starting with the most recent. Each result will show the date and time the test was taken.


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




CHAPTER 4: MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended.

Recharging the Battery

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

When the Empty Battery symbol () appears by itself on the screen, the meter cannot be used. You must recharge the battery before using your meter.

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)*

If you need the Micro USB cable or AC adapter which are not included in your kit, please contact your local distributor.



Caution:


- Do Not charge the meter outdoors or in a wet area.
- Do Not use the Micro USB cable, AC adapter or meter if it is damaged, discolored, abnormally hot, or has an unusual odour. Contact your local distributor.
- Do Not plug the AC adapter into a wall socket and leave it unattended.
- Verify that the wall socket voltage matches the AC adapter voltage.
- Do Not allow unsupervised children to charge the meter battery.



Caution:

Do Not insert a test strip when the meter is connected to a computer or wall outlet.

NOTE:

- *Using the Micro USB cable or AC adapter charges the battery in about 2 hours.*
- *When using the USB port on your computer to charge the battery, be sure the computer is turned on and not in standby mode. If the meter does not charge, try using another USB port on your computer.*
- *To optimise battery life, it is best to recharge the battery when the Low Battery symbol () appears.*



Caution:

- *If you use the AC adapter which not provided by VivaChek, be ensure it meets the standard EN 60950-1;*
- *If you use the USB port on your computer to charge the battery, be ensure it meets the standard IEC60950.*

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™ Fad Sync Blood Glucose 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™ Fad Sync Blood Glucose 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™ Fad Sync Blood Glucose Meter.

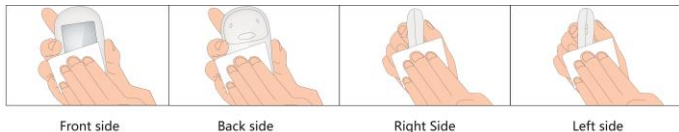
Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. After use and exposure to blood, all parts of this kit can potentially transmit infectious diseases. Disinfecting reduces the risk of transmitting infectious diseases.

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.

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.

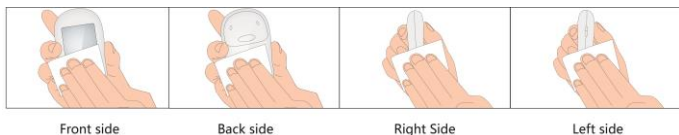


The meter should be cleaned whenever they are visibly dirty or a minimum of once per week. This pre-cleaning is to prepare the meter surface for a disinfection process.

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 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™ Fad Sync system. Clorox™ Healthcare Germicidal Bleach 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:



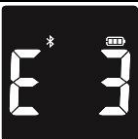


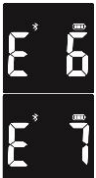
- Do not use alcohol or any other solvent.
- Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the data port.
- Do not squeeze the wipe or gauze into test strip port.
- Do not spray cleaning solution on the meter.
- Do not immerse the meter in any liquid.







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 800-951-8430 (available 7 days a week, 8 a.m.- 5 p.m. Eastern Time). Please contact your health care professional if you need help outside of these hours.

Troubleshooting Guide

What You See	What It Means	What You Should Do
	<p>Blood or control solution was applied to the test strip before the flashing blood drop appeared on the display</p>	<p>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.</p>
	<p>The meter is sensing a used or contaminated test strip.</p>	<p>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.</p>
	<p>Incorrect test strip.</p>	<p>Discard the test strip and repeat the test with a new test strip. Make sure that you are using a VivaChek™ Ino /Fad test strip from VivaChek Biotech (Hangzhou) Co., Ltd..</p>
	<p>Incorrect sample.</p>	<p>Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and VivaChek™ Ino/Fad control solution are used for the test.</p>
	<p>Temperature out of range.</p>	<p>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.</p>
	<p>Potential software or hardware issue.</p>	<p>Restart the meter. If the problem continues, contact VivaChek Customer Support at 800-951-8430 (available 7 days a week, 8 a.m.- 5 p.m. Eastern Time). Please contact your health care professional if you need help.</p>

	<p>A test strip was inserted while the meter was connected to a computer or wall outlet.</p>	<p>When the charge is completed (about 2 hours when charging an empty battery), remove the Micro USB cable from the meter, and then take a test.</p>
	<p>Insufficient sample.</p>	<p>Repeat the test and apply enough sample to fill the test strip check window.</p>
	<p>The test result is above 600 mg/dL.</p>	<p>Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.</p>
 <p>Caution: Glucose levels above 250 mg/dL may indicate a potential serious medical condition.</p>		
	<p>The test result is below 20 mg/dL.</p>	<p>Repeat the test using a new test strip. If your result still flashes LO, contact your health care professional as soon as possible.</p>
 <p>Caution: Glucose levels below 50 mg/dL may indicate a potential serious medical condition.</p>		

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

Warning:

If you are experiencing any of these symptoms, test your blood glucose. If your test result is under 50 mg/dL or above 250 mg/dL, contact your health care professional immediately.

CHAPTER 5: TECHNICAL INFORMATION

System Specifications:

Feature	Specification
Measurement Range	20 to 600 mg/dL
Test Measured	Glucose in fingertip capillary whole blood
Sample	Fresh capillary whole blood
Sample Volume	0.8 μ L
Test Time	5 seconds
Power Source	Rechargeable 3.7 Volt Lithium Ion battery
Charging Current	100mAh,  Direct current
Battery Type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Glucose Units of Measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 500 records with date and time
Automatic Shutoff	2 minutes after last action
Dimensions	82 mm x 54 mm x 23 mm
Display Size	32mm x 32 mm
Weight	Approximately 53g
Operating Temperature	41-113°F
Operating Relative Humidity	10-90% (non-condensing)
Hematocrit Range	VivaChek™ Ino: 20-70% VivaChek™ Fad: 0-70%
Data Port	Micro USB
Bluetooth	Version 4.1 (syncing with a Smartphone for data and time)

The VivaChek™ Fad Sync Blood Glucose monitoring system was tested by XX lay users using capillary blood samples and three VivaChek™ Ino test strip lots. The results were compared to the YSI Model 2300 STAT PLUS Glucose Analyzer, a laboratory instrument. The tables below show how well the two methods compared.

Table 1-Linear Regression Results

Slope Y-Intercept Correlation coefficient(R) Number of sample Range tested
--

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™ Fad Sync Blood Glucose meter result.	Within ±5%	Within ±10%	Within ±15%	Within ±20%
The percent (and number) of meter results that match true blood glucose level within x%				

Accurate Results (Meter result is +/-15% of laboratory result)	
More Accurate Results (Meter result is +/-10% of laboratory result)	
Most Accurate Results (Meter result is +/-5% of laboratory result)	

Warranty

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

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.