

# VivaChek

## *Ino Sound*

Blood Glucose Monitoring System

## User's Manual



**VivaChek™**

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## **Blood Glucose Monitoring System**

Dear VivaChek™ Ino Sound System User,

Thank you for choosing the VivaChek™ Ino Sound Blood Glucose Monitoring System! VivaChek™ Ino Sound 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™ Ino Sound 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™ Ino Sound System.

### **Principle and Intended Use**

VivaChek™ Ino Sound Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sound Blood Glucose Meter and the VivaChek™ Ino Blood Glucose Test Strips. The VivaChek™ Ino Sound Blood Glucose Monitoring System (Meter Model: VGM09) is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. It is used at home as a way to monitor the effectiveness of diabetes control programs. This system is intended to be used by a single patient and should not be shared.

The VivaChek™ Ino Sound Blood Glucose Monitoring System is not used for the diagnosis of or screening of diabetes or for neonatal use.

The VivaChek™ Ino Blood Glucose Control Solution is for use with the VivaChek™ Ino Sound Blood Glucose Meter and VivaChek™ Ino Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

## TABLE OF CONTENTS

<b>1. Understanding Your Testing Tools.....</b>	<b>1</b>
Your Meter System Overview.....	1
Your Meter Display.....	2
Important Safety Information.....	4
Limitations.....	5
<b>2. Setting Up Your System.....</b>	<b>6</b>
Set the Time and Date.....	6
Set sound feature.....	6
Pairing your meter with the Smartphone.....	7
Using your meter without the app.....	8
<b>3. Taking a Test.....</b>	<b>9</b>
Preparing the Test Strip.....	9
Getting a Blood Drop and Testing.....	10
Discard the Used Test Strip.....	11
Testing with Control Solution.....	15
Using the Meter Memory.....	17
<b>4. Maintenance and Troubleshooting.....</b>	<b>18</b>
Replace Batteries.....	18
Caring for Your Glucose Monitoring System.....	18
Cleaning and Disinfection.....	18
Troubleshooting Guide.....	20
Symptoms of High or Low Blood Glucose.....	22
<b>5. Technical Information.....</b>	<b>23</b>
System Specifications.....	23
Warranty.....	24

## CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

### Your Meter System Overview

The VivaChek™ Ino Sound Blood Glucose Meter and Strip

**Electrocode end:**  
this end is inserted into  
the test strip port on  
the meter with facing  
up




**Sample tip:**  
where the blood  
is drawn in





## 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  for 3 seconds to see the complete display. All display segments will appear for 10 seconds. If you need more than 10 seconds 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.



Icon	What it Means
<b>88/88</b>	The top left area on the screen indicates the date.
<b>88:88</b>	The top right area on the screen indicates the time.
<b>d/m</b>	Date, month.
<b>AMEM</b>	Indicates average memory
	Indicates the alarms have been set.
	Indicates a low battery or it needs to be replaced.

	Center area on the display that shows test results or error codes.
	Indicates the system is ready to test.
	Control test result.
	Pre-meal marker.
	Post-meal marker.
<b>mg/dL</b> <b>mmol/L</b>	Test results are displayed as mg/dL or mmol/L according to local government regulation.
	Indicates the temperature is not suitable for testing.
<b>Ketone?</b>	Ketone warning.
<b>Hypo</b>	Indicates that a low test result may cause hypoglycaemia.
	Bluetooth
	Sound on or off

**Notes:**

Your VivaChek™ Ino Sound 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 either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL). This depends on your country's standard unit of measurement. This unit of measure cannot be adjusted. The meter will be set to mg/dL by default when sold in the United States.
- 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 test strip with your VivaChek™ Ino Sound meter.
- Use only VivaChek™ Ino control solution with your VivaChek™ Ino Sound meter and VivaChek™ Ino strip.
- For self-testers, consult your physician or diabetes health care professional before making any adjustments to your medication, diet or activity routines.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.



### Potential Biohazard

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 safety lancet are for single patient use. Do not share them with anyone!
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. Cross-use of meter and lancing device may cause Bloodborne Pathogens Transmission. For more information, please refer to the FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) at

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.

You may also refer to the CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) at <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>.

## Limitations

- 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 > 3 mg/dL) then your glucose results using this meter may not be reliable.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 45 to 600 mg/dL.
- The VivaChek™ Ino Sound Blood Glucose Monitoring System has been tested and shown to work properly up to 9777ft (2980 meters).
- Critically ill patients should not be tested with this system.
- Patient who is taking oxygen therapy is not recommended for testing with VivaChek™ Ino Sound Blood Glucose Monitoring System.
- Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with VivaChek™ Ino Sound Blood Glucose Monitoring System.
- The VivaChek™ Ino Sound Blood Glucose Monitoring System should not be used following xylose absorption procedures.
- Not for neonatal use.
- Not for screening or diagnosis of diabetes mellitus.

**Note:** 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.

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

**Note:** 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.



## CHAPTER 2: SETTING UP YOUR SYSTEM

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

### Set the Time and Date

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

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

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

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

#### **Note:**


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

#### 2. Set the Time

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

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

### Set the sound feature

After set the time, the  and "On" will now flash. Press **side button** to select "On" or "OFF". Press and hold **power button** 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™ Ino Sound Meter and Smartphone to communicate with each other. The devices must be within 5 meters of each other to pair and sync. Download the GlucoWell™ app before pairing your meter and Smartphone.


**Note:** *it is compatible with iPhone mobile phones with iOS 8.0 or above operating system.*



### **WARNING**

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

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

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

**NOTE:** The button will continue to blink with blue light after successful pairing.

## Using your meter without the app

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

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


## CHAPTER 3: TAKING A TEST

Set up your meter correctly and have all the materials you will need ready before you begin testing. This including your VivaChek™ Ino Sound meter, the VivaChek™ Ino test strips and VivaChek™ Safety Lancets.

### Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial (or the foil pouch). Tightly close the vial cap immediately after you have removed the test strip.
3. Insert the test strip into the meter in the direction of the arrows. Meter turns on after a beep.



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

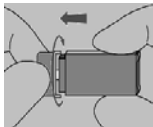
### Note:

Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month format. 2019/01 indicates January, 2019. Your VivaChek™ Ino test strips have 4 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.

## Getting a Blood Drop and Testing

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

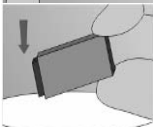
1. Carefully rotate and pull off the protective cap. Avoid placing your thumb or fingers over the uncapped end of the safety lancet.



2. Hold the safety lancet against the puncture site. **Note:** Before using a **single-use auto-disabling safety lancet** for blood sampling, wash both hands with soap and warm water and disinfect the puncture site with a topical skin antiseptic such as an alcohol swab.



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



4. Gently massage from the surrounding area toward the puncture site to collect the required blood volume.



For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make fingers sore and callused.

### Caution Statement

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

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



**Note:**

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

6. 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 slide the strip ejector to the direction of arrow. Meter turns off automatically after a beep.



**Potential Biohazard**

Dispose of the used test strips as medical waste.

**Alternative Site Testing**

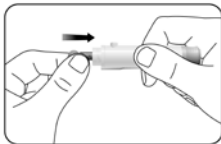
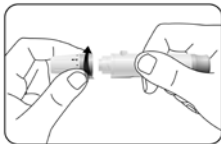
The forearm and palm areas have less nerve endings than the fingertip. Because of this, you may find that obtaining blood from these sites is less painful than from the fingertip. The procedure for forearm and palm sampling is different. You need the lancing device with clear cap to draw blood from these 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

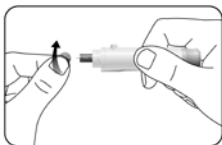
blood glucose levels are changing rapidly, such as after a meal, after insulin, and during or after exercise.

*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.*

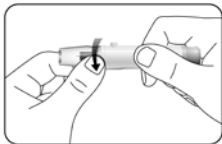
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it until the lancet is fully inserted.



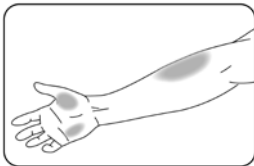
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it is loose, then pull the safety tab off the lancet. Save the safety tab for disposing of the used lancet.



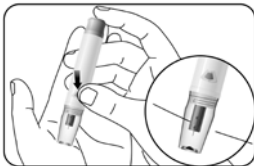
3. Screw the clear cap onto the lancing device.



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.



- 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.

### Expected Diabetes Control Goal:

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

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

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70-100	3.9 – 5.6
2 hours after meals	Less than 140	Less than 7.8

Reference:

1. ADA Clinical Practice Recommendations, 2015.

### 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.*
- *Do not change your medication therapy based on VivaChek™ Ino Sound test result before consult your health care provider.*
- *If you want to mark your result (only in Advanced Mode (L-2)) you will need to do it before removing the test strip.*

### 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 4 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.



## Testing with Control Solution

### Why Perform Control Tests

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

- At least once a week
- You open a new box of test 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

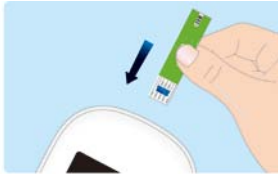
- Only use VivaChek™ Ino Control Solutions (1, 2 or 3) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not including in the average value calculation.
- Store the control solution at 36-86°F, 10-90% humidity.
- All expiration dates are printed in Year-Month format. 2019/01 indicates January, 2019.
- Do not use control solution that is past the expiration date or discard date (the control solution will expire 4 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.

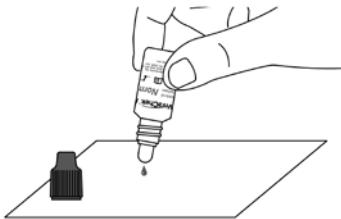
**Note:** Check the expiration and discard dates of the test strips. Do not use the expired test strip.

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.*

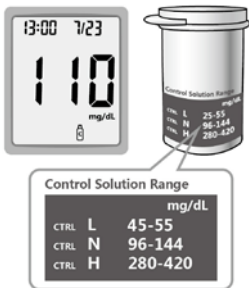
6. Hold it in the drop until the meter beeps, and then you see the meter count down on the screen and followed with your control test result after a beep.

**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 4 months. Discard any expired test strips or control solution.
- Confirm the temperature in which you are testing is between 59-104°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 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.

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



**Using the Meter Memory**

Your meter automatically stores up to 1000 results with the time and date. Test results are stored from the newest to the oldest.

**Notes:**

- If there are already 1000 records in memory, the oldest record will be erased to make room for a new one.
- It is very important to set the correct time and date in the meter, please make sure the time and date are correct after you change your batteries.

**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 for best results.

### Replace the Battery

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

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

**Note:**

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

3. Lift out the old batteries.
4. Place the new batteries under the prongs and into the battery compartment.
5. Slide the battery cover back into place, lining up with the open slots, and close firmly.



**Warning:**

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

### Caring for Your 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™ Ino Sound 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™ Ino Sound 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™ Ino Sound 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.

### **Cleaning your meter**

The meter should be cleaned whenever they are visibly dirty or a minimum of once per week. For cleaning, first use one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) to clean the entire meter surface for 1 minute. This pre-cleaning is to prepare the meter surface for a disinfection process.

### **Disinfecting your meter**

The meter should be disinfected a minimum of once per week. The meter disinfection process has been validated through repeated disinfection cycles, which is equivalent to 5 years of meter usage based on once daily cleaning and disinfection processes. This is to ensure that your meter will operate properly, even with the disinfection process applied to it for 5 years.

After cleaning your meter, use one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) to wipe the meter. The wipe will be wiped using 2 pass, where one pass equals a back and forth motion for a total of 4 motions. And then, please expose the meter to air dry for at least 2 minute as specified on the disinfectant wipe manufacturer's label.

Disinfection is performed using one wipe to ensure that the treated the surface of the meter remained visibly wet during the contact time.

Clorox™ Healthcare Bleach Germicidal Wipes containing Sodium hypochlorite 0.55%, which has been proven to be safe to use with the VivaChek™ Ino Sound system. Clorox™ Healthcare Bleach Germicidal Wipes are available through CLOROX PROFESSIONAL PRODUCTS CO. You can purchase them by visiting their website at [www.cloroxprofessional.com](http://www.cloroxprofessional.com). Clorox™ Healthcare Bleach Germicidal Wipes are also available at internet retailers such as [www.amazon.com](http://www.amazon.com), or for more information call 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.

Wash hands thoroughly with soap and water after disinfecting procedure.

### **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. Stop using the meter and please contact Customer Support for help.*

If you have questions about cleaning or disinfecting, 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.

**Troubleshooting Guide**

<b>What You See</b>	<b>What It Means</b>	<b>What You Should Do</b>
<b>E1</b>	Blood or control solution was applied to the test strip before the flashing drop appeared on the display	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
<b>E2</b>	The meter is sensing a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
<b>E3</b>	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a VivaChek™ Ino test strip from VivaChek Laboratories, Inc..
<b>E4</b>	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 can be used for the test.
<b>E5</b>	Temperature out of range.	Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test.

<b>E6,E7</b>	Potential software or hardware issue.	Take out batteries and 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.
<b>E10</b>	Insufficient sample.	Repeat test and apply enough sample to fill the test strip check window.
<b>E11</b>	Indicates a low battery.	Replace new batteries.
<b>Hi</b>	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 flashes HI, contact your health care professional as soon as possible.
 <b>Caution:</b> Glucose levels above 250 mg/dL(13.9 mmol/L) may indicate a potential serious medical conditions.		
<b>Lo</b>	Test result is below 45 mg/dL.	Repeat the test using a new test strip. If your result still flashes LO, contact your health care professional as soon as possible.
 <b>Caution:</b> Glucose levels below 50 mg/dL (2.8 mmol/L) may indicate a potential serious medical conditions.		

## 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	45 to 600 mg/dL
Result calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample volume:	0.8 $\mu$ L
Test time	5 seconds
Power source	Two AAA LR03 1.5V batteries
Glucose units of measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 1000 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	89 mm x 52 mm x 25 mm
Display size	32 mm x 32 mm
Weight	Approximately 63g
Operating temperature	41-113°F
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%
Data port	Micro USB
Bluetooth	Version 4.1

**Warranty**

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

**VivaChek Laboratories, Inc.**

913 N market Street

Wilmington, De, 19801, USA

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.*