

VivaChek™ Ino X

Blood Glucose Monitoring System

Dear VivaChek™ Ino X System User,

Thank you for choosing the VivaChek™ Ino X system! The VivaChek™ Ino X blood glucose monitoring system is designed for easy testing of blood glucose and helps you to keep your blood glucose under control. The VivaChek™ Ino X system is fully compliant with the new EN ISO 15197:2015 International Standard.

Read this User Manual carefully before you use your meter system. This manual will help you to become familiar with using the VivaChek™ Ino X blood glucose monitoring system and get reliable test results. Please keep your User Manual in a safe place; you may want to refer to it in the future.

Thank you again for choosing the VivaChek™ Ino X System.

Principle and Intended Use

The VivaChek™ Ino X system (Meter Model: VGM49) is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The VivaChek™ Ino X blood glucose test is based on the measurement of an electric current caused by the reaction of glucose with the reagents on the electrode of the test strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample then reacts with an enzyme and mediator, generating electrons, which produce a current that is proportional to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed. The meter is calibrated to display plasma-like concentration results.

The VivaChek™ Ino X system is intended for external use (*in vitro* diagnostic use) at home, by people with diabetes and by health care professionals in a clinical setting, as an aid to monitor the effectiveness of diabetes control. The system should not be used for the diagnosis of diabetes.

TABLE OF CONTENTS

1. Understanding Your Testing Tools.....	1
Your Meter System Overview.....	1
Your Meter Display.....	1
Important Safety Information.....	4
2. Setting Up Your System.....	5
Set the Time and Date.....	5
Set the audio feature.....	6
Set the test alarm	6
Set the Hypoglycaemia (Hypo) Warning.....	7
Set the Ketone Warning.....	7
3. Taking a Test.....	7
Preparing the Test Strip.....	7
Preparing the Lancing Device.....	8
Getting a Blood Drop and Testing.....	9
Marking Blood Glucose Results.....	10
Alternative Site Testing.....	13
Testing with Control Solution.....	14
Using the Meter Memory.....	18
4. Maintenance and Troubleshooting.....	19
Changing the Battery.....	19
Caring for Your Glucose Monitoring System.....	20
Troubleshooting Guide.....	20
Symptoms of High or Low Blood Glucose.....	22
5. Technical Information.....	23
System Specifications.....	23
Limitations.....	24
Index of Symbols.....	25
Warranty.....	26

CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

Your Meter System Overview

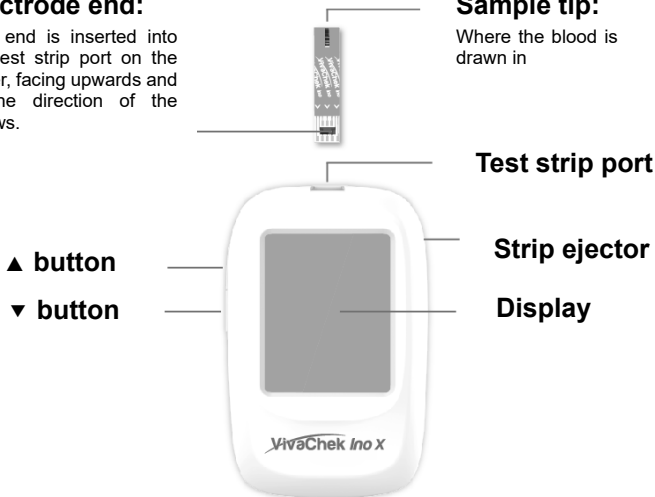
The VivaChek™ Ino X Blood Glucose Meter and Strip

Electrode end:

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

Sample tip:

Where the blood is drawn in





Your Meter Display

The picture below shows all the symbols that appear on your meter display. To make sure the display is working properly, with the meter off, press and hold ▼ button for 2 seconds to see the complete display. All display segments will appear for 3 seconds. If you need more than 3 seconds to check the display, shut down and restart. All of the segments should be clear and exactly like the picture below. If not, contact your local distributor for help.



Icon	What it Means
	The top left area on the screen indicates the date.
	The top right area on the screen indicates the time.
d/m/d	Date, month format.
	The meter failed to sync with the Smartphone.
M	Memory.
A	Indicates the average value.
	Indicates a low battery or it needs to be replaced.
	Indicates the alarms have been set.
	The centre area on the display, this shows test results or error codes.
	Indicates the system is ready to do a test.
Ketone?	Ketone warning.
	Pre-meal marker.
	Post-meal marker.

	Control test result.
mg/dL mmol/L	Test results are displayed as mg/dL or mmol/L according to local government regulations
	Indicates the temperature is not suitable for testing.
Hypo	Indicates that a low test result may cause hypoglycaemia.

Notes:

Your VivaChek™ Ino X meter is pre-set with a beep sound function, the meter will beep when:

- You turn on the meter.
- the test strip is inserted and it is ready for blood or control solution to be applied.
- sufficient blood or control solution is drawn 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 pre-set to display blood glucose concentration in either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on which unit of measurement is standard in your country. This unit of measurement cannot be adjusted.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extremes of temperature or humidity. Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Quality Control Test**.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to the **Caring for Your Meter** section for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used battery.

All Glucose systems preventive warnings with regard to EMC

1. This meter is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this meter in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause inaccurate results.
2. This meter complies with the emission and immunity requirements described in EN61326-1 and EN61326-2-6. Do not use this meter in close proximity to sources of strong electromagnetic radiation as it may interfere with proper operation of the meter.
3. For professional use, the electromagnetic environment should be evaluated prior to operation of this meter.

Important Safety Information

- 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 wet.
- Wash and dry your hands well before and after testing.
- Test strips and lancets are for single use only.
- **DO NOT DROP BLOOD DIRECTLY ON TO THE FLAT SURFACE OF THE TEST STRIP.**
- Check the expiry dates and discard dates on your test strips vial label and control solution bottle label.
- Use only VivaChek™ Ino test strips with your VivaChek™ Ino X system.
- Use only VivaChek™ Ino control solution with your VivaChek™ Ino X system.
- Following a self-test always consult your 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 will be impaired.



Potential Biohazard

Healthcare professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects, which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.

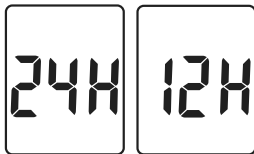
CHAPTER 2: SETTING UP YOUR SYSTEM

Before you use your meter for the first time or if you change your meter battery, you must check and update your meter settings.

Set the Time and Date

1. Enter the setting mode and set the clock

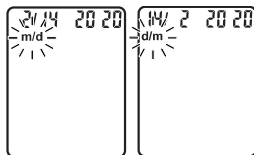
When the meter is off, press the ▼ button for 2 seconds to enter the meter setup mode. The meter will automatically enter the setup mode when turned on for the first time by any method.



Set the clock for either 12 or 24 hour mode. Press the ▲ button to switch between the two settings. Then press the ▼ button to save your choice and start setting the year, month and date.

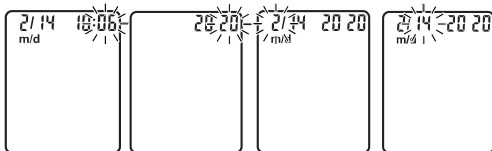
2. Set the Month and Date Format

d/m will now flash on the display. Press ▲ button to select the format you wish (d/m for date/month format or m/d for month/date format). Press ▼ button to set.



3. Set the date

The year will appear at the top of the display. Press the ▲ button until the correct year is displayed. Once you have selected the correct year, press the ▼ button to save your choice and start setting the month. Press the ▲ button until the correct month is displayed. Then press the ▼ button to save your choice and start setting the date. Press the ▲ button until the correct date is displayed. Then press the ▼ button to save your choice and start setting the time.



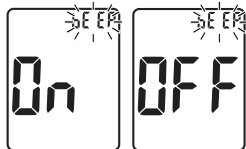
4. Set the time

The hour will appear at the top of the display. Adjust the hour with the ▲ button until the correct hour is displayed. Press the ▼ button to save your choice and

set the minutes. Press the ▲ button to change to the correct minute. Press the ▼ button to save your choice and move to set the audio feature.

Set the audio feature

After setting the time, the bEEP will now flash. Press the ▲ button to set ON or OFF, press ▼ button to save the audio setting.



Set the test alarm

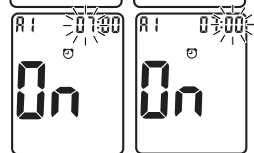
Your meter is pre-set with the test alarm function to “OFF”. You can set up to 5 test alarms per day. If you turn 5 test alarms on (A1, A2, A3, A4 and A5), your meter is pre-set with the following times for your convenience. You can adjust each time to suit your needs.

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

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



After you set the audio feature/ talking feature, the ☺ and the word “OFF” will be displayed, symbol “A1” flashes. Press ▲ button to turn the alarm function on or off, and press ▼ button to confirm.



If you select “On”, the hour flashes, “A1” and the ☺ remains on the display. Press ▲ button to select the hour. Press ▼ button to set.

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

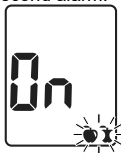
The next alarm “A2” flashes on the display with ☺ and “OFF”

You can set a second alarm by pressing ▲ button to turn on the second alarm.

Do the same procedures to set the rest of the alarms.

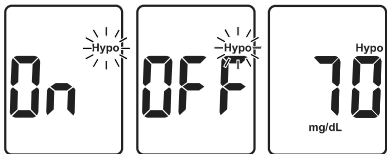
Set the Meal Marker

After setting the test alarm functions, the symbols of 🍏 🍷 will now flash, along with word “On” on the display. Press the ▲ button to turn the meal marker function on or off, press ▼ button to set



Set the Hypoglycemia (Hypo) Warning

After setting the meal marker, the **Hypo** flashes on the display along with “On” on the display. Press **▲** button to turning the Hypo alarm function on or off, press **▼** button to set. If you select the hypo alarm “on”, the display shows 70 mg/dL with the symbol of “Hypo” on the display, Press **▲** button to select the level you want, press **▼** button to set.

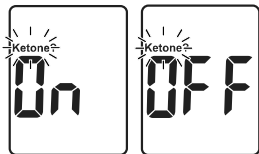


Set the Ketone Warning

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

After setting Ketone Warning, the screen will show all symbols which you have set before.

Press **▼** button for 2 seconds and the meter will be turned off.

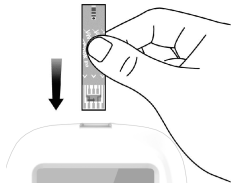


CHAPTER 3: TAKING A TEST

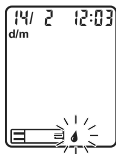
Set up your meter correctly and have all the materials you will need ready before you begin the test. This includes your VivaChek™ Ino X meter, the VivaChek™ Ino test strips and VivaChek™ lancing device with VivaChek™ lancets.

Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial or 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. The meter turns on after a beep.
 4. A symbol of a test strip with a flashing blood drop will appear letting you know the meter is ready to use.

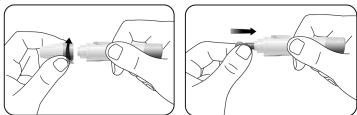


Note: Check the expiry and discard dates on the test strip vial. All expiration dates are printed in Year-Month format. 2021-01 indicates January, 2021. Your VivaChek™ Ino test strips have 6 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or wash with soapy water. Using warm water to wash your hands can help to increase blood flow if necessary. 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 of 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 is fully inserted.



Note:

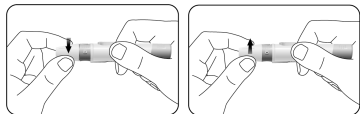
The VivaChek™ lancing device uses ONLY VivaChek™ sterile lancets.

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

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



- 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.



Adjusting the puncture depth:

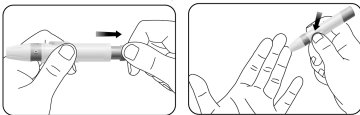
- 1 for delicate skin
- 2 and 3 for normal skin
- 4 and 5 for calloused or thick skin

Note:

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

Getting a Blood Drop and Testing

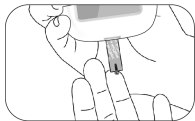
- Pull the cocking barrel back to set the lancing device. You may hear a click to indicate the lancing device is now loaded and ready for obtaining a drop of blood.
- Press the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device is activated.



3. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the blood drop. Lance on the side of the fingertip to help reduce any pain. Test immediately after a good blood drop has formed.



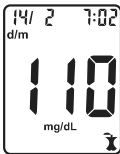
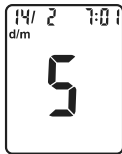
4. Immediately touch the tip of the test strip to the drop of blood. The blood is drawn into the test strip through the tip. Make sure that the blood sample has fully filled the sample tip on the test strip. Hold the tip of the test strip in the blood drop until the meter beeps.




Note:


If the blood sample does not fill the sample tip, 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.

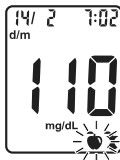





Marking Blood Glucose Results

You can set your meter to use meal marker options by using  on. Your meter will display two markers after you test your blood.

 Pre-meal marker: marks a test result that was taken before the meal.

 Post-meal marker: marks a test result that was taken after the meal.



After testing and your blood glucose result is displayed, pre-meal marker  and post-meal marker  appear on the meter display, and pre-meal marker 

flashes, press ▲ button to select the marker you want to set, press ▼ button to confirm.

If you do not want to mark the test result, simply remove the used test strip to automatically save the test result in the meter memory without the marker. The meter will turn off automatically. Dispose of the used test strip and lancet properly.

Discard the Used Test Strip

You can discard the used test strip by sliding the strip ejector forwards. The meter turns off automatically after a beep.



Potential Biohazard

Dispose of the used test strips as medical waste.

Expected Diabetes Control Goal:

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

The American Diabetes Association suggests the following targets for most non-pregnant adults with diabetes. More or less stringent glycemic goals may be appropriate for each individual. Consult your doctor or health care professional for the target value that is appropriate for you.

Expected blood glucose levels for most non-pregnant adults with diabetes:¹

Time	Range, mg/dL	Range, mmol/L
Before a meal	70 – 130	3.9 – 7.2
1-2 hours after beginning of the meal	Less than 180	Less than 10

Reference:

1. ADA Clinical Practice Recommendations, 2014.

Warning:

- If your blood glucose reading is under 50 mg/dL (2.8 mmol/L) or you see LO

(less than 10 mg/dL (0.6 mmol/L)) on the meter display, contact your doctor or health care professional as soon as possible.

- *If your test result is above 250 mg/dL (13.9 mmol/L) or you see HI (greater than 600 mg/dL (33.3 mmol/L)) on the meter display, contact your doctor or health care professional as soon as possible.*
- *Do not change your medication based on the VivaChek™ Ino X test result before you consult your doctor or health care professional.*
- *If you want to mark your result you will need to do it before removing the test strip.*

Questionable or Inconsistent Results:

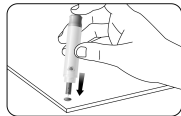
If your blood glucose result does not match how you feel, please:

- Check the expiry date and the discard date of the test strip. Make sure that the test strips vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is between 5 and 45°C (41-113°F).
- Make sure that the test strip vial has been tightly capped.
- Make sure the test strips have been stored in a cool, dry place.
- Make sure the test strip was used immediately after removing it from the test strip vial or foil pouch.
- Make sure that you followed the testing procedure correctly.
- Perform a control solution test (See **Performing a Control Test** for instructions).

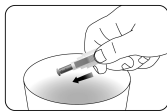
After checking all of the conditions listed above, repeat the test with a new test strip. If you are still unsure of the problem, please contact your local distributor.

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 discard the used lancet. Place the lancing device cover back on the lancing device.



Potential Biohazard

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



Caution:

- *Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.*
- *Do not use the lancet if the needle is bent.*
- *Take care whenever the lancet needle is exposed.*
- *Never share lancets or the lancing device with other people in order to prevent possible infections.*
- *In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.*
- *Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.*

Alternative Site Testing

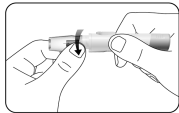
Blood samples for glucose testing may be taken from sites other than your fingertips. Alternative site testing using blood from the forearm or palm may give glucose results that significantly differ from fingertip blood. Differences occur when blood glucose levels are changing rapidly, such as after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

The forearm and palm areas have less nerve endings than the fingertip. You may find obtaining blood from these sites less painful than from the fingertip. The

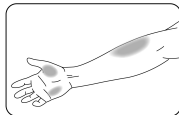
procedure for forearm and palm sampling is different. You need the clear cap to draw blood from these sites. The clear cap is not adjustable for puncture depth.

Follow Step 1 and 2 of “Preparing the Lancing Device” to insert the lancet and load the lancing device.

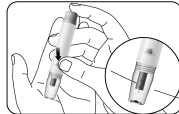
3. Screw the clear cap onto the lancing device.



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

Testing with Control Solution

Why Perform Control Tests?

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

- When you open a new box of test strips
- When you want to check the meter and test strips
- If your test strips were stored in extreme temperature or humidity
- After cleaning your meter
- If you dropped the meter
- If your test result does not match with how you feel

About the Control Solutions

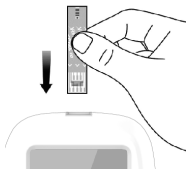
- Only use VivaChek™ Ino Control Solutions (Low, Normal or High) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not included in the average value calculation.
- All expiration dates are printed in Year-Month format. 2021-01 indicates January, 2021.
- Do not use a control solution that is past the expiry 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

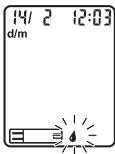
1. Remove a test strip from the test strip vial or foil pouch. Tightly close the vial cap immediately after you have removed the test strip.

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

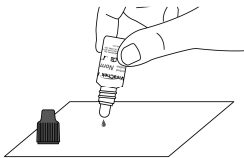
2. Insert a test strip into the meter in the direction of the arrows.



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.



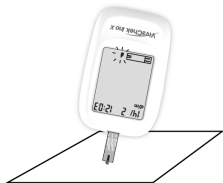
4. Shake the control solution bottle thoroughly. Squeeze the control solution bottle gently and discard the first drop. Squeeze out a second small drop on a clean nonabsorbent surface.



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

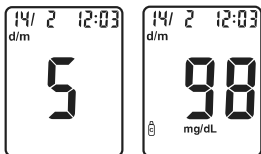
5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is drawn into the test strip through the strip tip.

Note: If the control solution sample does not fill the sample tip, do not add a second drop.



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

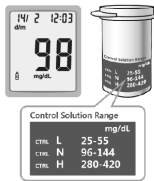
6. Hold the test strip in the control solution until the meter beeps, and then you will see the meter count down on the screen and the control test result will be shown after another beep.



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.

Understanding Your Control Test Result

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



Notes:

If your control test result is out of range:

- Check the expiry dates and discard dates of the test strips and control solution. Make sure that the test strips vial has not been opened for more than 6 months and the control solution bottle has 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 15 and 40°C (59-104°F).
- Make sure that the test strip vial and the control solution bottle have been

tightly capped.

- *Make sure the test strip was used immediately after removing it from the test strip vial or foil pouch.*
- *Make sure the control solution was shaken well before use.*
- *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 outside of the range indicated on the test strip vial label or on the foil pouch, your meter or test strips may not be working properly. **DO NOT** use the system to test blood. Contact your distributor for 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 not be included in your blood glucose averages.

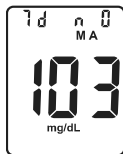
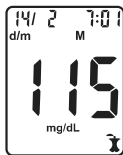
Using the Meter Memory

Your meter automatically stores up to 900 results with the time and date. Test results are stored from the newest to the oldest. The meter will also calculate the average values of records from the last 7, 14 and 30 days.

Notes:

- *If there are already 900 records in memory, the oldest record will be erased to make room for a new one.*
- *It is very important to set the correct time and date in the meter, please make sure the time and date are correct after you change your battery.*
- *Control results are not included in the 7, 14 and 30 day average calculation.*

1) When your meter is off, press ▼ button to turn the meter on, after a beep, a symbol of a test strip flashes on the display, press ▼ button again to enter memory mode. The most recent value and the word "M" will appear on the display.



2) If you are using the meter for the first time, the meter display will show three dashed lines (---), the letter "M" and the unit of measure. This shows that no data have been stored in memory.

3) The date and time will be displayed together with the results stored in memory.



4) Press the ▲ button to go through the stored records.

5) Press the ▼ button to view the data averages. The letter "A" will appear on the screen. If you do not wish to view your average glucose measurements, you can press the ▼ button again to turn off the display.

CHAPTER 4: MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended for best results.

Changing the Batteries

Batteries should be replaced when the meter continually displays , or the meter shows  then turns off.

1. Turn off your meter before changing the batteries.
2. Press firmly on the batteries cover and slide in the direction of the arrow.



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 batteries compartment.
5. Slide the batteries 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 battery according to your local environmental regulations.

Caring for Your Glucose Monitoring System

Blood Glucose Meter

Your VivaChek™ Ino X Blood Glucose Meter does not require special maintenance or cleaning. A damp cloth and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip or data ports. It is recommended that you store the meter in the carrying case after each use.


The VivaChek™ Ino X Blood Glucose Meter is a precision electronic instrument. Please handle it with care.

Lancing Device

Clean the lancing device using a soft cloth with mild soap and warm water as required. Use 70% Isopropyl Alcohol to disinfect the lancing device. Carefully dry the lancing device. **Do not immerse the lancing device in liquid.**

Troubleshooting Guide

What You See	What It Means	What You Should Do
E 1	Add sample or control solution before the flashing blood drop appears.	Discard the test strip and repeat the test with a new test strip. Add sample or control solution after you see the flashing blood drop on the display.
E 2	The meter is sensing the use of a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
E 3	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.

E 4	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using blood sample or VivaChek™ Ino control solution.
E 5	Temperature out of range.	Move to an area that is within the operating temperature for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test.
E 6 E 7	Potential hardware issue.	Take out battery and restart the meter. If the problem continues, contact your local dealer.
E 10	Insufficient sample.	Repeat test and apply enough sample to fill check window of the test strip.
E 11	Indicates a low battery.	Replace new batteries.
HI	Blood Glucose test result is above 600 mg/dL (33.3 mmol/L)	Wash and dry your hands, then repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.
 Caution: Glucose levels above 250mg/dL(13.9mmol/L) may indicate a potentially serious medical condition.		
LO	Test result is below 10 mg/dL (0.6 mmol/L).	Repeat the test using a new test strip. If your result still flashes LO, contact your doctor or health care professional as soon as possible.

**Caution:**

Glucose levels below 50mg/dL(2.8mmol/L) may indicate a potentially serious medical condition.

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
(Hypoglycaemia):**

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- fainting
- irritability
- seizure
- extreme hunger
- dizziness

**High blood glucose
(Hyperglycaemia):**

- 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 (2.8 mmol/L) or above 250 mg/dL (13.8 mmol/L), contact your doctor or health care professional immediately.

CHAPTER 5: TECHNICAL INFORMATION

System Specifications:

Feature	Specification
Measurement range	10 to 600 mg/dL (0.6-33.3 mmol/L)
Result calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample volume:	About 0.5 μ L
Test time	About 5 seconds
Power source	Two AAA LR03 1.5V batteries
Battery life	12 months or approximately 1,000 tests
Glucose units of measurement	The meter is pre-set to either millimoles per litre (mmol/L) or milligrams per decilitre (mg/dL) depending on the standard of your country
Memory	Up to 900 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	93.5 mm \times 60.5 mm \times 20 mm
Display size	47mm \times 37 mm
Weight	Approximately 67.4g (with battery installed)
Operating temperature	5-45°C
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%



















Limitations

The VivaChek™ Ino X meter, VivaChek™ Ino test strips and control solution have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.

- Fresh capillary blood may be collected into test tubes containing sodium heparin or lithium heparin if the blood is used within 10 minutes. Do not use sodium fluoride/oxalate or other anticoagulants or preservatives.
- Use only with whole blood. Do not use with serum or plasma samples.
- Very high (above 70%) and very low (below 20%) haematocrit levels can cause false results. Talk to your doctor or health care professional to find out your haematocrit level.
- Abnormally high levels of vitamin C and other reducing substances will produce false high blood glucose measurements.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 10 to 600 mg/dL (0.6-33.3 mmol/L).
- Fatty substances (triglycerides up to 3,000 mg/dL (166.7 mmol/L) or cholesterol up to 500 mg/dL (27.7 mmol/L)) have no major effect on blood glucose test results.
- The VivaChek™ Ino X Blood Glucose Monitoring System has been tested and shown to work properly up to 10,000ft (3,048 meters).
- Severely ill persons should not run the glucose test with the VivaChek™ Ino X Blood Glucose Monitoring System.
- Patients using oxygen therapy are not recommended for testing with VivaChek™ Ino X Blood Glucose Monitoring System.
- Blood samples from patients in shock, 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 X Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of materials.

Index of Symbols

These symbols may appear on the packaging and in the instructions for the VivaChek™ Ino X system.

Symbols	Explanation
	Consult instructions for use
	For <i>in vitro</i> diagnostic use only
	Manufacturer
	Temperature limitations
	Contains sufficient for <n> tests
	Use by
	Lot Number
	Authorised Representative
	Sterilised using irradiation
	Control range
	Catalogue number
	Model number
	Do not re-use
	Caution, consult accompanying documents
	Dispose of items according to local relevant laws regarding disposal and recycling
	Use by 6 months from the opening
	Series number
	Keep away from sunlight and heat

Warranty

Please complete the warranty card that came with this product and mail it to your distributor to register your purchase.

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.

Warranty Card

Please complete this warranty card to validate your warranty. Mail it within 30 days of purchase to the local dealer address labeled on the Starter Kit box to process the validation.

If the meter does not work for any reason other than obvious abuse in the first 5 years after purchase, we will replace it with a new or equivalent meter free of charge.

Date of purchase ____ / ____ / ____

Meter serial number (e.g.101A0000001)

Where purchased

Date of birth ____ / ____ / ____ Gender M F

Telephone number

Email address

Year/Age of Diabetes Diagnosis _____ / _____

How many times a week do you test your blood glucose?

What type of diabetes you have:

Type 1 Type 2 Pre-diabetes Gestational

Suggestion/Comments