



Dear EVOLUTION™ System Owner

Thank you for choosing The EVOLUTION™ blood glucose monitoring system. This manual contains everything you need to know about your new glucometer and how it works. Please take a moment to read the instructions carefully.

Customer Service is available 24 hours a day, 7 days a week, 365 days a year. Please call customer support toll free:

1-888-446-3246

Important information

The EVOLUTION™ system provides a quick and easy way for patients with diabetes to measure their blood sugar levels.

It should only be used with fresh capillary whole blood samples. It is designed for in-vitro diagnostics use only and should not be used for any purpose other than monitoring blood sugar levels. It should not be used for the diagnosis of diabetes or for the testing of newborns (neonates).

Warning:

Do not change your medication based on EVOLUTION™ meter test results without contacting your physician or healthcare professional.

Table of contents

About your new EVOLUTION™ system:

EVOLUTION™ KIT contents	6
EVOLUTION™ meter	7
EVOLUTION™ test strip	9

Before you test:

Comparing your meter and lab results	11
Setting the meter	13
Performing a control solution test	17

Performing your test:

Performing a blood test with your fingertip	20
Disposing of your test strips and lancets	26

Reviewing your results:

Reviewing your blood sugar	27
Reviewing your averages	28
Reviewing your results with user ID on	29

Alternate site test:

Performing a blood test with an alternate site	30
--	----

Caring for your EVOLUTION™ meter:

Cleaning and proper storage	38
Transferring your results	39
Battery installation	40
Troubleshooting	41
Warranty	46
Specifications	47

About Your New EVOLUTION™ System



The following items are included:

1. EVOLUTION™ meter
2. Owner's manual
3. Quick reference card
4. Warranty registration card
5. Carrying case
6. Patient logbook
7. Two 3V Li-CR2032 batteries

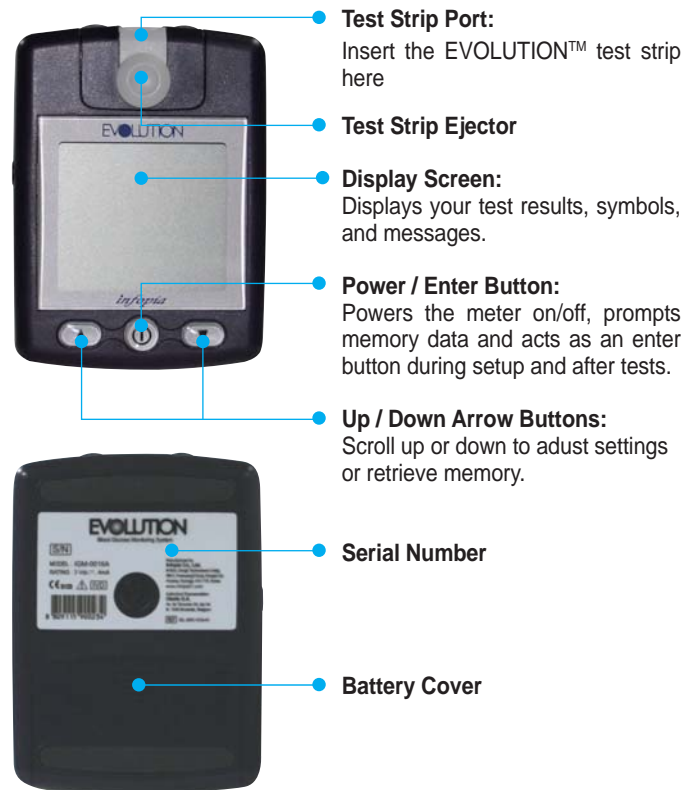
The following items may be included:

1. Lancing device
2. Lancet (5)
3. Control solution
4. Test strip (5)

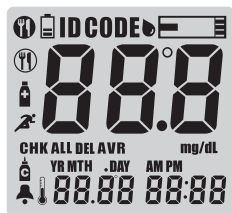
Your EVOLUTION™ blood glucose monitoring system has been sealed to protect the contents.

If you find your seal has been broken, please return it to the place of purchase.

About Your New EVOLUTION™ System



About Your New EVOLUTION™ System



Low battery warning



Test strip code



Ready for blood



Alarm clock



Before having a meal (full plate)



After having a meal (empty plate)



After taking medication



After exercise



Temperature / Date



Time



Test result unit



Control solution



Average test result

Use only EVOLUTION™ brand test strips with your EVOLUTION™ meter.



Target to apply blood

Confirmation Window

Contact Bar

1. Store the EVOLUTION™ test strip vials in a cool, dry place. Keep out of direct sunlight. Do not freeze.
2. Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
3. Immediately replace the vial cap and close tightly after removing any test strips from the vial.
4. Make a note of the discard date, which is three months from the date you first open a new vial of strips. Throw EVOLUTION™ test strips and vial away after the discard date.
5. Do not use the test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
6. EVOLUTION™ test strips are for single use only. DO NOT RE-USE.
7. Do not test at temperatures below 50°F or above 104°F.
8. Do not test with humidity below 10% or above 90%.
9. Do not bend, cut, or alter the test strip.
10. Avoid getting dirt, food, and water on the test strip. Do not handle test strips with wet hands.
11. Avoid getting dirt, food, and water on the color-coding label (backside of test strip).
12. Refer to additional information in the EVOLUTION™ test strip package.



Before Testing

Be sure to read this section and the test strip package insert found in the test strip box carefully. You will need to have all of the necessary items to begin testing:



1. EVOLUTION™ meter
2. EVOLUTION™ test strip
3. Lancing device
4. Sterile lancet

Always wash and dry your hands prior to testing.

If the meter is moved from one temperature to another, allow 30 minutes for the meter to adjust to the new temperature before testing.

Make sure that the EVOLUTION™ meter and test strips have adjusted to the temperature of the location from where you are testing.

Comparing your meter and laboratory results

Test results with the EVOLUTION™ blood glucose monitor are plasma-equivalent. This method will help you and your healthcare professional compare your meter results with laboratory test results. The EVOLUTION™ test result and laboratory test results both are expressed in plasma-equivalent units. However, your glucose monitor result may differ from your laboratory result due to normal variation. Your glucose monitor results can be affected by factors and conditions that do not affect laboratory results in the same way.

Your EVOLUTION™ monitor value is considered accurate when it is within $\pm 20\%$ of the laboratory measurement. There are some specific situations that could cause a difference of more than $\pm 20\%$.

1. You are severely dehydrated.
2. You have eaten recently. The blood glucose level from blood obtained from a fingertip can be up to 70mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.¹
3. Your hematocrit is above 60% or below 20%.

¹ Sacks, D.B.: *Carbohydrates: " Carboglydrates."* Burits, C.A. and Ashwood, E.R. (ed.), *Tietz Textbook of Clinical Chemistry*. Philadelphia: W.B. Saunders Company (1994), 959

Comparing your meter and laboratory results

You tested at a temperature near the low end of the operating range which could result in a false high blood sugar. Repeat the test in a warmer environment with a new test strip as soon as possible.

For additional information on possible limitations for accuracy on precision, please refer your test strip insert.

In order to make the most accurate comparison to your laboratory results. Please follow a few basic guidelines:

Before going to the lab

- Do not eat for at least two hours before you test your blood.
- Perform a control solution test to make sure the meter is working properly.
- Take your meter with you to the lab.

While at the lab

- Follow all instructions in this owner's booklet for performing a blood sugar test with your meter.
- Conduct your meter test within 15 minutes of lab test.
- Use only fresh, capillary blood obtained from the fingertip.

You may still experience a difference from the laboratory test results because blood sugars can change very rapidly over a short period of time. This can be for a variety of reasons, such as; exercise, medication, stress or loss of body fluids.

Setting Your Meter

The EVOLUTION™ meter has a wide variety of functions to choose from. From the setup mode you have the ability to turn the activity/meal flags on, set the date/time, designate three unique averages and set up to five daily alarms.



Press and hold the power button ⓘ for approximately 3 seconds to enter the setup mode.



The activity/meal flags will appear on the left hand side of your screen. Press and release either the ▲ or ▼ button to turn the flags on or off, then press and release ⓘ.

Setting Your Meter



The year will appear at the bottom of your screen. Press and release the ▲ or ▼ buttons to set the year. By pressing ▲ the number will increase. By pressing ▼ the number will decrease. Then press and release



The month, day, and time will appear on your screen with the month blinking.

Press and release either the ▲ or ▼ buttons to change the month, then press and release



The day will begin blinking.

Press and release either the ▲ or ▼ button to change the day, then press and release



The time will be blinking.

Press and release either the ▲ or ▼ button to change the hour and minutes, then press and release



Setting Your Meter



A '1' will appear on the right hand side of your screen. This stands for the first average you can set.

Press and release either the ▼ or ▲ button to set the number of days to be calculated for that average. That number will be blinking next to a 'd' at the bottom. Press and release



You can set up to 3 averages (from 1-99 days).



The Alarm icon will appear at the bottom of your screen.

Press and release either the ▼ or ▲ button to turn the alarm 'On/Off', then press and release



If the alarm is turned off, the set up mode is now complete. The meter will turn off automatically.

Setting Your Meter



If the alarm is On, press and release either the ▲ or ▼ button to set the alarm time, then press and release ⓘ.



The second alarm will appear.

Press and release either the ▲ or ▼ button to turn additional alarms on/off, then press and release ⓘ.

You have the ability to set up to 5 alarms.

Caution:

Make sure that the day and time are set properly to enable your data to be stored and downloaded properly.

Performing a Control Solution Test

Note:

- EVOLUTION™ control solution is sold separately. Please contact your local representative.
- It is recommended that control solution is stored at room temperature before testing.
- Use only EVOLUTION™ control solution with the EVOLUTION™ meter.

The control solution should be used when there is suspicion that the meter or the strips are not working properly.

For example:

- If your strips have been exposed to extreme conditions.
- If you drop the meter.
- Blood sugar results are inconsistent with your symptoms.



Firmly insert the test strip into the meter port with the 'Green color' facing up. Make sure the code number matches the code on the strip bottle. The EVOLUTION™ automatically adjusts the meter accordingly.

If activity/meal is ON



Scroll through the icons with the ▲ or ▼ buttons until the control solution bottle is blinking, press and release ⓘ.

If meal activity/meal is OFF



Press and release either the ▲ or ▼ button. The control solution bottle will appear at the bottom left hand corner, press and release ⓘ.

OR

Performing a Control Solution Test



Check the expiration date before performing a control solution test. Do not use if expired. Please note the expiration date on the control solution bottle.



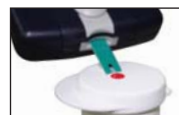
Gently shake the control solution before use.



Discard the 1st drop of control solution, this will eliminate any residue.



Place a drop of control solution on a clean dry surface (ex. the lid of the test strip vial)



Dip the test strip into the control solution.

Results will appear in 3 seconds.

Compare the result to the range printed on the test strip vial, the result should fall within that range.

Caution:

The control solution bottle is at the very bottom left, not to be confused with the medication bottle. This will allow you to differentiate between a control solution test and an actual blood test.

Performing a Control Solution Test

For example only:

If you are using the normal control solution, according to this particular vial of strips, your meter should show a number between 80 and 120.



If your control solution test falls out of range, please follow the next steps before contacting customer support:

- Check the expiration dates on all the products you are using. Be sure you are using EVOLUTION™ control solution.
- Try another control solution test.
If this test falls out of range, try another control solution test with a new unopened bottle of strips:
- After following the appropriate steps and the control test still falls out of range, do not perform a glucose test. Please contact an Infopia USA representative at **888-446-3246**.

Caution:

The control solution range is not the recommended range for your blood sugar level.

Performing Your Test

Step 1



Firmly insert the test strip into the meter port with the "Solid Green Color" facing up. The Infopia logo should be facing towards you. The meter automatically turns on displaying the code, room- temperature, date and time.



Make sure the code number matches the code on the strip bottle. The EVOLUTION™ automatically recognizes the test strip code number and adjusts the meter accordingly.



If during the setup process you chose to use the activity/meal flags (⏸ ⏹ ⚡ ⚡), press and release ▲ and ▼ button to select the activity that will correlate with your result, then press and release the power button.

Performing Your Test



A blinking test strip will appear at the top of the screen indicating the meter is ready for testing.

Caution:

- Inserting the test strip in the wrong direction will turn the meter on but testing will not be possible.
- If the meter does not power on, pull the test strip out of the port and reinsert the test strip.
- Be careful not to bend the test strip when inserting it into the port.
- For a more accurate test result avoid testing under direct sunlight.

Performing Your Test

Step 2



Unscrew the lancing device cap.



Insert a sterile lancet into the lancing device.



Twist the protective cover off. Do not discard.



Replace the lancing cap by twisting it back on tightly.



To adjust the depth setting:
Use 1-2 for soft skin, 3 for average skin, 4-5 for thick or calloused skin.

There are two different lancet device designs available.

First design



Pull the end of the lancet device back.



To prick your finger, push the center button.

OR

Second design



To prick your finger, push the trigger button.

Caution:

If the blood smears or runs, do not use that sample. Dry the area and gently squeeze another drop or puncture a new site.

Performing Your Test

Step 3

Correct



Completely filled



Incorrect



Insufficient amount of blood



- Place the edge of the test strip to the drop of blood.
- The blood will automatically be “drawn” into the test strip channel.
- When there is enough blood, your meter will automatically count down.

Warning:

You may get an inaccurate result if the blood sample is not completely filled.

Performing Your Test

Step 4



- The meter should begin counting down from 3 to 1 on the LCD display.



- The LCD window will display the result of your blood sugar level, temperature, and time.
- Once the test strip is removed, the meter turns off automatically.

Note:

If you are not finished testing within 3 minutes, the meter automatically turns off. You will need to start the test procedure from the beginning.

Caution:

If an error message appears on the screen, please refer to the troubleshooting (p. 41).

Disposing of Your Test Strips and Lancets

Disposing of your test strip



Once the test is complete, push the strip forward to remove the test strip from the meter.



Used test strips may be considered bio hazardous waste in your area. Be sure to contact your local representative for proper disposal.

Disposing of your lancet



Push the needle into the protective cover.

There are two different lancet device designs available.

First design



OR

Second design



Pull the lancet out and discard accordingly.

Pull the end back and press the ejector button forward. Discard accordingly.


Reviewing Your Results

The EVOLUTION™ meter stores up to 365 test results in its built-in memory. Test results and blood sugar averages can be retrieved any time.

Reviewing your blood sugars




Most recent result

- Press and release  button. The most recent result appears first. Note the time and day of your blood sugar result.




Previous result

- Press and release the  button and your previous result will appear on the screen.



Previous result



- Press and release the  button again, and the previous one before that will appear.

Reviewing Your Results

Reviewing your averages



7day average

- Press and release  button. The most recent blood sugar result will appear first.
- Press and release  button and the 1st pre-set average set will appear.

Number of tests

Average test result

Average test result days



14 day average

- Press and release  button and the 2nd pre-set average will appear.



21 day average

- Press and release  button and the 3rd preset average will appear.

Note:


When you have hundreds of results stored in the memory only the latest results will be calculated for the pre-set averages.

Reviewing Your Results With User ID On




Note :

This feature was designed for a clinical setting. You will need to contact an Infopia USA representative to activate the multiple ID feature.



- Press and release  button once and the multiple patient ID option will appear on the LCD screen.

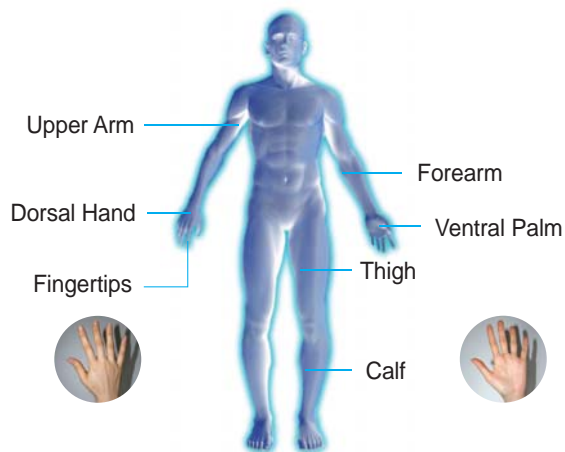


- Use the  and  to scroll and choose the correct ID number, then press and release button .



- After selecting the desired patient ID, you can review those patients' results exclusively.

Alternate Site Testing



The EVOLUTION™ system gives you the ability to obtain a blood sample for testing your sugar from different areas of your body. The figure shown above displays the areas where you can test using your EVOLUTION™ meter.

You may test your blood sugar from your forearm, upper arm, palm (ventral palm or dorsal hand), fingertips, thigh, or calf.

It is recommended that alternate site testing be used when sugars are stable: before meals and before bedtime. However, when sugars are changing, blood from the fingertip may show these changes sooner than blood from other sites.

How to select the puncture site.

Lancing and sampling from an alternate site area.

Sampling from your upperarm, forearm, dorsal hand, ventral palm, thigh, or calf allows you to use your fingertips less often. You may find that obtaining a blood sample from an alternate site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertip.

Ventral palm/Dorsal hand



Choose a fleshy area on the palm, below your thumb or pinky finger. Select a spot without any visible veins and away from any deep lines. This may cause your blood sample to smear.

Alternate Site Testing

Forearm



Upperarm



Calf



Thigh



Choose a fleshy area of the forearm, upperarm, thigh, or calf away from bone, visible veins and/or hair. Sometimes there is less blood flow to these areas than to the fingertips. To help you get a large enough drop of blood, you may gently massage or apply a heating pad to the site to increase blood flow.

Alternate Site Testing

Important :

We recommend that you test on your fingertip if you are testing for hypoglycemia (low blood sugar) or if you have a history of reoccurring hypoglycemia.



To ensure accurate results when lancing your arm (forearm or upperarm), leg (calf or thigh), or palm (ventral palm or dorsal hand), clean the test site with soap and water.

Make sure there is no cream or lotion on the test site.

Thoroughly dry your hands and test site.

Alternate Site Testing

The lancing device clear cap is used for alternate site testing.

Lance the test site with the lancing device:



1. Remove the lancing cap by twisting off.



2. Insert lancet and replace with the clear cap.



3. To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm. Applying heat may be helpful.



4. Adjust clear cap to the highest setting (5). Hold the clear cap down against a fleshy area on the alternative site. Press the release button. Do not lift up.

Alternate Site Testing



5. Continue to hold the lancing device and gradually increase pressure for several seconds.



6. While holding the lancing device on your test site, look through the clear cap; until a round drop of blood appears (approximately $0.3\mu\text{l}$).



7. Lift the lancing device straight up; be careful not to smear the blood on your testing site.



8. Place the edge of the test strip to the drop of blood. The blood will automatically be drawn up.

**Remember:**

- Consult with your healthcare professional before using alternate site testing.
- Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.
- If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your healthcare professional.

Caution:

Do not test on your forearm or palm when:

- You think your blood glucose is rapidly falling. For example within two hours of exercise, rapid-acting insulin injection, or an insulin pump bolus.
- Testing with a fingertip sample may identify hypoglycemia or an insulin reaction sooner than testing with a forearm or palm sample.

Information for Healthcare Professional

If you are considering recommending AST for your patients, you need to understand that there is a potential for a significant difference between fingertip and AST testing.

These physiological effects vary between individuals and can vary within a single individual based upon his or her behavior and relative physical condition.

If your patient is used to making treatment decisions based on finger-stick readings, he or she should consider the delay or lag-time affecting the reading obtained from an alternative site.

Caring for Your EVOLUTION™ System

Cleaning and storing your meter:

1. Your meter does not require special maintenance or cleaning.
2. It is recommended that you store the meter in its carrying case after each use.
3. A cloth dampened with water and mild detergent can be used to wipe down the outside of the meter. Your Element™ meter is a precision instrument. Please handle it with care.
4. Avoid getting dirt, dust, blood, control solution, or liquids on the meter, the test port, or data port.
5. Do not subject the meter to excessive heat.
6. Do not soak the meter in water or liquid.

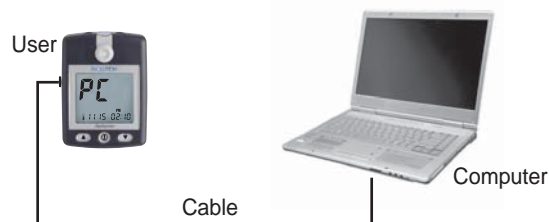
Lancet Device:

1. Clean the lancet device and caps with soap and luke warm water.
2. To disinfect the lancet device, prepare a disinfectant solution of one part household bleach to 10 parts water.
3. Dampen a cloth with this solution and wipe the lancet device thoroughly.
4. Soak only the cap for at least 30 minutes in the disinfectant solution. Do not soak the lancet device in liquid.
5. Rinse the lancet device and cap with water and dry thoroughly.

Download the Data

You can transfer test results from the EVOLUTION™ meter to a computer.

You will need to download the software from the following web site (<http://www.infopiausa.com>) and purchase the computer cable from your local representative. This is sold separately.



Battery Installation

The low battery icon will appear in the upper left corner of the LCD screen to alert you when the battery power is running low, indicating a new battery is needed.



Your EVOLUTION™ meter uses two 3V lithium batteries (CR2032), which are included. When replacing the batteries, only CR2032 or equivalent lithium batteries should be used.

After changing the batteries, please be sure to recheck your meter settings.

Note:




Make sure your date and time are correct after changing your battery.

Troubleshooting



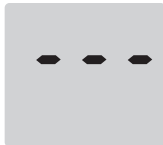
The following chart may help you identify certain problems, but may not solve all problems that can occur. Contact your authorized representative or Infopia USA customer support if the problem persists.

Message	Problem	Action Required
	Problem with the meter	Reset the battery and correct the setting. If the problem persists, please contact customer support.
	Wet or used strip	Insert a new test strip and try your test again. Refer to performing a blood test (p.20).
	Damaged strip	Insert a new test strip and try your test again.
	Applied blood before the "ready for blood" icon.	Insert new strip, wait for the "ready for blood" icon and try your test again. Refer to performing a blood test (p.20).

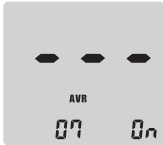
Troubleshooting

Message	Problem	Action Required
 The display shows "E-6" with "CHK" below it. At the bottom, it shows "MTH .DAY PM" and "11 15 12:21".	Problem with the Auto-coding label	Do not test in direct sunlight. Refer to test solution limitation. Insert a new strip and try your test again.
 The display shows "LoF" with "CHK" below it.	The ambient temperature is lower than 50°F	Place the meter in an area above 50°F for 30 minutes and try your test again.
 The display shows "HiF" with "CHK" below it.	The ambient temperature is higher than 104°F	Place the meter in an area below 104°F for 30 minutes and try your test again.

Troubleshooting

Message	Problem	Action Required
 The display shows "Lo" with "MTH .DAY PM" and "11 15 12:21" below it.	The test result is lower than 20mg/dL.	Check the accuracy of your test strip by performing a control solution test. If the result is within range try your blood test again. If "Lo" persists, consult your doctor immediately.
 The display shows "Hi" with "MTH .DAY PM" and "11 15 12:21" below it.	The test result is higher than 600mg/dL.	Check the accuracy of your test strip by performing a control solution test. If the result is within range try your blood test again. If "Hi" persists, consult your doctor immediately.
 The display shows three dashes "---".	There are no readings stored in the meter.	

Troubleshooting

Message	Problem	Action Required
	Not enough readings in the memory to display designated averages.	
The meter does not power on	Battery is dead or there is a problem with the meter.	Change the battery. The problem persists, contact your local representative.
Test does not start after applying blood sample	Insufficient amount of blood.	Please insert a new test strip and perform your test again. Refer to performing a blood test (p. 20).

Inconsistent or Unexpected Test Results

If you continue to get unexpected results, check your system with control solution (refer to page 17). If you experience symptoms that are not consistent with your blood sugar results, first be sure you have followed all instructions in this booklet, then contact your doctor.

Never ignore symptoms or make significant changes to your diabetes control program without speaking to your doctor.

Troubleshooting

Caution: Low Glucose Results

If your result is lower than 70mg/dL, it may mean hypoglycemia (low blood sugar). This may require immediate treatment according to your health care professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.

Caution: High Glucose Results

If your test result is higher than 180 mg/dL, it may mean hyperglycemia. If you are uncertain about your test result, consider re-testing. Your doctor can work with you to decide what actions, if any, you should take if your results are higher than 180 mg/dL.

If the meter displays HI always re-check your blood sugar. If the reading is still HI, it is important to follow instructions from your doctor or healthcare professional without delay.

Warranty

Manufacturer's Warranty:

Infopia USA warrants to the original purchaser that this instrument will be free from defects in workmanship for 3 years from the date of original purchase.

Limitations of Warranty:

This warranty is subject to the following exceptions and limitations:

1. Infopia USA shall not be required to replace any units which are damaged or malfunction due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than Infopia USA, or failure to operate in accordance with the instructions.
2. Infopia USA reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
3. Infopia USA has no knowledge of the performance of the instrument when the test strip is altered or modified in any manner.

For Warranty Service:

Purchaser must contact the Customer Service Department of Infopia USA, by calling toll free 888.446.3246, for assistance and/or instructions for obtaining service of this instrument.

Service Information:

Infopia USA has trained specialists to help you 24 hours a day, 7 days a week, 365 days a year.

Important:

Speak to an Infopia USA representative before returning your meter for any reason. You will be given the information needed to get your problem handled correctly and efficiently.

Have your meter, test strips, and control solution nearby when you call.

Specifications

Sample Type	Capillary whole blood
Sample Volume	0.3 µl
Test Range	20~600 mg/dl
Reading Time	3 seconds
Calibration	Plasma - Equivalent
Altitude	≤ 10,000 ft
Operating Temperature	50-104°F
Operating Humidity	10-90%
Strip Storage Temperature	35.6 - 86°F
Display Type	LCD
Dimension	2x3x .75 in. (55x82x18mm)
Weight	1.7 oz (48g) with batteries
Power Source	3 V , Li Battery (CR2032) X 2
Battery Life	1 Year Average