

IVD



Owner's Booklet

e-Cheker

Blood Glucose Monitoring System

Accurate, complete blood glucose monitoring through advanced biosensor technology



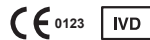
**Faster,
Easier,
Less Painful**



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Welcome to the e-CheKer Blood Glucose Monitoring System

Thank you for your purchase of the e-CheKer Blood Glucose Monitoring System. The system provides you with convenient, safe and less painful blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring. You'll receive an accurate result in only five seconds with a small (0.5 μl) blood sample.

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




Important Information: Read This First!

To receive safe and optimum system benefits, please read the entire manual contents before using the system. Please note:

Intended use

The e-CheKer Meter is used for the quantitative measurement of glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management at home or in clinical settings. e-CheKer N Blood Glucose System should be used only for self-testing outside the body (in vitro diagnostic use only). Do not use the system for the diagnosis of diabetes or for testing newborns. Testing sites include the traditional fingertip testing along with alternate sites testing on forearm, palm, thigh and calf.

The following chart explains the symbols you'll find in the e-CheKer Owner's Booklet, product packaging, and product inserts.

	For <i>in vitro</i> diagnostic use		Do not reuse
	This product fulfills the requirements for Directive 98/79/EC on in vitro diagnostic medical devices		
	Cautions for safety and optimum product use		
	Consult instruction for use		Temperature limitations
	Manufacturer		Serial number
	Authorized representative		Batch code
	Use by (unopened or opened test strip container)		
	Do not discard this product with other household-type waste		

- The e-CheKer blood glucose monitoring system is intended for self-testing outside the body (*in vitro* diagnostic use).
- The glucose in the blood sample mixes with special chemicals on the test strip to produce a small electrical current. The e-CheKer meter detects this electrical current and measures the amount of glucose in the blood sample.
- If you need assistance, please contact your authorized i-SENS sales representative or visit www.i-sens.com for more information.

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e-CheKer BGM System Components

Verify that all the following components are included in the system box.



- | | |
|---|-------------------------------------|
| ① e-CheKer Blood Glucose Meter | ⑥ Logbook |
| ② Battery (1) | ⑦ Owner's Booklet |
| ③ Lancets (10) | ⑧ Quick Guide |
| ④ e-CheKer Blood Glucose Test Strips (10) | ⑨ Zippered Portable Case |
| ⑤ Lancing Device | ⑩ e-CheKer Glucose Control Solution |

Please contact your authorized i-SENS sales representative if any component is missing or damaged.

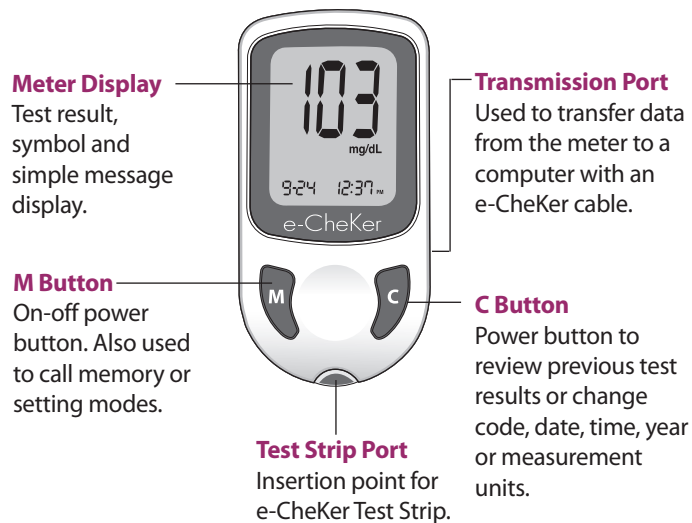
Helpful Tip

See page 17 for battery information and replacement instructions.



Use *only* e-CheKer Test Strips with the e-CheKer Blood Glucose Monitoring System.

e-CheKer Blood Glucose Meter



Meter Display
Test result, symbol and simple message display.

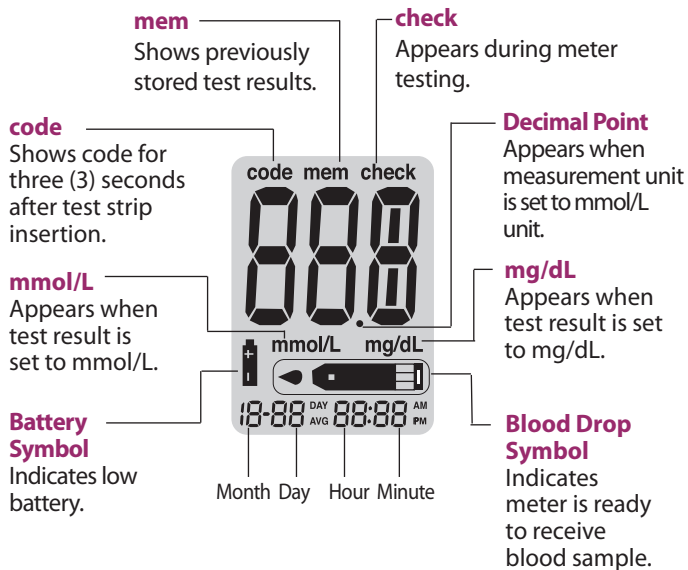
Transmission Port
Used to transfer data from the meter to a computer with an e-CheKer cable.

M Button
On-off power button. Also used to call memory or setting modes.

C Button
Power button to review previous test results or change code, date, time, year or measurement units.

Test Strip Port
Insertion point for e-CheKer Test Strip.

Meter Display



Setting the Meter

When you turn on your e-CheKer Meter the first time, press and hold the **M** button for three (3) seconds to set the display.

- Display format for the date: MM-DD (Month-Date)
- Display format for the time: 12 h (AM/PM) or 24 h
- Year: year of manufacture



Helpful Tip

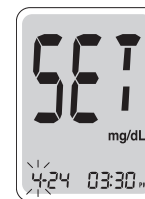
To set any date, time, or unit of measurement, you must begin by setting the month and date mode and consecutively go through the process.

Setting the Month & Date

Step 1

Setting the Month

Press and hold **M** button for three (3) seconds. A blinking number indicating the month will appear on the lower left display corner. Press and release **C** button until correct month appears. Press the **M** button to set. You are now ready to set date.



Setting the Meter

Step 2

Setting the Date

Press **C** button until blinking number represents correct date.

Press **M** button to set and move to time setting mode.



Helpful Tip

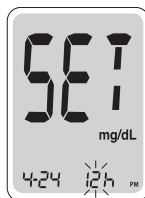
Press and hold the **M** button for three (3) seconds to begin and end the setting of the date, time, year or measurement unit on the meter. Use the **C** button for scrolling. To scroll more quickly, hold the **C** button down.

Setting the Time

Step 3

Setting the Time

The meter can be set in an AM/PM 12-hour or 24-hour format. Press **C** button to select format.



Step 4

Setting the Hour

Press **M** button to move to hour setting mode. Press **C** button until correct hour appears. After hour is set, press **M** button to enter minute setting mode.



Step 5

Setting the Minute

Press **C** button until correct minute appears. After minute is set, press **M** button to move to year setting mode.

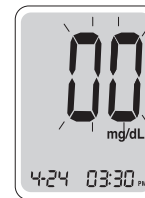


Setting the Year & Measurement Unit

Step 6

Setting the Year

The year will appear on the display when entering year setting mode for the first time. Press **C** button until correct year appears. After setting the year, press **M** button to move to unit setting mode.



Step 7

Setting the Measurement Unit

Press **C** button to change the unit to mmol/L or mg/dL. After selecting measurement unit, press **M** button for three (3) seconds to exit setting mode.



Helpful Tip

The mg/dL is a standard unit in the United States. The most commonly used unit in Australia, Canada, China and in some European countries is mmol/L.

Setting the Meter

Step 8

Setting the Sound On/OFF

On pressing button **M** the screen will display the On or OFF. Press the **C** button to confirm the selection.

The meter will beep in the following instances, if set to On.

- When the test strip is inserted in the meter
- When the blood sample is absorbed into the test strip and the test starts
- When the test result is displayed
- When you push the **C** button to check the memory

If the sound is set to OFF, none of the sound functions will work.

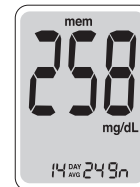


Storing Test Results in Meter Memory

The e-CheKer Meter provides storage for up to 250 blood glucose test results. It also stores the 14-day average and number of tests performed. The following procedure lets you store your test results.

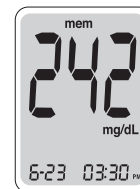
Step 1

Press **M** button to turn on meter. The current date and time will appear at the bottom of the screen for two (2) seconds, followed by the 14-day average and number of tests performed.



Step 2

Press **C** button. The most recent test result, its date and time will appear.



Helpful Tip

Each time you press the **C** button, you'll see previous test results, dates and times displayed in chronological order. To see test results displayed more quickly, press and hold the **C** button.

Step 3

Press **C** button to turn meter off.



Deleting Stored Test Results from Meter Memory

To delete all past stored test results, follow this procedure.

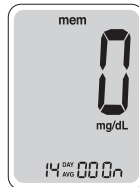
Step 1

Begin with meter off. Enter time and unit setting mode (see *Setting the Meter* pages 9-12). Press **M** button seven times to set meter to memory deleting mode. Press **C** button to call up Yes or No.



Step 2

To delete all memory, choose Yes. Press **M** button. All past stored test results and their dates and times will be deleted. The number zero will appear. Or, if you do not wish to delete the memory, choose No. Press **M** button to enter Step 1 of the time and unit setting mode.

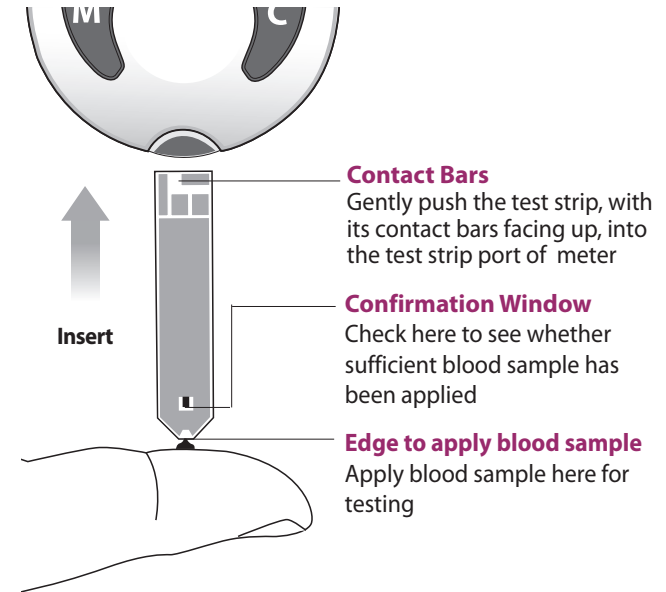


Helpful Tip

The meter will turn off if you press the **M** button for more than three (3) seconds at any stage of the setting. The meter will turn itself off after two (2) minutes if the **M** button is not pressed.

e-CheKer Blood Glucose Test Strip

The e-CheKer Test Strip supports the accurate measurement of glucose levels in a capillary whole blood sample.



Test Strip Storage and Handling

For safe and optimum use:

- Store test strips only in their original bottle.
- Store bottle in a cool and dry place between 1-30 °C (34-86 °F).
- Keep bottle away from direct sunlight and heat.
- Do not refrigerate or freeze test strips or bottle.
- Close bottle cap tightly immediately after removing a test strip.
- Use test strip immediately after taking out of bottle.
- Handle test strips only with clean and dry hands.
- Do not bend, cut or alter test strips in any way.
- Do not force a test strip into the meter.
- Apply *only* fresh whole capillary blood to test strip.
- Test strips in new, unopened containers and test strips in containers that have been opened can be used up until the expiration date printed on the test strip box and container label if the test strips are used and stored according to its storage and handling methods.
- Do not use test strips beyond the expiration date.
- Do not reuse test strips.

Helpful Tip

For detailed storage and usage information, refer to the e-CheKer Test Strip package insert.

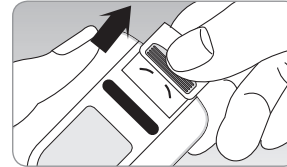


Keep test strips and the test strip bottle away from children. The test strips and bottle cap may be choking hazards. Drying agents in the bottle cap may be harmful if inhaled or swallowed or may cause skin or eye irritation.

Replacing Batteries

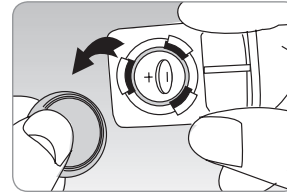


If you insert the battery upside-down on the first try, it will get stuck!



Step 1

Press down slightly and push the battery compartment cover in the direction of the arrow shown, to remove it.

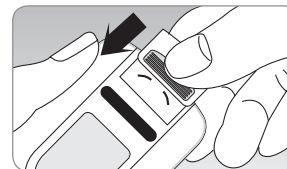
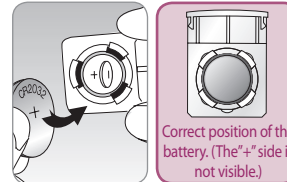


Step 2

Remove the old battery to replace with a new one.

Place the battery into the compartment on the cover with the "+" side facing inside the compartment so that once inserted, the "+" side is not visible.

※ The compartment cover might not open if the battery is placed upside down. Please do not attempt to remove it by force. If this happens, and contact the i-SENS representative in your area.



Step 3

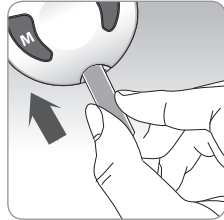
Press down slightly and push the battery compartment cover in the direction of the arrow shown, to insert it.

Coding Meter to Match Test Strips


For accurate results, the code numbers on the e-CheKer Meter and e-CheKer Test Strips must match. *You must code your meter before using it for the first time and each time you open a new bottle of test strips.* The code number on the meter display must match the one on the test strip bottle.

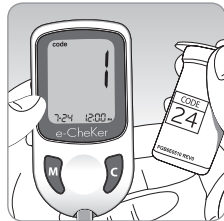
Step 1

Gently push test strip in until meter beeps. Code number will appear for three (3) seconds. Code number 1 will appear when meter is first used.



Step 2

Code number on display and test strip bottle should match. If so, wait until the  symbol appears on the screen to begin the test. If not, follow Step 3.




Step 3

Press M or C button to select the correct code number. Each time you press M button, the number will increase by one, and each time you press C button, the number will decrease by one. Press and hold C button to scroll code numbers down.




Step 4

After selecting correct code number, wait for three (3) seconds until  symbol appears on display.



Step 5

When the  symbol appears, meter is ready for testing.



You must code your meter before using it for the first time and each time you open a new bottle of test strips. The code number on the display and test strip bottle must match. If the meter is not correctly coded, you will receive inaccurate results.

Meter and Test Strip Performance Check



e-CheKer Control Solution:

It contains a known amount of glucose that reacts with a e-CheKer Test Strip to help you determine if the meter and test strips are working properly together. Running a check will also help you verify if you are following the correct blood glucose testing procedure.

Run a check when you:

- Want to practice the test procedure using the control solution instead of blood.
- Use the meter for the first time.
- Open a new bottle of test strips.
- Have symptoms that are inconsistent with your blood glucose test results.
- Believe your test results are not accurate.
- Suspect your meter and test strips are not performing properly.

e-CheKer Control Solution is sold separately. Contact your authorized i-SENS sales representative for more information.

e-CheKer Glucose Control Solution Storage and Handling

Discard the e-CheKer Control Solution after its expiration date on the bottle or discard date, whichever comes first. Add three (3) months to the date you open the bottle and write it on the bottle label. This is the discard date. *Do not* use the solution after the discard or expiration date, whichever comes first.

For accurate results:

- Store solution in tightly capped bottle at room temperature (8-30 °C/46-86 °F).
- Do not refrigerate or freeze.
- Keep the control solution, meter, and test strips at room temperature (20-25 °C/68-77 °F) for at least 30 minutes before testing.




Do not use the control solution after the expiration or discard date, whichever comes first. Only use e-CheKer Control Solution to test e-CheKer Test Strips and the e-CheKer Meter.

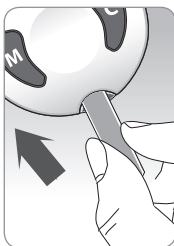
Testing Meter and Test Strip Performance

Perform the following steps to check the combined performance of your e-CheKer Meter and Test Strips or to assess proper testing procedure performance.


Step 1

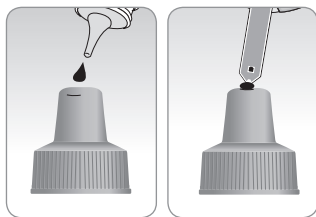
Insert test strip contact bars facing up into the meter's strip port. Gently push test strip into the port until meter beeps. A code number will appear for three (3) seconds.

The  symbol will show on the display. Confirm matching code numbers on display and test strip bottle. If code numbers do not match, see *Coding Meter to Match Test Strips* on pages 18-19.



Step 2

Shake bottle well. Discard first drop of solution. Wipe off bottle tip. After  symbol appears on the display, apply the solution to narrow top edge of the test strip until the meter beeps.

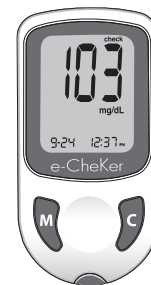


The glucose level printed on the bottle is for the e-CheKer Control Solution only. It *does not* refer to your blood glucose level.

Testing Meter and Test Strip Performance

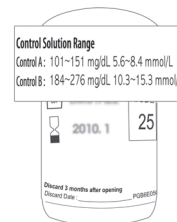
Step 3

Test results appear after the meter counts down from five-to-one (5-to-1). To mark test result, press and hold C button for three (3) seconds. CHECK will appear on the display. Marked test results will not be shown in your averages.



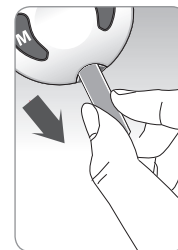
Step 4

Compare results with range printed on test strip bottle. If results fall within range, you are ready to test your blood.



Step 5

Remove used test strip. Meter will turn off.



Out of Range Result Factors

If your control solution test results do not fall within the range printed on the test strip bottle, repeat the test. Out of range results may be due to one or more of the following factors:

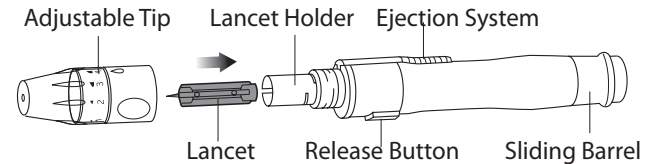
- Error in performing the test.
- Expired or contaminated control solution.
- Expired or damaged test strip.
- Mismatched meter and test strip bottle code numbers.
- Failure to shake bottle.
- Failure to discard first drop of control solution and wipe bottle tip clean.



If results continue to fall outside the range printed on the bottle, the e-CheKer Test Strip and e-CheKer Meter may not be working together properly. If so, do *not* use your system, please contact your authorized i-SENS sales representative.

Using the Lancing Device

You will need a lancing device in order to collect a blood sample. You may use the lancing device contained in the e-CheKer Blood Glucose Monitoring System or any other medically approved lancing device.



- The lancing device should be used by one individual and communal use is strongly discouraged.
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.



To avoid infection when drawing a sample, use a lancet *only* one time, and:

- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

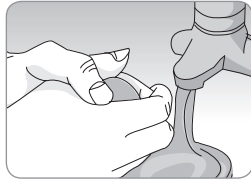
Helpful Tip

Repeated puncturing at the same sample site may cause pain or skin calluses. Choose a different site each time you test.

Preparing the Lancing Device for Blood Sample Retrieval

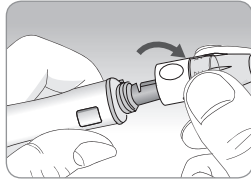
Step 1

Wash hands and fingertip sample site with soap and warm water. Rinse and dry thoroughly.



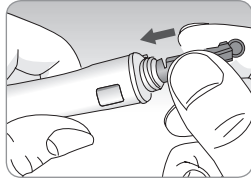
Step 2

Unscrew lancing device tip.



Step 3

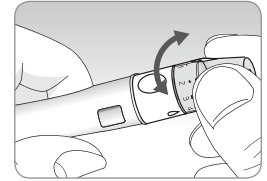
Firmly insert new lancet into carrier. Hold lancet firmly. Gently twist to pull off protective disk. Save disk to recap lancet after use. Replace lancing device tip.



Preparing the Lancing Device for Blood Sample Retrieval

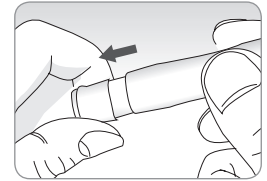
Step 4

Select a desired depth of one-to-five (1-5) on the lancing device's adjustable tip. Rotate ring to align desired number with arrow. A beginning setting of three (3) is recommended.



Step 5

To cock the lancing device, hold the tip in one hand. Pull the sliding barrel on with the other hand. The lancing device is cocked when you feel a click.



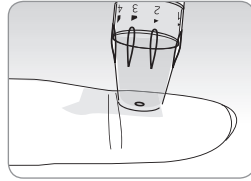
Helpful Tip

The skin depth to retrieve samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration for an adequate sample size. A beginning setting of three (3) is recommended.

Using the Lancing Device at Fingertip Sample Site

Step 1

Place cocked lancing device against fingertip side.

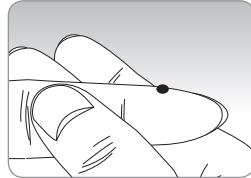


Helpful Tip

Choose a different fingertip each time you retrieve a sample to minimize discomfort.

Step 2


Press release button. Massage fingertip to obtain round drop (at least $0.5 \mu\text{l}$, actual size: ●) of blood. Apply test strip tip to blood sample.

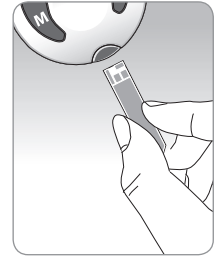


Abnormally viscous blood or insufficient amount of blood may return Er4 on the display after the measurement (See *Error Messages and Troubleshooting* on page 43-44).

Testing Your Blood Glucose Level


Step 1

Insert the test strip with contact bars facing up into the port. Push the strip gently until meter beeps. The code number will appear for three (3) seconds.  symbol will appear after three (3) seconds. The displayed code number should match the one on the test strip bottle. If not, see *Coding Meter to Match Test Strips* on pages 17-18.



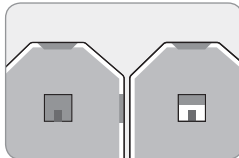
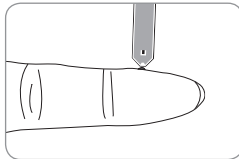
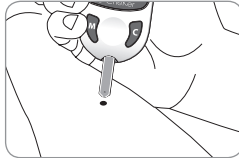
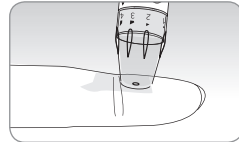
Testing Your Blood Glucose Level

Step 2

Use lancing device to get blood sample.
Sample must be at least 0.5 μL (actual size: ●) to fill the test strip reaction cell.
When the  symbol appears on display, apply blood sample to narrow top edge of test strip until meter beeps.

When testing from forearm, hold meter as shown.

If confirmation window hasn't filled in time because of abnormal viscosity or insufficient volume, Er4 message will appear. If the confirmation window is not completely filled when results appear, it is recommended that you perform a second test for more accurate results.



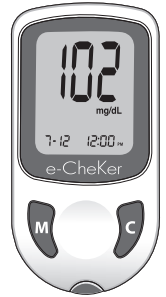
Good Sample Insufficient Sample


Helpful Tip


If the test strip does not receive a blood sample, please contact your authorized i-SENS sales representative.


Step 3

Meter will count down from five-to-one (5-1) on the display.
Test results, time, and date will appear and automatically store in meter memory.
Remove used test strip from port. Meter will turn off after three (3) seconds.



 The meter will automatically turn off if a sample is not applied within two (2) minutes. If this happens, remove the test strip from the port. Reinsert the test strip to restart the meter.

 Alternative site and fingertip results may differ significantly due to rapid changes in the glucose level after meals or exercise, hypoglycemic symptoms, dehydration or effects of drugs such as insulin. Rubbing the site before drawing the sample reduces these differences. If you suffer from hypoglycemia or have experienced hypoglycemic shock, secure blood samples from your fingertips.

 Discard used test strips and lancets properly in a container for sharp objects.

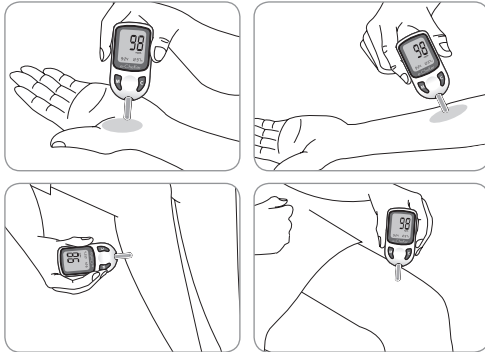
Alternative Site Testing

What is AST (Alternative Site Testing)?

Usually, when someone tests their glucose, they take the blood sample from the tip of the finger. However, since there are many nerve endings distributed there, it is quite painful. When doing a glucose test, using different parts of the body such as the arms, palms, thighs, and calves can reduce the pain during testing.

This method of testing with different parts of the body is called Alternative Site Testing. While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

Alternative Site for Testing



Alternative Site Testing

Things to know when using AST

Please understand the following things before testing outside of the fingertip (forearm, palm, thigh, and calf). The capillary blood of the fingertip shows the change in glucose more rapidly than AST. Therefore, the test results from the fingertip test and AST may differ. This is because things such as lifestyle and ingested food have an effect on glucose levels.

Acceptable situations for AST

- Fasting period
- Before a meal
- Before sleeping

Situations requiring fingertip test

- When the glucose levels are rapidly increasing during the two hours after a meal or exercise
- When sick or when glucose levels seem quite lower than test value
- When hypoglycemia is not well recognized
- When insulin has the biggest effect
- 2 hours after an insulin injection

Discarding Used Lancets

AST Precautions

- Do not ignore the symptoms of hyperglycemia or hypoglycemia.
- When the results of the test do not reflect one's opinion, retest using the fingertip test. If the test results do not reflect one's opinion, please consult a doctor.
- Do not rely on the AST results for changing one's treatment method.
- The amount glucose in alternative sites differs from person to person.
- Before using AST, please consult your regular physician.

Helpful Tip

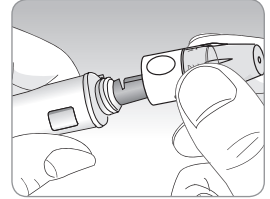
Results from alternative site and fingertip samples may appear differently as there is a time lag for the glucose levels to reach the same value. Use a fingertip for drawing if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.

- If the sample drop of blood runs or spreads due to contact with hair or with a line in you palm, do not use that sample. Try puncturing again in a smoother area.

Proper discarding of used lancets protects you and others from infection and injury. The following shows the correct process.

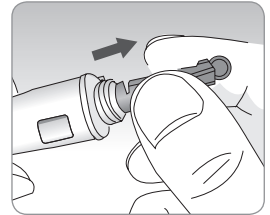
Step 1

Unscrew lancing device tip. Place protective disk on lancet and pull off the lancet.



Step 2

Throw away in a proper biohazard container



The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

Target Blood Glucose Ranges

Reminders

*Your target ranges
from your healthcare expert*

Time of day

Before breakfast

Before lunch or dinner

1 hour after meals

2 hours after meals

Between 2 a.m. and 4 a.m.

Reference

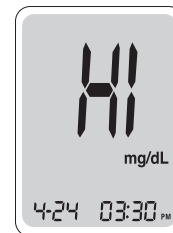
Source : *Diagnosis of Diabetes*, NIH Publication
No. 05-4642, January 2005

Hi and Lo Messages

The e-CheKer Meter displays test results between 20 to 600 mg/dL (1.1-33.3 mmol/L). Please refer to the instructions below if you receive a Hi or Lo message.

Hi Message

If your test result is above 600 mg/dL (33.3 mmol/L), HI appears on the display. A test result above 600 mg/dL (33.3 mmol/L) may indicate hyperglycemia (high blood glucose).



Lo Message

If your test result is below 20 mg/dL (1.1 mmol/L), Lo will appear on the display. This may indicate hypoglycemia (low blood glucose).



⚠ If you receive a Hi or Lo message, repeat the test. If the result is the same, contact your physician immediately.

⚠ If Hi or Lo message does not reflect how you feel, contact your authorized i-SENS sales representative.

Reading Variation Factors

An abnormally high or low red blood cell count (hematocrit levels over 60% or below 20%) may produce inaccurate results.

A normal red blood cell count is in the 30-50% range. It may be below or over the normal range in newborns, pregnant women or those suffering from serious anemia.

Test results below 70 mg/dL (3.9 mmol/L) indicate low blood glucose levels (hypoglycemia). Results above 240 mg/dL (13.3 mmol/L) indicate high blood glucose levels (hyperglycemia).

Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.



Consult your healthcare professional immediately if you have properly followed all the testing instructions and:

- You consistently receive hypoglycemia or hyperglycemia results,
- You are suffering from severe dehydration, or
- Your symptoms are not consistent with your blood glucose test results.

Caring for the Meter

Use a soft cloth or tissue to wipe the meter exterior. If necessary, a small amount of alcohol on a soft cloth or tissue may be used. Organic solvents such as benzene, acetone, household industrial cleaners can cause irreparable damage to the meter.

It's important to:

- Not expose the meter to direct sunlight or heat for an extended period of time.
- Not allow dirt, dust, blood or water near the meter's test port.
- Not drop the meter.
- Not try to fix or alter the meter in any way.
- Keep the meter away from strong electromagnetic fields such as cell phones and microwave ovens.

Helpful Tip

Keep all system components in the zippered portable case to prevent loss.



Do not clean the meter with household or industrial cleaning solvents, benzene or acetone.

e-CheKer Blood Glucose Monitoring System Specifications

- Test Range: 20-600 mg/dL (1.1-33.3 mmol/L)
- Sample Size: Minimum 0.5 μ l
- Test Time: 5 seconds
- Test Sample: Fresh capillary whole blood
- Calibration: Plasma-equivalent
- Assay Method: Electrochemical
- Power: One (1) 3.0V lithium battery
(non-rechargeable, replaceable, type CR2032)
- Battery Life: 1,000 tests
- Memory: 250 blood glucose values
- Dimension: 84 x 40 x 17 (mm)
- Weight: 38.5 g (battery included)
- Operating Range
Temperature: 10-40 /50-104
Relative Humidity: 10-90%
Hematocrit: 20-60%

Performance Evaluation

The performance of e-CheKer Blood Glucose Monitoring System Strips has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the e-CheKer BGM System (Model GM505FA) was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by 115 diabetic patients at clinic centers.

Slope	0.961
Y-intercept	3.5 mg/dL
Correlation coefficient(r)	0.995
Number of samples	115
Range tested	40-521 mg/dL

Accuracy results for glucose concentration < 75 mg/dL
(4.2 mmol/L)

Within \pm 5 mg/dL (Within \pm 0.28 mmol/L)	Within \pm 10 mg/dL (Within \pm 0.56 mmol/L)	Within \pm 15 mg/dL (Within \pm 0.83 mmol/L)
13/19 (68%)	18/19 (95%)	19/19 (100%)

Accuracy results for glucose concentration \geq 75 mg/dL
(4.2 mmol/L)

Within \pm 5%	Within \pm 10%	Within \pm 5%	Within \pm 20%
66/96 (69%)	92/96 (96%)	96/96 (100%)	96/96 (100%)

Performance Evaluation





Precision: Precision studies were performed in a laboratory using the e-CheKer BGM System.

Within Run Precision		
Blood average	39.5 mg/dL (2.2 mmol/L)	SD=1.2 mg/dL (0.07 mmol/L)
Blood average	76.7 mg/dL (4.3 mmol/L)	SD=1.6 mg/dL (0.1 mmol/L)
Blood average	128.9 mg/dL (7.2 mmol/L)	CV=1.7%
Blood average	203.5 mg/dL (11.3 mmol/L)	CV=1.7%
Blood average	298.1 mg/dL (16.6 mmol/L)	CV=1.9%


Total Precision		
Control average	44.4 mg/dL (2.5 mmol/L)	1.9 mg/dL (0.11 mmol/L)
Control average	136.1 mg/dL (7.6 mmol/L)	3.5%
Control average	356.4 mg/dL (19.8 mmol/L)	4.5%

This study shows that there could be variation of up to 4.5%

Error Display Messages and Troubleshooting

Message	Possible Cause	Solution
	<i>Test strip has been used.</i>	Use a new strip.
	<i>Blood sample applied before  symbol appeared. Repeat test with a new strip.</i>	Wait until  symbol appears before applying sample.
	<i>Test has been performed outside the operating temperature range.</i>	Take system where temperature is within operating range (10-40 /50-104) and repeat test after 30 minutes.

Error Display Messages and Troubleshooting

Message	Possible Cause	Solution
	<i>The blood sample did not fill the confirmation window of the test strip during measurement because of abnormally high viscosity or insufficient volume.</i>	Repeat test with new test strip and adequate blood sample.



Contact your authorized i-SENS sales representative if error messages persist after following above actions.

General Troubleshooting

Meter does not turn on after test strip insertion.

- Remove test strip from port. Reinsert.
- Make sure meter is on by pressing M button. If meter doesn't turn on, battery may be low. Change the battery.
- Be sure the battery has '-' facing up. If not, reinstall correctly.

Meter does not countdown from five-to-one (5-to-1) after applying blood sample.

- Check test strip confirmation window for adequate blood sample. Repeat test with a new test strip.

Test result not consistent with your expectation.

- Ensure test strip bottle and meter code numbers match. Repeat test with new test strip.
- Make sure sample was applied in time. Repeat test with new test strip.
- Draw sample from another fingertip or alternate site. Repeat test with a new test strip.

Warranty Information

Manufacturer's Warranty

i-SENS, Inc. warrants that the e-CheKer Meter shall be free of defects in material and workmanship in normal use for a period of five (5) years. The meter must have been subjected to normal use. The warranty does not cover improper handling, tampering, use, or service of the meter. Any claim must be made within the warranty period.

The i-SENS company will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty. As a matter of warranty policy, i-SENS will not reimburse the consumer's purchase price.

Obtaining Warranty Service

To obtain warranty service you must return the defective meter or meter part along with proof of purchase to your nearest i-SENS Authorized Warranty Station.

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