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GLUCOCARD® **Shine XL**

BLOOD GLUCOSE MONITORING SYSTEM



User Manual

For single user / home use only

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Important Information: Read This First

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

- **Do not** use the system for diagnosis or screening of diabetes
- Use only fresh capillary whole blood samples for testing
- Alternate site and fingertip test results may differ significantly due to rapid changes in the blood glucose level after eating, insulin injection or exercise.

Intended Use

- The GLUCOCARD® Shine XL Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternate sites such as the forearm, palm, thigh and calf.
- Alternate site testing (AST) should be used only during steady-state blood glucose conditions.
- The GLUCOCARD® Shine XL Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro*) by people with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates, and is not for the diagnosis or screening of diabetes.
- GLUCOCARD® Shine Blood Glucose Test Strips are for use with the GLUCOCARD® Shine family of blood glucose meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternate sites.
- GLUCOCARD® Shine Control Solutions are for use with the GLUCOCARD® Shine family of meters and GLUCOCARD® Shine Test Strips to check that meter and test strips are working together properly, and the test is performing correctly.

Important Health-related Information

- The GLUCOCARD Shine XL Blood Glucose Monitoring System is intended for self-testing *in vitro* (outside the body) diagnostic use.
- The GLUCOCARD Shine XL Blood Glucose Meter is designed to minimize code related errors in monitoring by using the no-coding function.
- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The GLUCOCARD Shine XL Meter detects this electrical current and measures the amount of glucose in the blood sample.
- The GLUCOCARD Shine XL Blood Glucose Meter should only be used with GLUCOCARD Shine Test Strips.
- An abnormally high or low red blood cell count (hematocrit level over 60 % or below 20 %) may produce inaccurate results.
- Inaccurate results may occur in severely hypotensive (having low blood pressure) individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with blood glucose meters.
- Inaccurate results may occur in patients undergoing oxygen therapy.
- For questions or concerns, contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

Important Health-related Information

This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices or long-term care facilities because it has not been cleared by the FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.

Use of this device on multiple patients may lead to the transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Specifications

Product Specifications	
Measurement range	20–600 mg/dL
Sample size	Minimum 0.5 μ L
Test time	Five seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	3,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	250 test results
Size	3.66 x 1.85 x 0.59 inch (93 x 47 x 15 mm)
Weight	1.82 oz (51.5 g) with batteries

Operating Ranges	
Temperature	50–104 °F (10–40 °C)
Relative humidity	10–90 %
Hematocrit	20–60 %

Specifications


Storage/Transport Conditions		
Temperature	Glucose Meter (with batteries)	32–122 °F (0–50 °C)
	Test strip	34–86 °F (1–30 °C)
	Control solution	46–86 °F (8–30 °C)
Relative humidity	Test strip	20–80 %

GLUCOCARD Shine XL Blood Glucose Monitoring System

GLUCOCARD Shine XL Blood Glucose Monitoring System includes the following items:

- ① GLUCOCARD Shine XL Blood Glucose Meter
 - ② User Manual
 - ③ Quick Reference Guide
 - ④ Batteries (2)
 - ⑤ Lancing Device
 - ⑥ Lancets (10)
 - ⑦ Logbook
 - ⑧ Carrying Case
-
- Check all the components after opening the GLUCOCARD Shine XL Blood Glucose Monitoring System package.
 - GLUCOCARD Shine Test Strips and Control Solutions are necessary but not included.
 - GLUCOCARD Shine Control Solutions and the data cable for the diabetes management system can be ordered separately. Please contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

Inserting or Replacing the Batteries

- The GLUOCARD Shine XL Meter comes with two 3.0 V lithium batteries.
- Before using the meter, check the battery compartment and insert batteries if empty.
- When the  symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible.
- The test results may not be saved if the batteries run out completely.

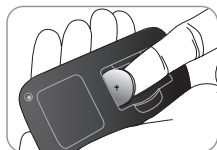
Step 1

Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.



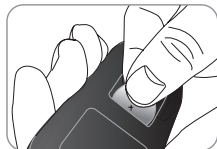
Step 2

Remove the used batteries. Insert two new batteries with the '+' side facing up and make sure the batteries are inserted firmly.



Step 3

Place the cover on the battery compartment. Push down firmly to close the cover.

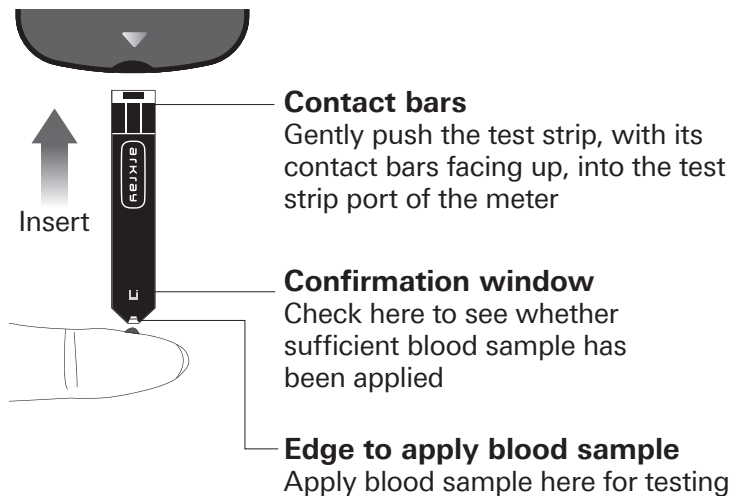


NOTE

- Removing the meter batteries will not affect your stored result. However, meter settings may need to be reset. See pages 16–19.

GLUCOCARD Shine Blood Glucose Test Strips

The GLUCOCARD Shine XL Blood Glucose Monitoring System measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the test strip.



Important Safety Instructions

- GLUCOCARD Shine Test Strips should be used only with fresh capillary whole blood samples.
- **Do not** reuse test strips.
- **Do not** use GLUCOCARD Shine Test Strips beyond the expiration date. This may cause inaccurate results.
- When test strips are used and stored according to correct storage and handling methods, both new, unopened vials and vials that have been opened can be used until the expiration date printed on the test strip box and vial label.
- Store test strips in a cool and dry place at a temperature between 34–86 °F (1–30 °C) and 20–80 % relative humidity.
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original vial.
- Close the vial tightly after taking out a test strip for testing and use the test strip immediately.
- Avoid getting any liquid or moisture in the test strip vial. This can affect the test strips and cause inaccurate test results.
- **Do not** apply samples other than capillary whole blood or control solution to the test strip.
- Handle test strips only with clean, dry hands.
- **Do not** bend, cut or alter test strips in any way.
- For detailed storage and usage information, refer to the GLUCOCARD Shine Test Strip package insert.

- Keep the meter and testing supplies away from young children.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed, and may cause skin or eye irritation.

CAUTION

Do not allow any foreign substances or liquid substances, such as dirt, blood, or water, enter into the meter. The meter may be damaged or may malfunction. Follow the warning information provided below to prevent possible damage to the meter.

- **Do not** apply the blood or control solution samples directly to the test strip port.
- **Do not** apply the blood or control solution samples to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood or control solution samples may run down the surface of the test strip and flow into the test strip port.
- **Do not** store your meter in unsanitary or contaminated sites.
- Make sure to follow the procedures found in the Caring for the GLUCOCARD Shine XL System section of this user manual.

NOTE

- You can get more safety information at CDC Clinical Reminder (<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>).

GLUCOCARD Shine XL Blood Glucose Meter

Data Port

Used to transfer data from the meter to a computer with a cable

<Button

Turns the meter on and selects or changes information

ⓘ Button

Turns the meter on/off and confirms menu selections



Display

Shows results and messages

>Button

Selects or changes information

Test Strip Port
Insert test strip here

NOTE

- The data cable for the diabetes management system can be ordered separately. Please contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

GLUCOCARD Shine XL Blood Glucose Meter Display

mem

appears when test results stored in the memory are displayed

alarm

appears when the time alarm has been set

Battery symbol

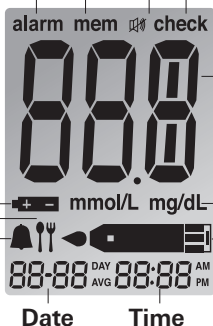
indicates meter batteries are running low and need to be replaced

Post-meal test mark

appears during post-meal testing and when post-meal test results are displayed

Alarm symbol

appears when the post-meal alarm has been set



Mute symbol

appears only when the sound is set to 'OFF'

check

appears when the control solution test results are saved or displayed

Test results

test results display panel

mg/dL

unit for measuring blood glucose

Blood insertion symbol

indicates meter is ready for the application of a drop of blood or control solution

NOTE

- The unit of measurement for your GLUCOCARD Shine XL Meter is preset and fixed in mg/dL.

Setting Up the GLUCOCARD Shine XL System

The meter settings, such as time and date, should be checked and updated before using the meter, or after changing the meter batteries.

Press and hold the $\text{\textcircled{1}}$ button for three seconds to enter the 'SET' mode. While setting up the meter, current settings will appear on the display. Press and hold the $>$ button to scroll faster. To complete the settings and exit from the 'SET' mode, press and hold the $\text{\textcircled{1}}$ button for three seconds again.

Adjusting the Date and Time

Step 1 Entering the SET Mode

Press and hold the $\text{\textcircled{1}}$ button for three seconds. After all the segments flash across the screen, 'SET' is displayed on the screen. Press the $\text{\textcircled{1}}$ button again to progress to the next step.



Step 2 Setting the Year

Press the $<$ or $>$ button until correct year appears. Press and hold the $>$ button to scroll faster. After setting the year, press the $\text{\textcircled{1}}$ button to confirm the selection and progress to the next step.



Step 3 Setting the Month

A number indicating the month will blink on the bottom left corner of the screen. Press the < or > button until the correct month appears. Press the \odot button to confirm the selection and progress to the next step.



Step 4 Setting the Date

Press the < or > button until blinking number shows the correct date. Press the \odot button to confirm the date and progress to the next step.



Step 5 Setting the Time Format

The meter can be set in the 12-hour (AM/PM) or the 24-hour clock format. Press the < or > button to select a format. AM and PM are not displayed in the 24-hour format. After selecting the format, press the \odot button to progress to the next step.



Step 6 Setting the Hour

Press the < or > button until the correct hour appears. Press the Ⓜ button to confirm the hour and progress to the next step.



Step 7 Setting the Minute

Press the < or > button until the correct minute appears. After setting the minute, press the Ⓜ button to progress to the next step.



Setting the Sound 'On'/'OFF'

Step 8

On pressing the < or > button, the screen will display 'On' or 'OFF'. Press the $\text{\textcircled{1}}$ button to confirm the selection. The meter will beep in the following instances if set to 'On'.


- When the $\text{\textcircled{1}}$ or < button is pushed to turn on the meter
- 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 the < button is pushed to set the post-meal (PP2) alarm
- When it is time for a preset blood glucose test



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

After setting the sound, press and hold the $\text{\textcircled{1}}$ button for three seconds to save all settings and turn off the meter.

NOTE

-  symbol is displayed only when the sound is set to 'OFF'.
- At any stage, if the $\text{\textcircled{1}}$ button is pressed for three seconds, time and date will be saved, and the meter will be turned off.
- Press and hold the > button to scroll through numbers quickly.

Checking the System



The GLUCOCARD Shine XL Meter and GLUCOCARD Shine Test Strips should be checked using GLUCOCARD Shine Control Solution, available in two levels (Level 1 and 2). The GLUCOCARD Shine Control Solutions contain known amounts of glucose and are used to check that the meter and test strips are working properly.

The test strip vials have GLUCOCARD Shine Control Solution ranges printed on their labels. Compare the result displayed on the meter to the control solution range printed on the test strip vial.

Before using a new meter or new vial of test strips, you should conduct a control solution test using GLUCOCARD Shine Control Solutions.

Follow the procedure that begins on page 21.

NOTE


- Use GLUCOCARD Shine Control Solutions only.
- Check the expiration date printed on the bottle. When the control solution bottle is first opened, record the discard date (date opened plus three months) in the space provided on the label.
- Make sure the meter, test strips and control solutions are at room temperature before testing. Control solution tests must be done at room temperature (68–77 °F, 20–25 °C).
- Before using the control solution, shake the bottle, discard the first one or two drops and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature between 46–86 °F (8–30 °C).

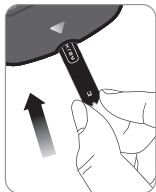
Use GLUCOCARD Shine Control Solution when:

- You want to practice the test procedure, instead of using blood
- You use the meter for the first time
- You begin using a new vial of test strips
- You suspect the meter or test strips are not working properly
- You think your test results are inaccurate or they do not reflect how you feel
- The meter is dropped or damaged

Control Solution Testing

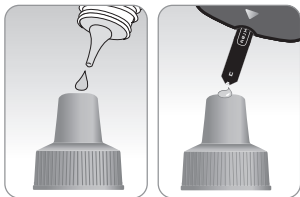
Step 1


Insert a test strip into the meter's test strip port, with the contact bars facing upwards. Gently push the test strip into the test strip port until the meter automatically turns on and the  symbol appears.





Step 2

Shake the GLUCOCARD Shine Control Solution bottle well before each test. Remove the cap and squeeze the bottle to discard the first one or two drops. Then wipe the tip with a clean tissue or cloth.



Dispense a drop of control solution onto a clean non-absorbent surface. While the  symbol blinks, apply the control solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window of test strip fills completely.

NOTE

- The meter will switch off if the control solution sample is not applied within two minutes of the  symbol appearing on the screen.
- If the meter turns off, press the  or < button and start from step two.

Step 3

A test result will appear after the meter counts down from '5' to '1'.

After your control solution result appears on the display, press the > button for three seconds until 'check' appears on the display.

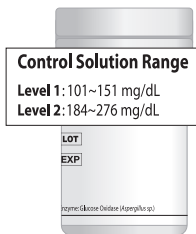
When 'check' is displayed, the result is stored in the meter's memory but it is not included in the 14-day averages.



Step 4

Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within that range.

Used test strips should be discarded safely in disposable containers.



Caution

- The ranges printed on the test strip vial are for GLUCOCARD Shine Control Solutions only.
- They do not have any connection to your blood glucose level.

Comparing the Control Solution Test Results

The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of this range.

Out of range results may occur due to the following factors:

Situations	Actions
<ul style="list-style-type: none">• When the control solution bottle was not shaken well• When the meter, test strip or the control solution were exposed to high or low temperatures• When the first one or two drops of control solution were not discarded, or the tip of the bottle was not wiped clean• When the meter is not functioning properly	Repeat the control solution test by referring to the ' NOTE ' on page 20.
<ul style="list-style-type: none">• When the control solution is past the expiration date printed on the bottle• When the control solution is past its discard date (the date the bottle was opened plus three months)• When the control solution is contaminated	Discard the used control solution and repeat the test using a new bottle of control solution.

If results continue to fall outside the range printed on the test strip vial, the GLUCOCARD Shine XL Meter and GLUCOCARD Shine Test Strips may not be working properly. Do NOT use your system and contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

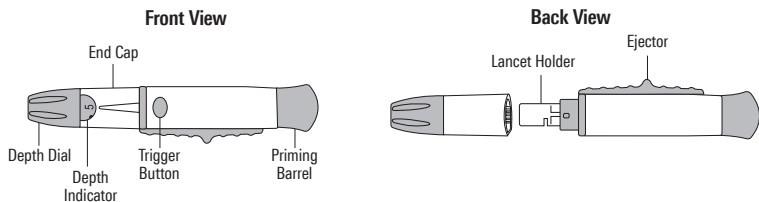
NOTE

- GLUCOCARD Shine Control Solutions can be obtained by contacting Customer Service: 800.566.8558.

Using the Lancing Device

A lancing device is needed in order to collect a blood sample. You may use the lancing device contained in the GLUCOCARD Shine XL Blood Glucose Monitoring System or any other medically approved lancing device.

For specific lancing device use instructions, see the lancing device insert.



- The lancing device is for use by a single user only and should not be shared with anyone, including other family members.

CAUTION

To reduce the chance of infection:

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

NOTE

- Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin)
- Choose a different site each time you test

Warning

- For use only on a single person. Disinfect reusable components according to manufacturer's instructions between each use.
- Used lancet blades must be safely discarded after a single use.
- Do not use on more than one person. Improper use of blood lancets can increase the risk of inadvertent transmission of blood-borne pathogens, particularly in settings where multiple people are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one person.
- Do not draw more blood than necessary for testing.
- Persons younger than 18 years old should be supervised by adults when using the subject device, or adults should perform the procedure on persons younger than 18 years old.
- Risk of injury. If the penetration depth is too deep, the puncture can injure children. Before using the lancing device for the first time on children, ask your healthcare professional. Start with the lowest penetration depth.

Preparing the Lancing Device

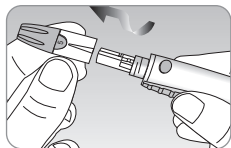
Step 1

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



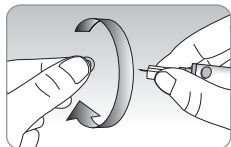
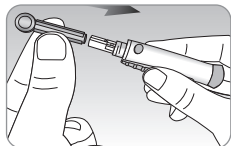
Step 2

Unscrew and remove the adjustable cap.



Step 3

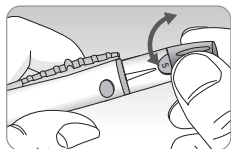
Insert a new disposable lancet firmly into the lancet holder. Twist off the protective cover of the lancet and set it aside, then replace the adjustable cap. Keep the protective cover to put on top of the used lancet after testing.



Step 4

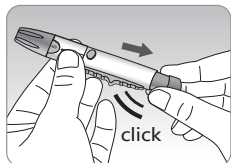
The lancing device has multiple puncture depth settings. The smaller numbers are for a shallower puncture and the larger numbers are for a deeper puncture.

Choose a depth of penetration by rotating the top portion of the adjustable tip until the setting number matches the arrow. Finer adjustments can be made by setting the arrow between numbers.



Step 5

Cock the lancing device by holding the body in one hand and pulling on the barrel until a click is heard.




NOTE

- The skin depth to retrieve samples will vary for various people at different sample sites.
- The lancing device's adjustable cap allows the best depth of skin penetration for an adequate sample size.
- The lancing device cannot puncture at the selected depth when the lancet is not inserted fully.

Preparing the Meter and Test Strip




Step 6

Insert a test strip with the contact bars facing up into the meter's test strip port.

Push the test strip gently into the test strip port until the meter automatically turns on and the  symbol appears.




Flagging Post-meal Test Results

- GLUCOCARD Shine XL Meter allows post-meal test to be flagged with the  symbol.
- The post-meal flag () can be attached and deleted just before applying the blood sample.
- Once the test result is saved with the post-meal flag (), it cannot be deleted.

Step 7

To attach a post-meal flag (🍴) to a test result, press and hold the > button for three seconds after inserting the test strip.

The post-meal flag (🍴) and the  symbol will appear on the screen.

The test result will also be displayed with the post-meal flag (🍴).

If you do not want to save the result as a post-meal test, move on to step 8 after step 6. If you want to delete the post-meal flag (🍴) that has been attached, press and hold the > button for three seconds again before applying the blood sample.



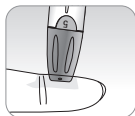
Applying the Blood Sample

Step 8


Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers.

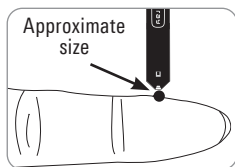
Press the release button. Remove the lancing device from the finger. Wait a few seconds for a blood drop to form.

A minimum volume of 0.5 μ L is needed to fill the confirmation window.




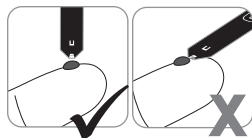
Step 9

After the  symbol appears on the screen, apply the blood sample to the narrow end of the test strip until the meter beeps.






If the blood sample does not fill the confirmation window completely, an 'Er4' message may appear because of abnormal viscosity or insufficient volume.

Then discard the test strip, insert a new one, and apply the blood sample again after the  symbol appears on the screen.



NOTE

- The meter will switch off if the blood sample is not applied within two minutes of the  symbol appearing on the screen.
- If the meter turns off, press the  or < button and apply the blood sample after the  symbol appears on the screen.

Step 10

The test result will appear after the meter counts down from '5' to '1'.

The result will be automatically stored in the meter memory.

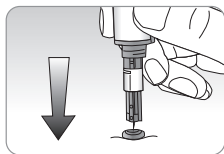
If the test strip is removed after the test result has been displayed, the meter will automatically switch off after three seconds. Discard used test strip safely in a disposable container.



Discarding Used Lancets

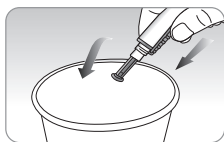
Step 1

Unscrew the lancing device's adjustable cap and place the protective cover on the lancet.



Step 2

Remove lancet and dispose of the used lancet in a proper biohazard container.



CAUTION

- Check for damage before using the lancet. If it has been damaged, please discard it and use another lancet.
- The lancet is very sharp. Please keep away from children.
- Keep the lancets in a cool and dry place.
- The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

Alternate Site Testing

What is AST (Alternate Site Testing)?

When someone tests their glucose, they usually take the blood sample from the tip of the finger.

However, since there are many nerve endings in the fingertip, it can be painful. When doing a glucose test, using different

parts of the body, such as the forearms, palms, thighs and calves, can reduce pain during testing.

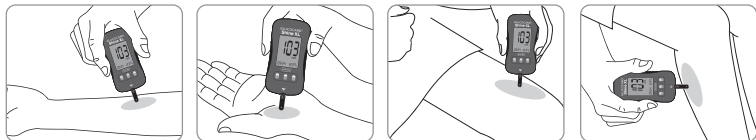
This method of testing with different parts of the body is called Alternate Site Testing (AST). While AST may reduce pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

NOTE

The lancing device included in this box is not intended to be used for AST.

To obtain a lancing device for AST contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

Alternate Site Blood Sampling (forearm, palm, thigh, calf)



Select a clean, soft and fleshy sample site area free of visible veins and hair, and away from bones.

Gently massage the sample site to help blood circulation to minimize result differences between fingertip and alternate site sampling.

Firmly press and hold the lancing device against site. Wait until the skin surface under the lancing device changes color. Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until sufficient (at least 0.5 μ L) blood is drawn.

Carefully lift the lancing device away from your skin.

CAUTION

- AST results should never be used to calibrate Continuous Glucose Monitoring Systems nor entered into an insulin dosing calculator or pump for dosing recommendations.

Things to Know When Using AST

Please read the following before testing at alternate sites (forearms, palms, thighs and calves).

The capillary whole blood of fingertips reflects changes in glucose levels more rapidly than in alternate sites. The test results from fingertip testing and AST may differ due to factors such as lifestyle and eating food which affect glucose levels.

Acceptable Situations for AST

- When your blood glucose levels are stable
- Fasting period
- Before a meal
- Before going to bed

Situations Requiring Fingertip Test

- When your blood glucose levels are NOT stable
- Two hours after a meal or exercise
- When sick or when glucose levels seem quite lower than test value
- When hypoglycemia is not well recognised
- When insulin has the biggest effect
- Two hours after an insulin injection

AST Precautions

- Do not ignore the symptoms of hyperglycemia or hypoglycemia.
- When the results of the test do not reflect the way you feel, retest using the fingertip. If the fingertip result still does not reflect the way you feel on retesting, please consult your healthcare professional.
- Do not rely on the AST results for changing your treatment method.
- The amount of glucose in alternate sites differs from person to person.
- Before using AST, please consult your healthcare professional.

NOTE

- Results from alternate site and fingertip samples may differ from each other, as there is a time lag for the glucose levels to reach the same value.
- Use a fingertip sample 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 lines on your palm, do not use that sample. Try puncturing again in a smoother area.

'HI' and 'Lo' Messages

'HI' Message

The meter displays results between 20–600 mg/dL. 'HI' appears when the blood glucose level is greater than 600 mg/dL and indicates severe hyperglycemia (much higher than normal glucose levels).

If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.



'Lo' Message

'Lo' appears when a test result is less than 20 mg/dL and indicates severe hypoglycemia (very low glucose levels).

If 'Lo' is displayed again upon retesting, please contact your healthcare professional immediately.



NOTE

- If messages for hyperglycemia or hypoglycemia are displayed even if you do not have those conditions, please contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

Target Blood Glucose Ranges

Reminders

Time of day

*Your target ranges
from your healthcare professional*

Before breakfast

Before lunch or dinner

One hour after meals

Two hours after meals

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

Expected Values: Normal blood glucose levels for an adult without diabetes are below 100 mg/dL before meals and fasting* and are less than 140 mg/dL two hours after meals.¹

*Fasting is defined as no caloric intake for at least eight hours.

Reference

1. American Diabetes Association (Standards of Medical Care in Diabetes - 2021. *Diabetes Care*, January 2021, vol. 44, Supplement 1, S15-S33)

Transferring Test Results

Test results stored in GLUCOCARD Shine XL Meter can be transferred from the meter to an electronic logbook via a data cable that connects the meter with a computer or smartphone app.

For more information visit
datamanagement.arkrayusa.com
or contact Customer Service: 800.566.8558,
24 hours a day, 7 days a week.



Meter Memory

The GLUCOCARD Shine XL Meter can save up to 250 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

The GLUCOCARD Shine XL Meter calculates and displays the averages of total test results, pre-meal test results and post-meal test (Ⓜ) results from the last 14 days.

Viewing Stored Test Results

Step 1

Press the < or Ⓛ button to turn the meter on.

The current date and time will be displayed on the bottom of the screen followed by the average value and the number of the test results saved within the last 14 days.

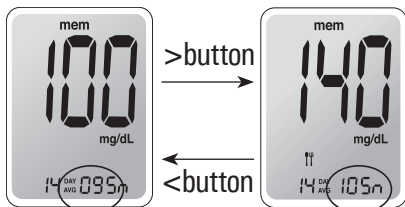


The number of tests for the last 14 days

Step 2

Press the > button to view the average values and the number of tests performed before eating a meal for the last 14 days.

On pressing the > button again, the average values and the number of tests performed post-meals for the same period will appear on the screen.



The number of pre-meal tests for the last 14 days

The number of post-meal tests for the last 14 days

Step 3

Use the > button to scroll through the test results, starting from the most recent and ending with the oldest.

Press the < button to return to the previous result.

After checking the stored test result, press the Ⓛ button to turn off the meter.

NOTE

- Press and hold the > button to scroll through the test results.

Setting the Alarm Function

Four types of alarms can be set in the GLUCOCARD Shine XL Meter. One post-meal alarm (PP2 alarm) and three time set alarms (alarm 1–3).

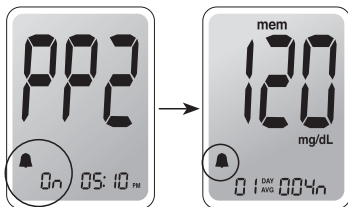
- The 'PP2' alarm goes off two hours after setting the alarm.
- The alarms ring for 15 seconds and can be silenced by pressing the <, > or Ⓛ button or by inserting a test strip.

Setting the Post-meal Alarm (PP2 Alarm)

Step 1 Setting the PP2 Alarm On

Without inserting a test strip, press and hold the < button for three seconds to set the post-meal alarm. 'PP2', the 📌 symbol and 'On' will be displayed.

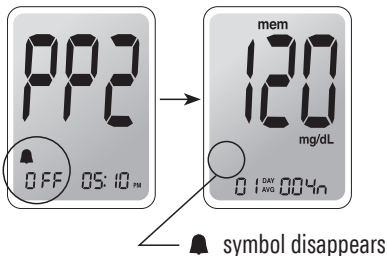
The screen will then automatically change to the memory check mode. At this time, the 📌 symbol, indicating that the 'PP2' alarm has been set, will be displayed on the screen.



Step 2 Setting the PP2 Alarm 'OFF'


To turn off the 'PP2' alarm, press and hold the < button for three seconds. 'PP2', the 📌 symbol and 'OFF' will appear on the screen.

Then the screen will change automatically to the memory check mode without 📌 symbol displayed.



Setting the Time Alarms (Alarm 1–3)

Step 1

Without inserting a test strip, press the < and  buttons simultaneously for three seconds to enter the time alarm mode.

While 'OFF' blinks on the screen, alarm 1 will be displayed.



Step 2

On pressing the > button, alarm 1 is set and 'On' is displayed on the screen.

Press the > button again to cancel alarm 1 and 'OFF' will blink on the screen.



Step 3

Press the < button to adjust the hour of alarm 1.

A number indicating the hour will blink on the screen.

Press the > button to set the hour.



Step 4

Press the < button to adjust the minute of alarm 1.

A number indicating the minute will blink on the screen.

Press the > button to set the minute.



Step 5

Press the ⓪ button to finish and enter alarm 2 mode.

Repeat steps 2 to 4 to set the remaining time alarms (alarm 2 and 3).



Step 6

Press and hold the ⓪ button for three seconds to finish and turn the meter off.

Caring for the GLUCOCARD Shine XL System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the soft cloth or tissue in a small amount of alcohol.

Do not use organic solvents such as benzene, acetone, or any household and industrial cleaners that may cause irreparable damage to the meter.

CAUTION







- For the lancing device: For use only on a single person. Disinfect reusable components according to manufacturer's instructions between each use.
- Inspect the lancing device after cleaning. If residual blood, debris, dust or lint remain, repeat the cleaning step. Do not use the lancing device if it is not visually clean after several repetitions of the cleaning step.




CAUTION

Storage and Handling

- **Do not** expose the meter to direct sunlight or heat for extended periods of time.
- **Do not** let dirt, dust, blood or water enter into the meter's test strip port.
- **Do not** drop the meter or subject it to strong shocks.
- **Do not** try to fix or alter the meter in any way.
- Keep the meter in a cool and airy place.
- Store all meter components in the carrying case to prevent loss.
- Avoid getting any liquid or moisture in the test strip vial. This can affect the test strips and cause inaccurate test results.
- **Do not** apply samples other than capillary whole blood or control solution to the test strip.

Understanding Errors and Other Messages

Message	What it means	What to do
	A used test strip was inserted.	Remove the test strip and insert a new test strip.
	The blood or control solution sample was applied before the  symbol appeared.	Repeat the test with a new test strip and wait until the  symbol appears before applying the blood or control solution sample.
	The temperature during the test was above or below the operating range.	Move to an area where the temperature is within the operating range (50–104 °F) and repeat the test after the meter and test strips have reached a temperature within the operating range.
	The blood sample is of insufficient volume or blood is too thick.	Repeat the test using a new test strip.

Message	What it means	What to do
	<p>This error message may appear when the wrong blood glucose test strip is used instead of the GLUCOCARD Shine Test Strip.</p>	<p>Repeat the test with a GLUCOCARD Shine Test Strip. Insert the test strip with the contact bars facing up, and push in gently until the meter turns on.</p>
	<p>There is a problem with the meter.</p>	<p>Do NOT use the meter. Contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week.</p>
	<p>An electronic error occurred during the test.</p>	<p>Repeat the test with a new test strip. If the error message persists, contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week.</p>

NOTE

- If the error messages persist, contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

General Troubleshooting

Problem	Troubleshooting
The display is blank even after inserting a test strip.	<ul style="list-style-type: none">• Check whether the test strip is inserted with the contact bars facing up.• Check if the test strip has been inserted completely into the test strip port.• Check if the appropriate test strip was used.• Check if the batteries are inserted correctly.• Replace the batteries.
The test does not start even after applying the blood sample on the test strip.	<ul style="list-style-type: none">• Check if the confirmation window is filled adequately.• Repeat the test after inserting a new test strip.
The test result does not match the way you feel.	<ul style="list-style-type: none">• Check to make sure the test strip has not expired.• Repeat the test after inserting a new test strip.• Perform control solution test.

NOTE

- If the problem is not resolved, please contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

Performance Characteristics

The performance of GLUCOCARD Shine XL Blood Glucose Monitoring System has been evaluated in laboratory and clinical tests.

Accuracy: The GLUCOCARD Shine XL Blood Glucose Monitoring System is calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the GLUCOCARD Shine XL System (Model GM505NA, GM505NB, GM505NC) was tested by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a lab instrument. The results below were obtained by diabetic patients at clinic centers.

	Obtained by healthcare professionals	Obtained by lay users
Slope	1.023	1.032
Y-intercept	-1.86 mg/dL	-3.63 mg/dL
Correlation coefficient(r)	0.995	0.985
Number of samples	110	105
Range tested	30–485 mg/dL	67–413 mg/dL

Accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
14/17 (82 %)	17/17 (100 %)	17/17 (100 %)

Accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
54/93 (58 %)	82/93 (88 %)	93/93 (100 %)	93/93 (100 %)

Precision: Precision studies were performed in a laboratory using the GLUCOCARD Shine XL Blood Glucose Monitoring System

<i>Within Run Precision</i>		
Blood avg.	38 mg/dL	SD = 1.9 mg/dL
Blood avg.	86 mg/dL	SD = 3.2 mg/dL
Blood avg.	125 mg/dL	CV = 4.1 %
Blood avg.	189 mg/dL	CV = 2.6 %
Blood avg.	334 mg/dL	CV = 2.8 %

<i>Total Precision</i>		
Control avg.	35 mg/dL	SD = 1.2 mg/dL
Control avg.	116 mg/dL	CV = 2.4 %
Control avg.	324 mg/dL	CV = 2.3 %

This study shows that there could be variation of up to 4.1 %.

Alternate Sites Testing Evaluation

Comparison of results using various AST sites with the results of YSI measurements.

- Alternate site test results for glucose concentration < 75 mg/dL

Test site	Within \pm 5 mg/dL	Within \pm 10 mg/dL	Within \pm 15 mg/dL
Fingertip	1/2 (50 %)	2/2 (100 %)	2/2 (100 %)
Forearm	1/2 (50 %)	2/2 (100 %)	2/2 (100 %)
Palm	2/2 (100 %)	2/2 (100 %)	2/2 (100 %)
Thigh	1/2 (50 %)	2/2 (100 %)	2/2 (100 %)
Calf	1/2 (50 %)	2/2 (100 %)	2/2 (100 %)

- Alternate site test results for glucose concentration ≥ 75 mg/dL

Test site	Within ± 5 %	Within ± 10 %
Fingertip	27/48 (56.3 %)	46/48 (95.8 %)
Forearm	19/48 (39.6 %)	42/48 (87.5 %)
Palm	28/48 (58.3 %)	38/48 (79.2 %)
Thigh	17/48 (35.4 %)	36/48 (75.0 %)
Calf	27/48 (56.3%)	46/48 (95.8 %)

Test site	Within ± 15 %	Within ± 20 %
Fingertip	48/48 (100 %)	48/48 (100 %)
Forearm	47/48 (97.9 %)	48/48 (100 %)
Palm	46/48 (95.8 %)	48/48 (100 %)
Thigh	46/48 (95.8 %)	48/48 (100 %)
Calf	48/48 (100 %)	48/48 (100 %)

Warranty Information

Warranty

The manufacturer warrants that the GLUCOCARD Shine XL Meter shall be free of defects in material and workmanship in normal use for a period of five 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 manufacturer 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, the manufacturer 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.

Returns

For instructions on how to return your meter, contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

Meters returned without this authorization will not be accepted.

MEMO

MEMO

Welcome to the GLUCOCARD® Shine XL Blood Glucose Monitoring System

Thank you for choosing the GLUCOCARD® Shine XL Blood Glucose Monitoring System. The system provides you with safe, fast and convenient blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring. You can obtain accurate results in just five seconds with a small (0.5 µL) blood sample.

DISTRIBUTED BY:

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Customer Service

800.566.8558

24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

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