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GLUCOCARD® Shine

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 manual contents before using the system. Please note the following instructions:

- Do not use the system for the 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 glucose level after eating, insulin injection or exercise.

Intended use:

The GLUCOCARD® Shine 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 should be used only during steady-state blood glucose conditions. The GLUCOCARD® Shine Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro*) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

The GLUCOCARD® Shine Blood Glucose Test Strips are for use with the GLUCOCARD® Shine Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternate sites.

The GLUCOCARD® Shine Control Solutions are for use with the GLUCOCARD® Shine Meter and GLUCOCARD® Shine Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

Important Health-Related Information

- The GLUCOCARD® Shine Blood Glucose Monitoring System is intended for *in vitro* (outside the body) diagnostic use only and for the quantitative measurement of glucose in capillary whole blood.
- The GLUCOCARD® Shine Blood Glucose Monitoring System is intended for use by a single user only. Do not share the meter or lancing device with another person.
- The GLUCOCARD® Shine Blood Glucose Meter is designed to minimize code related errors in monitoring by using the no-coding function.
- The glucose in the blood sample mixes with special chemicals on the test strip to produce a small electrical current. The GLUCOCARD® Shine meter converts this electrical current to glucose concentration.
- The GLUCOCARD® Shine Blood Glucose Meter should be used only with the GLUCOCARD® Shine Test Strip.
- 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 (high blood sugar) or hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed pre-cleaning and disinfection.

- The GLUCOCARD® Shine Blood Glucose Monitoring System is waived under CLIA document number CR140380. To obtain further information about this waiver, visit the FDA website at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/search.cfm>
- 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.

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.

Meaning of Symbols Used:



Caution



Biological risks

Specifications

- Product specifications**

Measurement range	20–600 mg/dL
Sample size	Minimum 0.5 µL
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	500 test results
Size	3.74 x 1.30 x 0.75 in
Weight	1.45 oz (with batteries)

- Operating ranges**

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

- 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 Blood Glucose Monitoring System

Components

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

- * GLUCOCARD® Shine Blood Glucose Meter
- * User's Manual
- * Quick Reference Guide
- * Batteries

GLUCOCARD® Shine Blood Glucose Monitoring System may include the following items:

- * GLUCOCARD® Shine Blood Glucose Test Strips
 - * Lancing Device
 - * Lancets
 - * Logbook
 - * Carrying Case
- Check all the components after opening the GLUCOCARD® Shine Blood Glucose Monitoring System package.
 - The GLUCOCARD® Shine Control Solutions (Level 1 and 2) are necessary but not included. The GLUCOCARD® Shine Control Solutions and the cable for the data transmission to a PC can be ordered separately. Please contact Customer Service at 800.566.8558, 24 hours a day, 7 days a week.

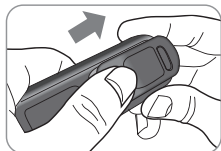
CAUTION: The meter and lancing device are only intended for a single user. Do not share them with anyone including other family members. Never use on multiple users.

Inserting or Replacing the Batteries

The GLUCOCARD® Shine Meter uses 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 for the first time, the batteries should be replaced as soon as possible. The test results might not be saved if the batteries run out.

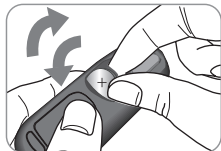
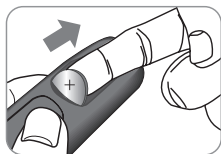
Step 1

Make sure the meter is turned off. Press down and slide off the battery compartment cover.



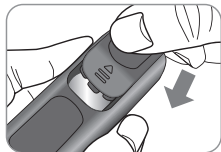
Step 2

Remove the used batteries one at a time. Slip your index finger under the battery to lift and pull out as shown. Insert two new batteries with the + side facing up and make sure the batteries are inserted firmly in place.



Step 3

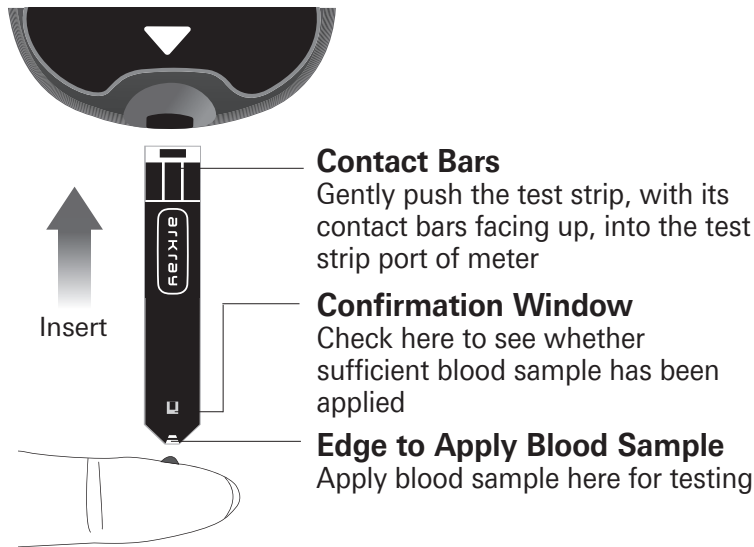
Place the cover on the battery compartment. Push down until you hear the tab click into place.



NOTE: Removing the meter batteries will not affect your stored result. However, you may need to reset your meter settings. See pages 15–19.

GLUCOCARD® Shine Blood Glucose Test Strip

The GLUCOCARD® Shine 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 Instruction

- All components that come into contact with blood samples should be considered to be biohazards capable of transmitting viral diseases, even after disinfection.
- Do not share your meter or lancing device with another person.

- The GLUCOCARD® Shine Test Strip 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 as this may cause inaccurate results.
- If the test strips are used and stored according to its storage and handling methods, test strips in new, unopened vials and test strips in 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 of 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 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.

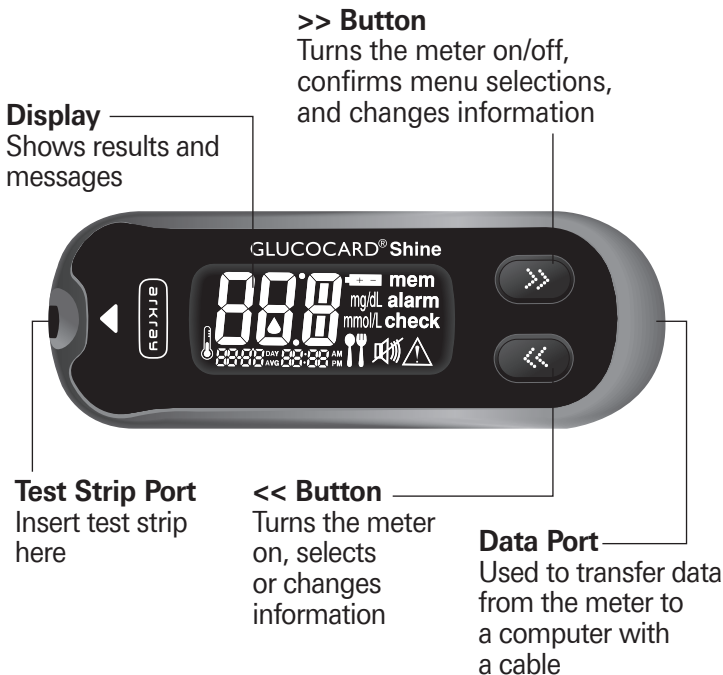
CAUTION:

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 Pre-cleaning and Disinfection procedures found in the Caring for Your System section of this user manual.

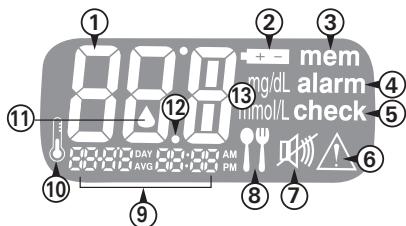
NOTE: You can get more safety information at FDA Public Health Notification (<http://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>) or at CDC Clinical Reminder (<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>).

GLUCOCARD® Shine Blood Glucose Meter



NOTE: The cable for data transmission to a PC can be ordered separately. Please contact Customer Service at 800.566.8558, 24 hours a day, 7 days a week.

GLUCOCARD® Shine Blood Glucose Meter Display



- ① **Test results:** test results displaying panel
- ② **Battery symbol:** indicates meter battery is running low and needs to be replaced
- ③ **mem:** appears when test results stored in the memory are displayed
- ④ **alarm:** appears when the post-meal alarm has been set
- ⑤ **check:** appears when test results have not been saved
- ⑥ **Hypoglycemia symbol:** appears when the test result is below the hypoglycemic level
- ⑦ **Mute symbol:** appears only when the sound is set to OFF
- ⑧ **Post-meal test flag:** appears during post-meal testing and when post-meal test results are displayed
- ⑨ **Month / Day / Hour / Minute**
- ⑩ **Temperature symbol:** displays recorded temperature when blood glucose levels are tested
- ⑪ **Blood insertion symbol:** indicates meter is ready for the application of a drop of blood or control solution
- ⑫ **Decimal point:** appears when the blood glucose measuring unit is set to mmol/L
- ⑬ **mg/dL, mmol/L:** unit for measuring blood glucose

NOTE: The unit of measurement is fixed in mg/dL and it cannot be changed to mmol/L by the user.

Setting Up Your System

Press and hold the >> button for three seconds to enter the set mode. After all settings are finished, press and hold the >> button for three seconds to turn off the meter.

Press << to reach the accurate value. Press and hold << to scroll faster.

Adjusting the Date and Time

Step 1 Entering the SET Mode

Press and hold the >> button for three seconds to enter the set mode. After all the segments flash across the screen, "SET" is displayed on the screen.

Press the >> button again to progress to the next step.



Step 2 Setting the Year

Press and release << to adjust until the correct year appears. After setting the year, press the >> button to confirm your selection and progress to the next step.



Step 3 Setting the Month

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



Step 4 Setting the Date

Press << until the screen displays the correct day. Press the >> button to confirm the date and progress to the next step.



Step 5 Setting the Time Format

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



Step 6 Setting the Hour

Press << until the correct hour appears. After the hour is set, press the >> button to progress to the next step.



Step 7 Setting the Minute

Press << 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 screen will display the "On" or "OFF". Press the >> button to confirm the selection and move to the next mode.

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

- When you push the >> button or << button 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 you push the << button 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.

NOTE: When the sound is set to OFF, the  symbol appears on the display.

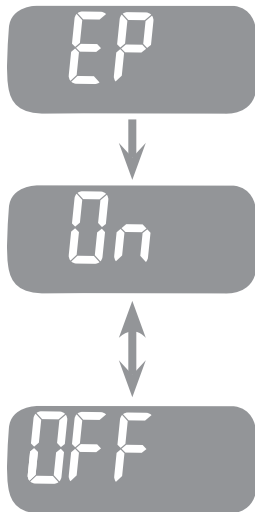
Turning on the Test Strip Expiration Date Indicator

Step 9

This mode allows you to turn the test strip expiration date indicator on or off.

When “EP” blinks on the screen, press <<. The screen will display “On” or “OFF”. Press the >> button to confirm the setting and move to the next mode.

This mode turns the function on or off only. See page 40 to set the test strip expiration date.




NOTE: If the pre-set expiration date expires, the meter will display the following. For example, in the case when the expiration date is set to October of 2027, the meter displays “EP” at the start of November of 2027.



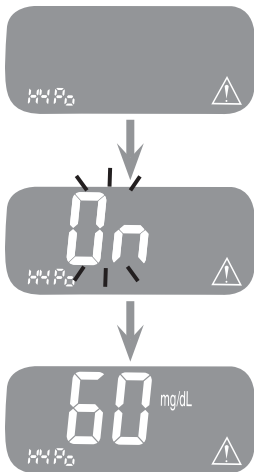
Turning on the Hypoglycemia (HYPO) Indicator

Step 10

This mode allows you to turn the hypoglycemia indicator (possible low blood sugar) on or off and to select the desired level for the indicator. You will be alerted any time your test result is lower than the selected level.

When "Hypo" is displayed (along with the hypoglycemia symbol ) , press <<. The screen will display "On" or "OFF". Press the >> button when "On" appears to set the desired level.

Then press << until the desired hypoglycemic level (between 20 and 60 mg/dL) is being displayed. Then press the >> button to confirm the level.



If you do not want to set the indicator, press the >> button while the screen displays "no". The screen will then return to step 2 (see page 15).

When you are done setting all the modes, turn the meter off by pressing and holding the >> button for three seconds.

NOTE: If the test result is lower than the pre-set hypoglycemia level, the meter will display the following.



CAUTION: Before the HYPo indicator is set, ask your doctor or diabetes nurse to help you decide what your hypoglycemia level will be.

Checking the System



You should check your meter and test strips using the GLUCOCARD® Shine Control Solutions (Level 1 and 2). The GLUCOCARD® Shine Control Solutions contain known amounts of glucose and are used to check that the meter and the test strips are working properly. The test strip vials have GLUCOCARD® Shine Control Solution ranges printed on the labels. Compare the result displayed on the meter to the GLUCOCARD® Shine Control Solution range printed on the test strip vial. Before using a new meter or a new vial of test strips, you should conduct a control

solution test following the procedure on pages 21–22 with two different levels of control solutions (Level 1 and 2).

Notes:

- GLUCOCARD® Shine Meter and GLUCOCARD® Shine Test Strips only can be used with GLUCOCARD® Shine Control Solutions.
- Check the expiration dates printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three months) in the space provided on the label.
- Make sure your 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 of 46–86 °F (8–30 °C).

You should do a control solution test:

- When you want to practice the test procedure using the control solution instead of blood
- When using the meter for the first time
- Whenever you open a new vial of test strips

- If the meter or test strips do not function properly
- If your symptoms are inconsistent with the blood glucose test results and you feel that the meter or test strips are not working properly
- If you drop or damage the meter
- When using the meter for blood glucose test after any disinfection procedure

Control Solution Testing

Step 1

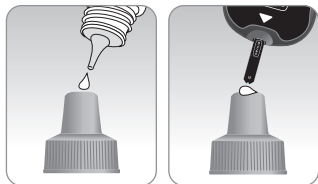
Insert a test strip into the meter's test strip port, with the contact bars facing upwards. Gently push the test strip into the test strip port until the meter beeps. Be careful not to bend the test strip while pushing it in. The ▲ symbol will be displayed on the screen.




Step 2

Shake the GLUCOCARD® Shine Control Solution bottle 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.

After the ▲ symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.



NOTE: If the control solution sample is not applied within two minutes of the  symbol appearing on the screen, the meter will switch off. If the meter turns off, remove the test strip, reinsert, and start from step 1.

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 << for three seconds until the 'check' symbol appears on the display. When the 'check' symbol is displayed, the result is not stored in the meter's memory and is not included in the 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 strips should be discarded safely in disposable containers.



CAUTION: The ranges printed on the test strip vial are for the 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 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 drop of the control solution was 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 "Notes" 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.

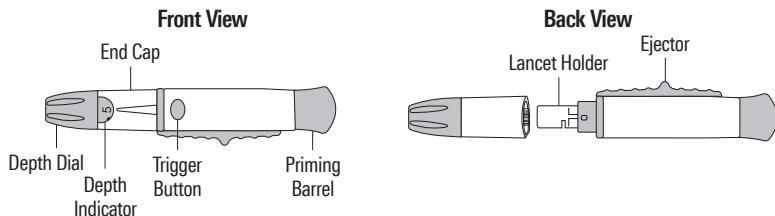
CAUTION: If results continue to fall outside the range printed on the test strip vial, the test strip and meter may not be working properly. Do not use your system and contact Customer Service at 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional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

NOTE: The GLUCOCARD® Shine Control Solution can be purchased separately. Contact Customer Service at 800.566.8558, 24 hours a day, 7 days a week.

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 GLUCOCARD® Shine 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

- All components that come into contact with blood samples should be considered to be biohazards capable of transmitting viral diseases, even after disinfection.
- Do not use a lancet that has been used by another person and never share your meter and lancing device with anyone.
- Wash your hands thoroughly with soap and water after handling your meter, lancing device, or test strips.
- Keep your meter and lancing device clean. See the pre-cleaning and disinfection section on page 41.

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

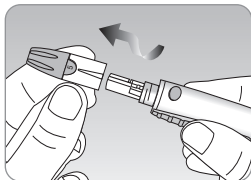
Step 1

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



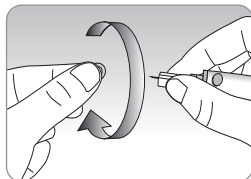
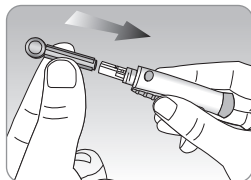
Step 2

Unscrew and remove the adjustable cap.



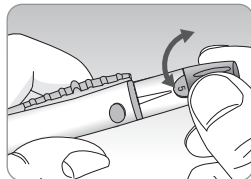
Step 3

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.



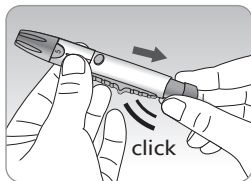
Step 4

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 cap 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




With the contact bars facing up, insert a test strip into the meter's test strip port. Push the test strip gently into the test strip port until the power automatically turns on and the  symbol appears.




Flagging Post-meal Test Results

The GLUCOCARD® Shine Meter allows you to flag a result of a post-meal test with  symbol. The post-meal test flag () can be attached just before applying the blood sample. Once you attach the post-meal flag () to the test results, it cannot be deleted.

Step 7

If you want to attach a post-meal flag () to a test result, press and hold **<<** 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 the step 8 after the step 6.



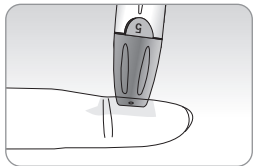
Applying the Blood Sample

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.

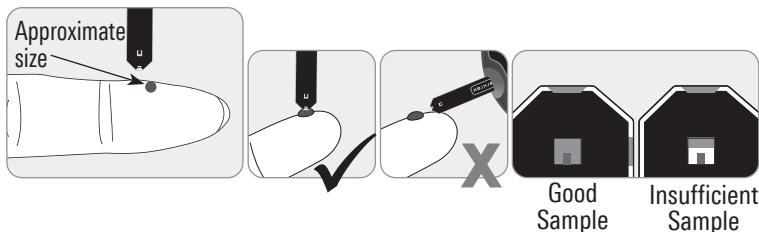
Remove the device from the finger.



Wait a few seconds for a blood drop to form. A minimum volume of 0.5 μL 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. If an Er4 message appears, retest with a new test strip.



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, remove the test strip, reinsert it, and apply the blood sample after  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's memory.

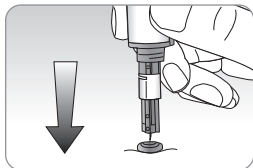
If the test strip is removed after the test result is displayed, the meter will automatically switch off after three seconds. Discard used test strip safely in a disposable container.



Discarding Used Lancets

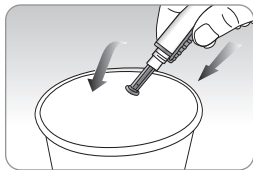
Step 1

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 damages before using the lancet. If they have been damaged, please discard it and use other lancet.
- The lancet is very sharp. Please keep away from children.
- Keep the lancets in a cool and dry place.

CAUTION: 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)?

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 can be quite painful. When doing a glucose test, using different parts of the body, such as the forearms, palms, thighs, and calves, can reduce the pain during testing.

This method of testing with different parts of the body is called Alternate Site Testing (AST). While AST may reduce the 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 understand the following before testing at sites other than the fingertip (forearms, palms, thighs, and calves). The capillary whole blood of the fingertips shows changes in glucose levels more rapidly than from alternate sites. Therefore, the test results from the fingertip testing 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

Situations requiring fingertip test

- When the glucose levels are rapidly increasing, such as 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
- 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, please consult your healthcare professional.
- Do not rely on 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.

NOTE: If the sample drop of blood runs or spreads due to contact with hair or with a line in 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 on retesting, please contact your healthcare professional immediately.

Lo Message

“Lo” appears when the result is less than 20 mg/dL and indicates severe hypoglycemia (very low glucose levels). If “Lo” is displayed again on retesting, please contact your healthcare professional immediately.



* When the hypoglycemia indicator is on,  symbol also appears.



NOTE: If messages for hyperglycemia or hypoglycemia are displayed even if you do not have those conditions, please contact Customer Service at 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 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.



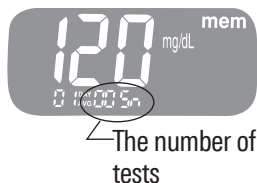
Meter Memory

The GLUCOCARD® Shine Meter can save up to 500 glucose test results with the 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 Meter calculates and displays the averages of total test results, pre-meal test (Pr) results, and post-meal test (P) results from the last 1, 7, 14, 30 and 90 days.

Viewing Averages

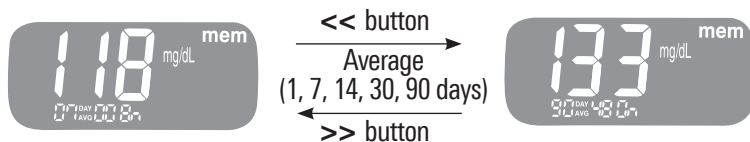
Step 1

Press the << or >> button to turn the meter on. The current date and time will be displayed on the bottom of the screen for two seconds, followed by the one day average value and the number of the test results saved within the current day.



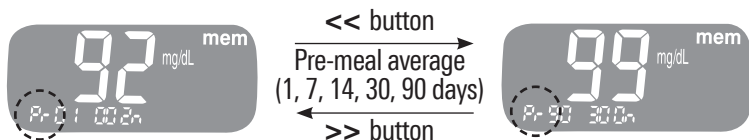
Step 2 Viewing Averages

Press the << to view 7-, 14-, 30- and 90-day average values and the number of tests performed for the last test period.



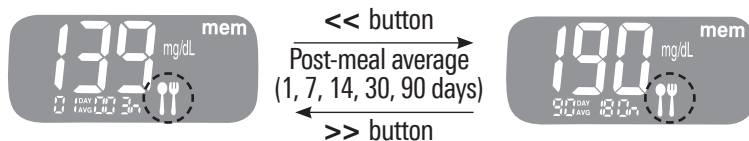
Step 3 Viewing Pre-meal Averages

Repeatedly press the << to view 1-, 7-, 14-, 30- and 90-day average value and the number of tests performed pre-meals with the 'Pr' symbol for the last test period.



Step 4 Viewing Post-meal Averages

On pressing the << again, 1-, 7-, 14-, 30- and 90-day average value and the number of tests performed post-meals for the last test period will appear on the screen. Hold the >> button to turn off the meter.

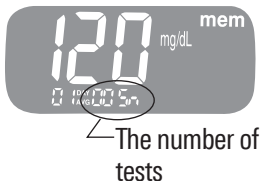


Use the >> button to scroll back through the averages seen previously.

Viewing Test Results

Step 1

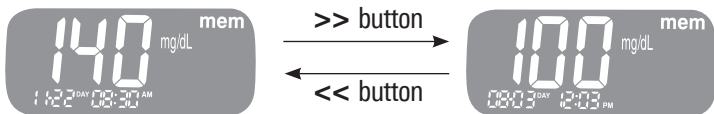
Press << or the >> button to turn the meter on. The current date and time will be displayed on the bottom of the screen for two seconds, followed by the one day average value and the number of test results saved within the current day.



Step 2

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

Press the << to return to the result seen previously. The test date and the recorded temperature will display alternately. After checking the stored test result, hold the >> button to turn off the meter.



Setting the Post-meal Alarm (PP2 Alarm)

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

Step 1 Setting the PP2 alarm On

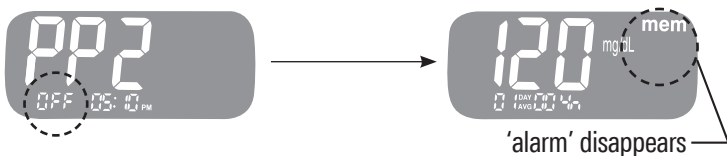
Without inserting a test strip, press and hold << for three seconds to set the post-meal alarm. The “PP2”, the “alarm” and then the “On” will be displayed.

The screen will then automatically change to the memory check mode. At this time, the “alarm”, 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 << for three seconds. The “PP2” and the “OFF” will appear on the screen. Then the screen will change automatically to the memory check mode without the “alarm” being displayed.



Setting the Test Strip Expiration Date Indicator

The test strip expiration date indicator can be set in the GLUCOCARD® Shine Meter. The test strip expiration date is printed on the test strip vial.

At any stage, if the >> button is pressed for three seconds, the meter will be turned off.

To turn on the indicator function, see page 18 to view how to turn on the indicator.

Step 1 Enter the Expiration Date Setting

Press and hold the << and >> button at the same time for three seconds to enter the expiration date settings. After all segments flash across the screen, "EP" will be displayed on the screen. Press the >> button to change the date.

NOTE: The test strip expiration date is printed on the test strip vial.

Step 2 Setting the Year

A number indicating the year will blink in the left corner of the screen. Press the << button until the correct year appears.

Press the >> button to confirm the year and set the month.



Step 3 Setting the Month

A number indicating the month will blink in the left corner of the screen.

Press the << button until the correct month appears. After finishing the setting, press and hold the >> button for three seconds to turn off the meter.



Caring for Your System

- To minimize the risk of transmission of blood-borne pathogens, the pre-cleaning and disinfection procedure should be performed as recommended in the instructions below.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.
- 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.

Pre-cleaning and Disinfection:

The pre-cleaning procedure is needed to clean dirt as well as blood and other body fluids on the exterior of the meter and lancing device before performing the disinfection procedure. The disinfection procedure is needed to prevent transmission of blood-borne pathogens.

- For the meter and lancing device, this pre-cleaning and disinfection procedure should be performed **once per week**.

NOTE:

The life span of a GLUCOCARD® Shine Meter is five years. We recommend disinfecting both the meter and lancing device at least once per week. We have validated a total of 260 cleaning and disinfecting cycles (260 pre-cleaning and 260 disinfection cycles) to represent weekly cleaning and disinfecting over the use life of your meter and lancing device.

1 pre-cleaning and 1 disinfection cycle per week * 52 weeks per year * 5 years = 260 pre-cleaning and 260 disinfection cycles

- We have validated **Clorox Healthcare Bleach Germicidal Wipes** with 0.55 % sodium hypochlorite as the active ingredient for disinfecting the GLUCOCARD® Shine Meter and lancing device. It has been shown to be safe for use with the meter and lancing device. This disinfectant is available commercially in towelette form. In addition to GLUCOCARD® Shine Blood Glucose Monitoring System instruction, **please read the instructions provided by the manufacturer of Clorox Healthcare Bleach Germicidal Wipes before using it.**

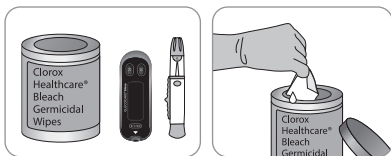
Name	Clorox Healthcare® Bleach Germicidal Wipes	
Manufacturer	Clorox Professional Products Company [Phone] 1 800 234 7700 [Website] www.cloroxpro.com	
EPA registration number	67619-12	
Active ingredients	Sodium Hypochlorite: 0.55 %	

NOTE:

The disinfectant products can be purchased through online retailers (e.g. Amazon or Walmart) or by calling the Clorox® company. To find out where to purchase the disinfectant product, please contact the Clorox® company or visit their website as listed above.

Pre-cleaning and Disinfection Procedures:

- ① Open the cap of the Clorox Healthcare Bleach Germicidal Wipes container and pull out 1 towelette and close the cap.



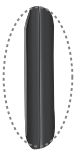
- ② Wipe the entire surface of the meter three times horizontally and three times vertically using one towelette to pre-clean blood and other body fluids.



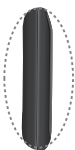
Front



Back



Both sides



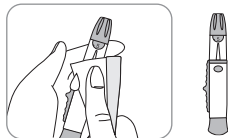
- ③ Dispose of the used towelette in a trash bin.



- ④ Pull out one new towelette and wipe the entire surface of the meter three times horizontally and three times vertically using a new towelette to remove blood-borne pathogens.



- ⑤ Dispose of the used towelette in a trash bin.
- ⑥ Allow exteriors to remain wet for one minute.
- ⑦ Repeat the same procedure for the lancing device (step ① to step ⑥).



*** After the pre-cleaning and disinfection procedure, the control solution should be tested to confirm that the meter works properly before using the meter. Control solution tests should be performed with two different levels of control solutions (Level 1 and 2). Verify that the test results are within the range printed on the test strip vial. See pages 21–22 for how to do a control solution test.**

NOTE: If any of the following deterioration signs appear after pre-cleaning or disinfecting, please stop using the system and contact Customer Service at 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

- When the inscriptions on the exterior of the meter (or lancing device) have been removed
- When the color of the meter (or lancing device) has changed or faded
- When cracks or roughness develop on the meter (or lancing device)

- When a part of the segment on the meter display does not flash
- When control solution test results do not fall within the stated range on the test strip vial

CAUTION:

- Do not use other cleaners or disinfectants because other chemicals have not been validated and may damage the meter.
- Do not get fluids inside the meter through the test strip port, data transmission port or battery compartment. Never immerse the meter or hold it under running water because this will damage the meter.

Storage and Handling Caution:

- Do not expose the meter to direct sunlight or heat for an extended period 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.
- The GLUCOCARD® Shine Meter should be used only with GLUCOCARD® Shine Test Strips.
- 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.






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 Pre-cleaning and Disinfection procedures found in the Caring for Your System section of this user manual.

NOTE: You can get additional information or technical assistance by calling our Customer Service at 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.

Understanding Error and Other Messages

	<p>A used test strip was inserted.</p> <p>> Remove the test strip and reinsert a new test strip.</p>
	<p>The blood or control solution sample was applied before the ▲ symbol appeared.</p> <p>> Repeat the test with a new test strip and wait until the ▲ symbol appears before applying the blood or control solution sample.</p>
	<p>The blood sample is of insufficient volume or blood is too thick.</p> <p>> Repeat the test using a new test strip.</p>
	<p>This error message may appear when the wrong blood glucose test strip is used instead of a GLUCOCARD® Shine Blood Glucose Test Strip.</p> <p>> Repeat the test with a GLUCOCARD® Shine Test Strip.</p>
	<p>There is a problem with the meter.</p> <p>> Do not use the meter. Contact Customer Service at 800.566.8558, 24 hours a day, 7 days a week. In case of emergency, please contact your healthcare professional or emergency medical response.</p>

	<p>An electronic error occurred during the test.</p> <ul style="list-style-type: none"> > Repeat the test with a new test strip. <p>If the error message persists, please contact Customer Service: 800.566.8558, 24 hours a day, 7 days a week.</p>
	<p>The temperature during the test was above the operating range.</p> <ul style="list-style-type: none"> > Move to an area where the temperature is within the operating range of 50–104 °F (10–40 °C) and repeat the test after the meter and test strips have reached a temperature within the operating range.
	<p>The temperature during the test was below the operating range.</p> <ul style="list-style-type: none"> > Move to an area where the temperature is within the operating range of 50–104 °F (10–40 °C) and repeat the test after the meter and test strips have reached a temperature within the operating range.

NOTE: If the error messages persist, please contact Customer Service at 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 whether the batteries are inserted with the '+' side facing up.• 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 completely.• Repeat the test after inserting a new test strip.
The test result doesn't match the way you feel.	<ul style="list-style-type: none">• Repeat the test after inserting a new test strip.• Check the expiration date of the test strip.• Perform control solution test.

NOTE: If the problem is not resolved, please contact Customer Service at 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 the GLUCOCARD® Shine Blood Glucose Monitoring System has been evaluated in laboratory and clinical tests.

ACCURACY: The GLUCOCARD® Shine Blood Glucose Monitoring System is calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the GLUCOCARD® Shine Blood Glucose Monitoring System 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	1.006
Y-intercept	-2.07 mg/dL	-0.41 mg/dL
Correlation coefficient(r)	0.996	0.994
Number of samples	100	100
Range tested	66–321 mg/dL	66–321 mg/dL

Accuracy results for glucose concentration < 75 mg/dL

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

Accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
79/95 (83.2 %)	94/95 (98.9 %)	95/95 (100 %)	95/95 (100 %)

Precision: Precision studies were performed in a laboratory using the GLUCOCARD® Shine system.

Within Run Precision

*Blood avg.	39 mg/dL	SD = 1.9 mg/dL
*Blood avg.	82 mg/dL	SD = 2.7 mg/dL
*Blood avg.	145 mg/dL	CV = 2.9 %
*Blood avg.	179 mg/dL	CV = 3.9 %
*Blood avg.	341 mg/dL	CV = 2.5 %

Total Precision

*Control avg.	32 mg/dL	SD = 1.7 mg/dL
*Control avg.	121 mg/dL	CV = 3.6 %
*Control avg.	354 mg/dL	CV = 4.3 %

This study shows that there could be variation of up to 4.3 %.

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

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip	5/5 (100 %)	5/5 (100 %)	5/5 (100 %)
Forearm	5/5 (100 %)	5/5 (100 %)	5/5 (100 %)
Palm	5/5 (100 %)	5/5 (100 %)	5/5 (100 %)
Thigh	4/5 (80 %)	5/5 (100 %)	5/5 (100 %)
Calf	3/5 (60 %)	5/5 (100 %)	5/5 (100 %)

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

	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Fingertip	95/95 (100 %)	95/95 (100 %)	95/95 (100 %)	95/95 (100 %)
Forearm	69/95 (72.6 %)	91/95 (95.8 %)	94/95 (98.9 %)	95/95 (100 %)
Palm	61/95 (64.2 %)	87/95 (91.6 %)	93/95 (97.9 %)	95/95 (100 %)
Thigh	56/95 (58.9 %)	86/95 (90.5 %)	86/95 (90.5 %)	95/95 (100 %)
Calf	57/95 (60 %)	87/95 (91.6 %)	93/95 (97.9 %)	95/95 (100 %)

Warranty Information

Manufacturer's Warranty

ARKRAY USA, Inc. warrants that the GLUCOCARD® Shine 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 ARKRAY USA, Inc. 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, ARKRAY USA, Inc. 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 ARKRAY USA, Inc.

MEMO

Welcome to the GLUCOCARD® Shine Blood Glucose Monitoring System

Thank you for choosing the GLUCOCARD® Shine 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:

ARKRAY USA
8260 NW 27th St, Suite 403
Miami, FL 33122 USA

U.S. Support

800.566.8558
www.arkrayusa.com

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.

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