arkray

GLUCOCARD®
Shine Connex

BLOOD GLUCOSE MONITORING SYSTEM

User Manual

For single user / home use only

Welcome to the GLUCOCARD® Shine Connex Blood Glucose Monitoring System

Thank you for choosing the GLUCOCARD Shine Connex Blood Glucose Monitoring System. The system provides you with rapid 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.

Test results can be sent to a smartphone through a Bluetooth® wireless connection.

Bluetooth® Wireless Technology

Bluetooth® wireless technology is used by some smartphones and many other devices. GLUCOCARD® Shine Connex Meter uses Bluetooth® wireless technology to pair* and to send your glucose test results to a smartphone.

When using the GLUCOCARD Shine Connex Blood Glucose System, we suggest you pair your GLUCOCARD Shine Connex Meter with your smartphone and track your test results.

* The process of creating a connection between two Bluetooth® devices. An auto-generated passkey has to be exchanged between the two devices. Once the devices are paired (connected), they will automatically communicate with each other when the Bluetooth® feature is activated.

⚠ WARNING

Turn off the Bluetooth® feature in areas where the use of wireless devices is restricted, such as hospitals, some healthcare professional offices, and airplanes.

Trademarks

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth® SIG, Inc. and any use of such marks by the manufacturer is under license. All other trademarks and trade names are those of their respective owners.

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This equipment should be installed and operated with minimum distance eight inches (20 cm) between the radiator and your body.

Any changes or modifications not expressly approved by the manufacturer could void the user's authority to operate this equipment.

Table of Contents

Important Information: *Read This First*

Intended use

- The GLUCOCARD Shine Connex Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.
- The GLUCOCARD Shine Connex 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.
- The system 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 the GLUCOCARD® Shine family of blood glucose meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.
- The GLUCOCARD® Shine Control Solutions are for use with the GLUCOCARD Shine family of blood glucose meters and the GLUCOCARD Shine Blood Glucose Test Strips to check that the meter and test strips are working together properly, and that the test is performing correctly.

Important Safety Information

- Please use this device only for the intended use described in this user manual.
- Please follow the suggested cleaning and disinfection procedures described in this user manual.
- GLUCOCARD Shine Blood Glucose Test Strips are intended for single use only. They should be disposed of in an appropriate container immediately after use.
- The GLUCOCARD Shine Connex 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 Connex Meter detects this electrical current and measures the amount of glucose in the blood sample.
- If your test result is below 60 mg/dL or above 240 mg/dL, consult a healthcare professional immediately.

Meaning of Symbols Used:


Caution


Biological risks

Limitations of GLUCOCARD Shine Connex Blood Glucose Monitoring System

- An abnormally high or low red blood cell count (hematocrit level over 65 % or below 15 %) may produce inaccurate results.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hypoglycemic hyperosmolar state, with or without ketosis.
- Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Altitudes of higher than 10,000 ft. (3,048 m) above sea level may have an effect on the performance of the test strip.
- This system is for single-patient use only and should **not** be shared.
- **Not** for neonatal use.
- **Do not use** for diagnosis of or screening for diabetes mellitus.
- **Not for use** on critically ill patients.
- **Not for use** on anyone undergoing oxygen therapy.
- For *in vitro* diagnostic use only.
- The GLUCOCARD Shine Connex Blood Glucose Meter should only be used with GLUCOCARD Shine Blood Glucose Test Strips.

For questions or concerns, contact ARKRAY Technical 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 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 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 µL
Test time	Five seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	1,000 test results
Size	4.06 x 2.23 x 0.63 inches (103 x 54 x 16 mm)
Weight	2.54 oz. (72.1 g) with batteries
Bluetooth® technology	• Frequency range: 2.4–2.4835 GHz • Operating range distance: maximum 32 feet (10 meters) unobstructed • Operating channels: 40 channels • Security encryption: 128-bit AES (Advanced encryption standard)

Operating ranges

Temperature	42.8–111.2 ˚F (6–44 ˚C)
Relative humidity	10–90 %
Hematocrit	15–65 %

GLUCOCARD Shine Connex Blood Glucose Monitoring System

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

① GLUCOCARD Shine Connex Blood Glucose Meter
② User Manual
③ Quick Reference Guide
④ Bluetooth® Pairing Quick Guide
⑤ Batteries (2)
⑥ Lancing Device
⑦ Lancets (10)
⑧ Logbook
⑨ Carry Case

- Check all the components after opening the GLUCOCARD® Shine Connex 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 ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

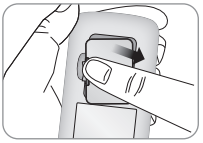
Inserting or Replacing the Batteries

- The GLUCOCARD Shine Connex 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 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.

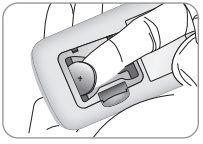
Push the cover in the direction of the arrow to open the battery compartment.



Step 2

Remove the used batteries and insert two new batteries with the '+' side facing up.

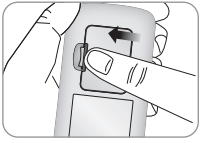
Make sure the batteries are inserted firmly.



Step 3

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

A click may be heard.

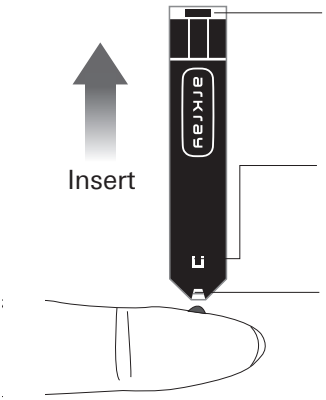


NOTE

- Removing the meter batteries will not affect your stored results.
- However, meter settings may need to be reset. See page 18.

GLUCOCARD Shine Blood Glucose Test Strip

The GLUCOCARD Shine Connex 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.



Contact bars

Gently push the test strip, with its contact bars facing up, into the test strip port of meter.

Confirmation window

Check here to see whether sufficient blood sample has been applied.

Edge to apply blood sample

Apply blood sample here for testing.

Warning

- GLUCOCARD Shine Blood Glucose Test Strips should only be used with fresh capillary whole blood samples.
- **Do not** reuse test strips.
- **Do not** use test strips past the expiration date.
- 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 and dry hands.
- **Do not** bend, cut or alter test strips in any way.
- For detailed storage and usage information, refer to the GLUCOCARD Shine Blood Glucose Test Strip package insert.

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 the GLUCOCARD Shine Connex System section of this user manual.

CAUTION

- Keep the meter and testing supplies away from young children.
- Drying agents in the vial cap may be harmful if inhaled or swallowed, and may cause skin or eye irritation.

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 (www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html).

GLUCOCARD Shine Connex Blood Glucose Meter

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

Display
Shows results and messages

<, > Button
Turns the meter on, selects or changes information

ⓘ Button
Turns the meter on/off, confirms menu selections, and changes information

Test Strip Port
Insert test strip here

Test Strip Ejector
Slide down to discard the used test strips

NOTE

- The cable for the data management system can be ordered separately. Please contact ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.
- The unit of measurement is fixed in mg/dL and cannot be changed by the user.

GLUCOCARD Shine Connex Blood Glucose Meter Display

① **Memory recall mode:** appears when test results stored in the memory are displayed
② **PP2 Alarm:** appears when the post-meal alarm has been set
③ **Bluetooth® symbol:** appears when Bluetooth® is turned on
④ **Mute symbol:** appears only when the sound is set to OFF
⑤ **Control Solution flag:** appears when the control solution test results are saved or displayed
⑥ **Test results:** test results displaying panel
⑦ **alarm:** appears when the time alarm has been set
⑧ **mg/dL:** unit for measuring blood glucose
⑨ **Battery symbol:** indicates meter battery is running low and needs to be replaced
⑩ **Blood insertion symbol:** indicates meter is ready for the application of a drop of blood or control solution
⑪ **Pre-meal test flag:** used for tests done before eating
⑫ **Post-meal test flag:** used for tests done after eating
⑬ **Fasting test flag:** used for tests done after fasting for at least 8 hours
⑭ **Month/Day/Hour/Minute**

NOTE

- It is recommended to check if the display screen on the meter matches the illustration above every time the meter turns on.
- **Do not** use the meter if the display screen does not exactly match the illustration as the meter may show incorrect results.

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

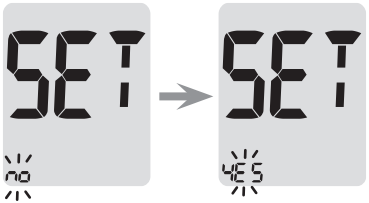
Press and hold the ⏻ button for three seconds to enter 'SET' mode. After all settings are finished, press and hold the ⏻ button for three seconds to turn off the meter.

Press the < or > button to change values. Press and hold the < or > button to scroll faster.

Step 1 Entering the 'SET' Mode

Press and hold the ⏻ button for three seconds to enter 'SET' mode. After all the segments flash across the screen, 'SET' will show up.

Press the < or > button to select 'YES' and press the ⏻ button to go to the next step.



NOTE

- Follow step 2 to pair your meter and smartphone.
- Pairing allows the meter to communicate wirelessly with your smartphone.
- Ensure that devices are within the maximum Bluetooth® range of 32 feet (10 meters).

Step 2 Bluetooth® Pairing

① **Setting Up Bluetooth®:** By default, your GLUCOCARD Shine Connex Meter will have the Bluetooth® feature turned on. If you wish to turn off Bluetooth®, use the < or > arrow button and ① to confirm your selection. The meter will go to Step 3, Setting the Year.

② **Pairing Your Meter and Another Bluetooth® Device and/or App:** Initiate your meter's Bluetooth® pairing mode by one of the following three methods:

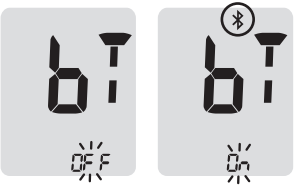
- Take a blood glucose reading. Upon removal of the test strip, the meter will automatically go into Bluetooth® pairing mode. Or, press and hold down your meter's right arrow button for three seconds. This will place your meter into Bluetooth® pairing mode.
- The Bluetooth® icon will blink, indicating your meter is in Bluetooth® pairing mode.
- Follow the pairing instructions of the Bluetooth® device and/or application you are pairing your meter with.

NOTE

For information on mobile apps that are compatible with your GLUCOCARD Shine Connex, visit datamanagement.arkrayusa.com

NOTE

- The ᛒ symbol will appear on the screen when the Bluetooth® feature is on.
- When the ᛒ symbol is not present on the screen, the Bluetooth® feature is off.



- When you need to turn the Bluetooth® feature on or off, press the ⓘ button when 'On' or 'OFF' blinks on the screen.

NOTE

- Some smartphones, especially those that are not tested or approved by the manufacturer may **NOT** be compatible with your meter.
- A list of compatible smartphones is available on the Apple App Store and Android Google Play.

Adjusting the Date and Time

Step 3 Setting the Year

A number indicating the year will blink on the screen.

Press the < or > button to adjust until the correct year appears.

After setting the year, press the ⏻ button to confirm your selection and to go to the next step.

Step 4 Setting the Month

A number indicating the month will blink on the screen.

Press the < or > button until the correct month appears.

Press the ⏻ button to confirm your selection and to go to the next step.

Step 5 Setting the Date

A number indicating the date will blink on the screen.

Press the < or > button until the correct date appears.

Press the ⏻ button to confirm the date and to go to the next step.

Step 6 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. The AM•PM symbol is not displayed in the 24-hour format.

After selecting the format, press the ⏻ button to go to the next step.

Step 7 Setting the Hour

A number indicating the hour will blink on the screen.

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

Step 8 Setting the Minute

A number indicating the minute will blink on the screen.

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

Setting the Sound On/OFF

Step 9

On pressing the < or > button, the screen will display 'On' or 'OFF'. Press the ⏻ button to confirm the selection.

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

- When a button is pressed 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 pressed and held 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 the ⏻ button to progress to the next step.

NOTE

- The 🔇 symbol is displayed only when the sound is set to 'OFF'.

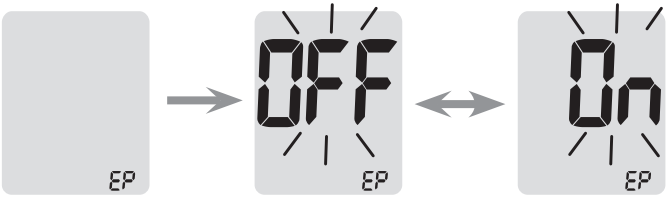
Turning on the Test Strip Expiration Date Indicator

This setting allows you to turn the test strip expiration date indicator 'On' or 'OFF'. This setting turns the function 'On' or 'OFF' **only.** See page 26 to set the test strip expiration date.

Step 10

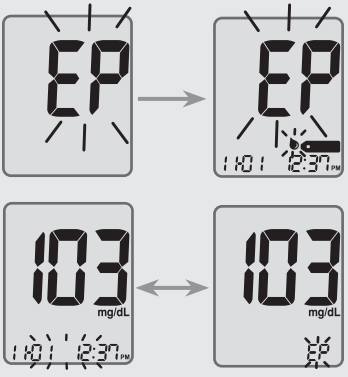
When 'EP' appears on the screen, press the < or > button. The screen will display 'On' or 'OFF'. Press the ⏻ button to confirm the setting.

If you do not want to set the indicator, press the ⏻ button while the screen displays 'OFF'.



NOTE

- If the preset expiration date expires, the meter will display 'EP' when the test strip is inserted.
- The display will alternate between 'EP', and the date and time when the test result is displayed right after the test.
- If the expiration date is set to October of 2027, the meter will display 'EP' at the start of November, 2027.



Turning on the Hypoglycemia (HYPo) Indicator

This setting 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.

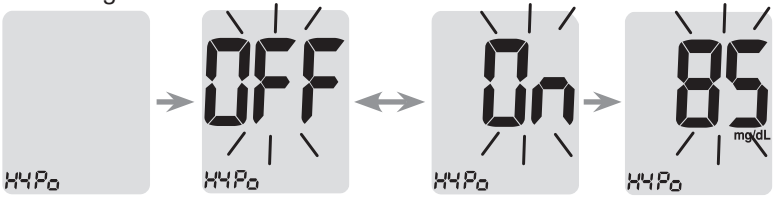
Step 11

On pressing the < or > button, the screen will display 'On' or 'OFF'.

Press the ⏻ button when 'On' appears to enter the setting.

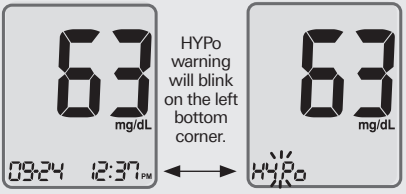
Press the < or > button until the desired hypoglycemia level between 20 and 90 mg/dL appears.

Press the ⏻ button for three seconds to confirm the level, save all settings and turn off the meter.



NOTE

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



CAUTION

- Ask your healthcare professional to help you decide what your hypoglycemia level is before setting your hypoglycemia level.

Setting the Test Strip Expiration Date Indicator

Step 1 Entering the Expiration Date Setting

Press and hold the < and > buttons at the same time for three seconds to enter the expiration date settings. After all segments flash across the screen, 'EP' will show up.

NOTE

- The test strip expiration date is printed on the test strip vial.

Step 2 Setting the Expiration Year

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

Press the < or > button until the correct year appears.

Press the ⏻ button to confirm the year and go to the next step.

Step 3 Setting the Expiration Month

A number indicating the month will blink at the bottom of the screen.

Press the < or > button until the correct month appears.

After setting the month, press and hold the ⏻ button for three seconds to save your setting and turn off the meter.

Checking the System

The GLUCOCARD Shine Connex Meter and GLUCOCARD Shine Blood Glucose Test Strips should be checked using GLUCOCARD Shine Control Solutions, available in two levels (Level 1 and 2).

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 test result displayed on the meter to the GLUCOCARD Shine 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 following the procedure on pages 28–30.

NOTE

- Use GLUCOCARD Shine Control Solutions **only** (available for purchase separately).
- 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 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 between 46–86 °F (8–30 °C).

Use GLUCOCARD® Shine Control Solution when:

- You want to practice the test procedure using the control solution, instead of 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.

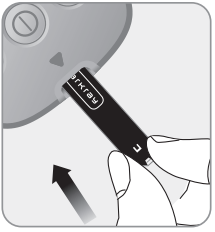
Control Solution Testing

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 beeps. Be careful not to bend the test strip while pushing it in.

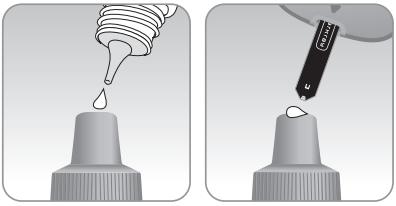
The symbol will appear.



Step 2

You can flag the control solution test result by pressing the > button for three seconds. To undo the control solution flag, press the > button for three seconds again.

Step 3



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.

Wipe the tip with a clean tissue or cloth. Dispense a drop of control solution onto a clean non-absorbent surface. It helps to squeeze a drop onto the top of the cap as shown.

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.

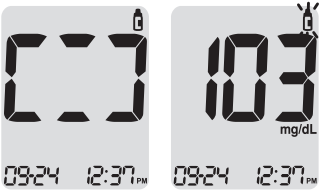
NOTE

- The meter may 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, remove the test strip, reinsert, and start from step 1.

Step 4

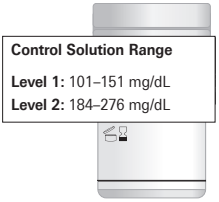
The display segments will rotate clockwise and a test result will appear after the meter counts down from '5' to '1'.

When flagged, the test result is stored in the meter's memory but it is not included in the averages.



Step 5

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



CAUTION

- The range printed on the test strip vial is for GLUCOCARD Shine Control Solutions **only**. It has nothing to do with your blood glucose level.

NOTE

- GLUCOCARD Shine Control Solutions can be ordered separately by contacting ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

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 the range. Out of range test results may occur in following situations:

Situations	Do This
• When the control solution bottle was not shaken well. • When the meter, test strip or control solution have been 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 page 28–30.
• 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 Blood Glucose Test Strip and GLUCOCARD Shine Connex Meter may not be working properly.

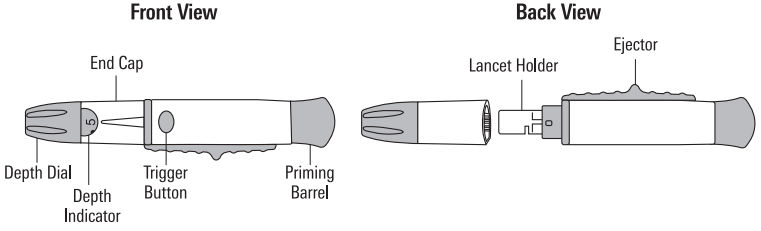
Do not use your system and contact ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

Using the Lancing Device

A lancing device is needed in order to collect a blood sample.

You may use the lancing device that is included in the GLUCOCARD Shine Connex 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.

CAUTION

- To avoid infection when drawing a sample, **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.

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.

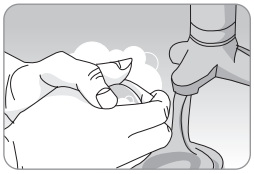
Warning

- 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

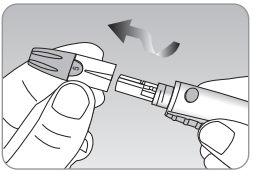
Step 1

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



Step 2

Unscrew and remove the lancing device cap.

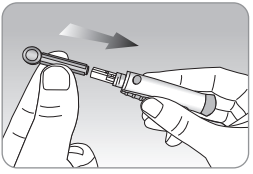


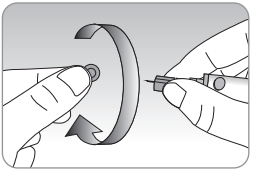
Step 3

Insert a new disposable lancet into the lancet holder.

Twist off the protective cover of the lancet and set it aside, then replace the adjustable cap.

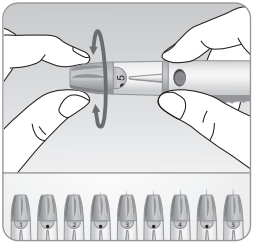
Keep the protective cover to replace on top of the used lancet after testing.





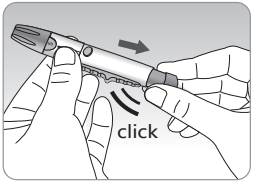
Step 4

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 get blood samples will vary by person at different sample sites.
- The lancing device's adjustable cap allows the best depth of skin penetration to get 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

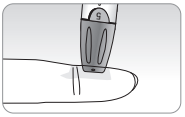
Step 6

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

Push the test strip in gently until the meter beeps. Be careful not to bend the test strip. The symbol will appear on the screen.

Applying Blood Sample

Step 7



Obtain a blood sample using the lancing device. Place the lancing 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.

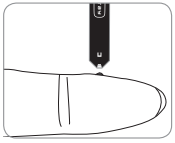
A minimum volume of 0.5 µL is needed to fill the confirmation window. (Approximate size of 0.5 µL: •)

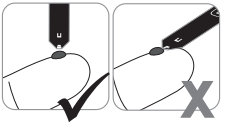
Step 8

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 confirmation window is not filled in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the **Er4** message may appear.

It is recommended to place the test strip vertically into the blood sample site as shown below.





Good Sample | Insufficient Sample

NOTE

- The meter may 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 start from step 2.

Step 9

At this time, the display segments will rotate clockwise while the blood sample is going into the test strip.

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

The test 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.

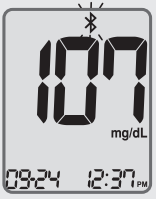
Discard used test strips safely in a disposable container.

If the Bluetooth® feature is activated, the meter will send the test result to the connected smartphone.

Test result

NOTE

- To transmit glucose data using the Bluetooth® feature:
  - The Bluetooth® feature on the meter must be turned on.
  - The meter and a smartphone must be paired.



- The meter will transmit data in the following cases:
  - When the test strip is ejected after measuring.
  - When the meter is turned on (only when untransmitted data exists).

Step 10

You can attach a flag to a test result to indicate particular situations **while the test strip is still in the meter.**

When the result is displayed right after a test, press the < or > button to select a Pre-meal flag ( ), a Post-meal flag ( ), a Fasting flag ( ) or a Control solution flag ( ).

When you remove the test strip while the desired flag is blinking, the test result is stored with the flag.

If you do not want to add any flags on the test result, remove the test strip after the test result is displayed.

No flag

Pre-meal flag

Post-meal flag

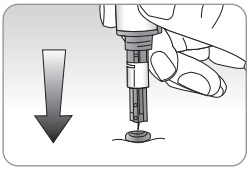
Fasting flag

Control solution flag

Discarding Used Lancets

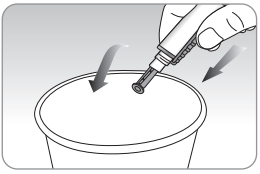
Step 1

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.

‘HI’ and ‘Lo’ Messages

‘HI’ Message

The meter displays test 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 the message persists, please contact ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

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 Connex 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.

NOTE

- To pair your meter and smartphone, see pages 19–20.

Meter Memory

The GLUCOCARD Shine Connex Blood Glucose Meter can save up to 1,000 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 meter calculates and displays the averages of total test results, Pre-meal ( ) test results, Post-meal test results ( ), and Fasting test results ( ) from the last 1, 7, 14, 30 and 90 days.

Viewing Past Test Averages

Step 1

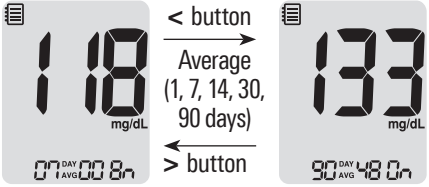
Press any button to turn the meter on.

The current date and time will be displayed at the bottom of the screen followed by the 1-Day Average value and the number of the test results saved within the current day.

The number of tests within the current day

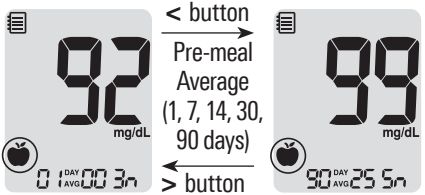
Step 2 Viewing Averages

Press the < button to view 1-, 7-, 14-, 30- and 90-Day Average values, and the number of tests performed for the last test period.



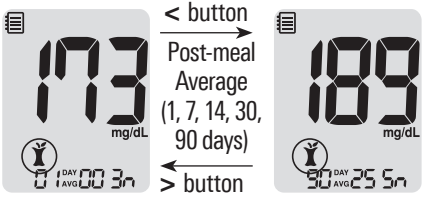
Step 3 Viewing Pre-meal Averages

Continue to press the < button to view 1-, 7-, 14-, 30- and 90-Day Average values, and the number of tests performed pre-meals with the symbol for the last test period.



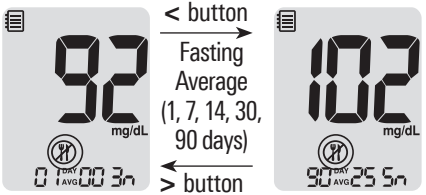
Step 4 Viewing Post-meal Averages

Press the < button to view 1-, 7-, 14-, 30- and 90-Day Average values, and the number of tests performed post-meals with the symbol for the last test period.



Step 5 Viewing Fasting Averages

Press the < button to view 1-, 7-, 14-, 30- and 90-Day Average values, and the number of tests performed during fasting with the symbol for the last test period.



Step 6

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

Press the ⏻ button to turn off the meter.

NOTE

- The control solution test results saved with the symbol are **not included** in the averages.

Viewing Test Results

Step 1

Press any button to turn the meter on.

The current date and time will be displayed on the bottom of the screen followed by the 1-Day Average value and the number of the test results saved within the current day.

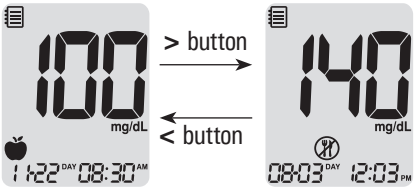
The number of tests within the current day

Step 2

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

Press the < button to return to the result seen previously.

After checking the stored test results, press and hold the ⏻ button to turn off the meter.



NOTE

- The control solution test results saved with symbol will be displayed with symbol when you review the stored test results.

Setting the Alarm Function

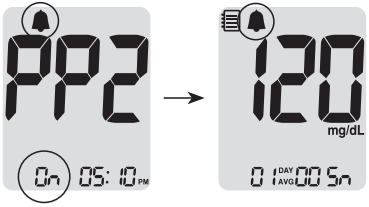
Four types of alarms can be set in the GLUCOCARD Shine Connex Meter: one post-meal alarm (PP2 Alarm) and three time set alarms (alarm 1–3).

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

Setting the Post-meal Alarm (PP2 Alarm)

Step 1 Turning 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 recall mode.

At this time, the 🔔 symbol, indicating that the PP2 Alarm has been set, will be displayed on the screen.

NOTE

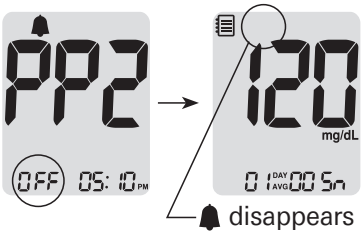
- The PP2 Alarm will automatically turn off if the meter's time setting is adjusted to more than two hours before or just past the currently activated PP2 Alarm time.

Step 2 Turning 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 recall mode without the 🔔 symbol displayed.



Setting the Time Alarms (Alarm 1–3)

Step 1

Without inserting a test strip, press the < and ⓘ buttons at the same time for three seconds to enter the time alarm setting.

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

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'.

'OFF' will blink on the screen.

Step 3

Press the < button to adjust the time of ‘alarm 1’.

A number representing the hour will blink on the screen.

Press the > button to set the hour.

Step 4

On pressing the < button, the number indicating the minute will start blinking.

Press the > button to set the minute.

Step 5

Press the ⏻ button to finish and to go to ‘alarm 2’ setting.

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

Step 6

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

- To minimize the risk of transmission of bloodborne 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 handling 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 bloodborne pathogens.

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

NOTE

- The life span of a GLUCOCARD Shine Connex Meter is five years. We recommend disinfecting both the meter and lancing device at least once a 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 life of your meter and lancing device.
  1 pre-cleaning and 1 disinfection cycle per week X 52 weeks per year X 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 Connex 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 Connex Blood Glucose Monitoring System instruction, **please read the instructions provided by the manufacturer of Clorox Healthcare Bleach Germicidal Wipes before using them.**

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 product 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.

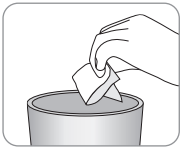
Pre-cleaning and Disinfection Procedures

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

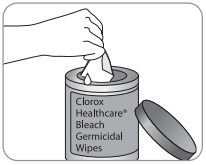
2. Wipe the entire surface of the meter three times horizontally and three times vertically using one towelette to pre-clean blood and other body fluids.

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 disinfect the meter.



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).

NOTE

- 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 GLUCOCARD Shine Control Solutions (Level 1 and 2).
- Verify that the test results are within the range printed on the test strip vial.
- See pages 28–30 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 ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

- The inscriptions on the exterior of the meter or lancing device have been removed.
- The color of the meter or lancing device has changed or faded.
- Cracks or roughness develop on the meter or lancing device.
- A part of the segment on the meter display does not flash.
- 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.

CAUTION

Storage and Handling

- Store the meter in a cool and dry place between 32–122 °F (0–50 °C) and 20–80 % relative humidity.
- **Do not** expose the meter to direct sunlight, heat or excessive humidity 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 shock.
- **Do not** try to fix or alter the meter in any way.
- Store all meter components in the carry case to prevent loss and to help keep the meter clean.
- 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 the GLUCOCARD Shine Connex System section of this user manual.

NOTE

- For additional information or technical assistance contact ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

Understanding Error Messages

Message	What it means	What to do
	A used test strip was inserted.	Repeat the test with 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 42.8–111.2 °F (6–44 °C). 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 after inserting a new test strip.

Message	What it means	What to do
	This error message may appear when the wrong blood glucose test strip is used instead of GLUCOCARD Shine Blood Glucose Test Strip.	Repeat the test with a GLUCOCARD Shine Blood Glucose Test Strip.
	There is a problem with the meter.	**Do not** use the meter. Contact ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.
	There is a problem with Bluetooth® communication	Contact ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.
	An electronic error occurred during the test.	Repeat the test with a new test strip. If the error message persists, contact ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

NOTE
If the error messages persist, contact ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

General Troubleshooting

Problem	Troubleshooting
The display is blank even after inserting a test strip.	• 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 correctly inserted with the '+' side facing up. • If the display is still blank, replace the batteries.
The test does not start even after applying the blood sample on the test strip.	• 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.	• 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 ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

Performance Characteristics

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

Accuracy

The accuracy of the GLUCOCARD Shine Connex Blood Glucose Monitoring System was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument.
The following results were obtained by diabetic patients at clinic centers.

Slope	1.0223
Y-Intercept	-1.3686
Elation coefficient (r)	0.9934
Number of subjects	371
Range tested	48–553 mg/dL

Accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
61.0 % (25/41)	97.6 % (40/41)	100 % (41/41)

Accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
70.0 % (231/330)	96.1 % (317/330)	100 % (330/330)	100 % (330/330)

User performance results for glucose concentrations between 48 mg/dL and 553 mg/dL.

Within ± 15 mg/dL and Within ± 20 %
371/371 (100 %)

Precision
Precision studies were performed in a laboratory using the GLUCOCARD Shine Connex Blood Glucose Monitoring System.

Within Run Precision			
Blood avg.	43 mg/dL	SD = 1.9 mg/dL	CV = 4.3 %
Blood avg.	71 mg/dL	SD = 2.1 mg/dL	CV = 2.9 %
Blood avg.	135 mg/dL	SD = 3.8 mg/dL	CV = 2.8 %
Blood avg.	203 mg/dL	SD = 5.2 mg/dL	CV = 2.6 %
Blood avg.	343 mg/dL	SD = 11 mg/dL	CV = 3.2 %

Between Run Precision			
Control avg.	36 mg/dL	SD = 1.4 mg/dL	CV = 3.8 %
Control avg.	114 mg/dL	SD = 3.4 mg/dL	CV = 3.0 %
Control avg.	341 mg/dL	SD = 8.2 mg/dL	CV = 2.4 %

Warranty Information

Warranty

The manufacturer warrants that the GLUCOCARD Shine Connex 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 ARKRAY Technical Customer Service: 800.566.8558, 24 hours a day, 7 days a week.

Meters returned without this authorization will not be accepted.

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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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