

Assure Platinum[®]

BLOOD GLUCOSE MONITORING SYSTEM



Quality Assurance / Quality Control (QA/QC) Reference Manual

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Introduction

The Assure Platinum® Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. Testing is done outside the body (*in vitro* Diagnostic Use). It is indicated for use by healthcare professionals in a clinical setting, or at home (over the counter [OTC]) by persons with diabetes, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The Assure® Platinum Blood Glucose Monitoring System is designed for institutional/clinical and/or multi-patient settings. We recommend that healthcare professionals wear gloves when handling a blood glucose meter as contact with blood presents a potential infection risk. We also suggest cleaning and disinfecting the meter between residents/patients. Please refer to the appropriate user instruction manual or this QA/QC manual for additional information on testing and cleaning.

This comprehensive manual has been designed to provide you with a thorough reference source for the Assure Platinum Blood Glucose Monitoring System including:

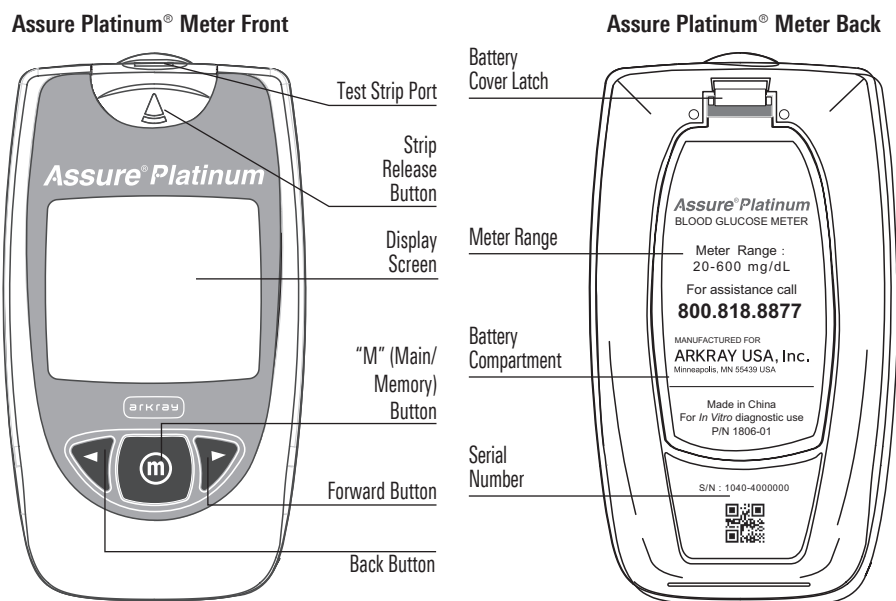
- Product operations
- Training and in-services
- Guidelines for policies and procedures
- Quality Assurance and Quality Control (QA/QC) programs
- Reviews of regulatory materials

All of these materials have been designed to assist you in meeting the necessary requirements for various programs and agencies.

We trust that this Quality Assurance/Quality Control manual will provide you with the needed support tools for your blood glucose monitoring program. If you have any questions after reviewing the manual, please call ARKRAY's Technical Customer Service Department at **800.818.8877, option 5**, 24 hours a day, 7 days a week.

NOTE: This Quality Assurance/Quality Control reference manual should be used as a reference only. It does not replace the instructions supplied with the Assure Platinum Blood Glucose Monitoring System, Assure Platinum Test Strips or Assure Dose Control Solution. Please see the instructions included with each product for additional detail.

System Components



ORDERING DETAILS

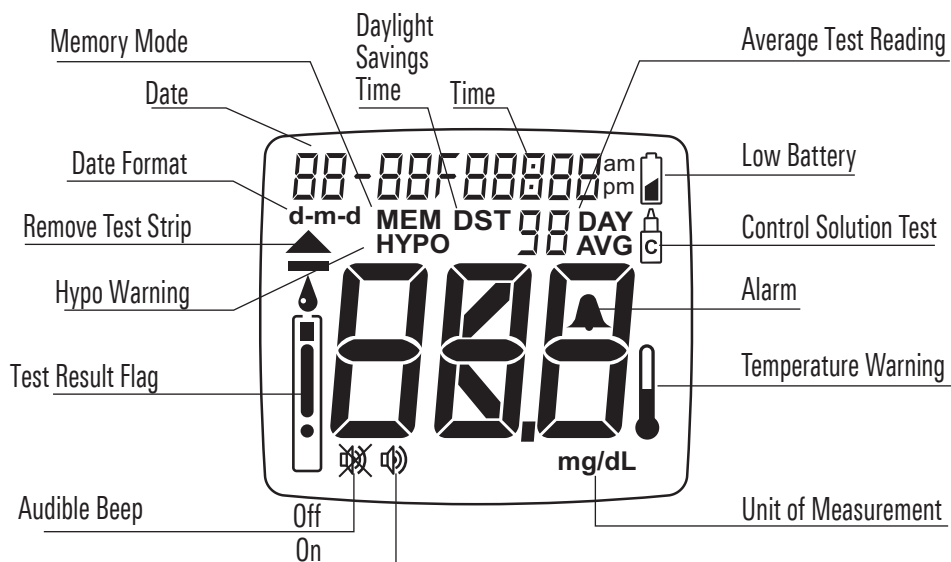
ARKRAY Product Code# 500001 Reimbursement # 08317-5000-01

ASSURE PLATINUM® METER

Test Strip Port:	Insertion site for test strip. Located on the top of the meter.
Strip Release Button:	When pushed forward, releases the test strip from the test strip port.
Display Screen:	Shows blood glucose result and symbols that guide you through the test.
M (Main/Memory) Button:	Used to access memory.
Forward Button:	Used to scroll through formats and memory. Press to set meter in control solution mode.
Back Button:	Used to scroll through formats and memory. Press to set meter in control solution mode.
Battery Cover Latch:	Located on the back of the meter. Press latch to open battery cover.
Meter Range:	Results Range for the Assure Platinum Meter. Located on the back of the meter.
Battery Compartment:	Located on the back of the meter and holds two AAA batteries. Powers the system.
Serial Number:	Located on the back of the meter.

ASSURE PLATINUM[®] METER DISPLAY SCREEN

Full Display Screen Layout



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.
- The unit of measurement for your Assure Platinum Blood Glucose Meter is preset and fixed in mg/dL.

ASSURE PLATINUM® METER SPECIFICATIONS

For additional information refer to the Assure Platinum® User Manual.

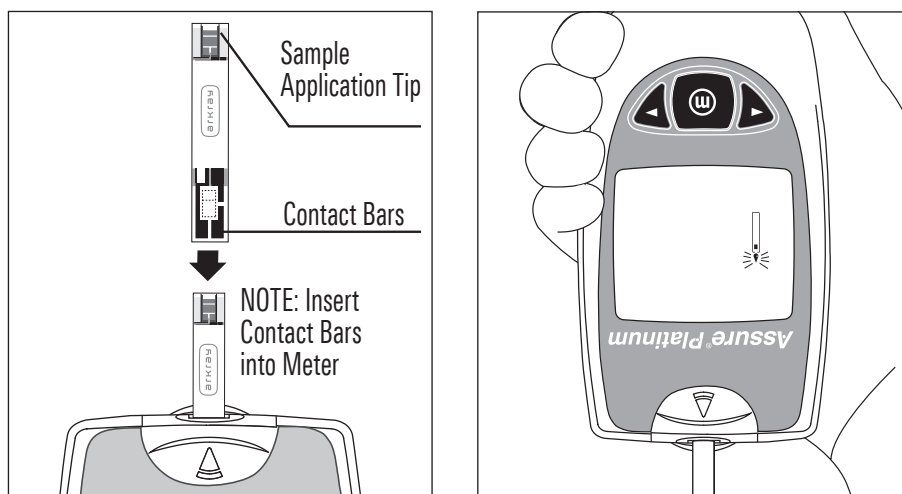
Product Specifications	
Test strips	Assure Platinum Test Strips
Result range	20–600 mg/dL
Calibration	Plasma referenced
Sample size	Minimum 0.5 µL
Blood source	Capillary whole blood
Test time	7 seconds
Assay method	Biosensor, Glucose oxidase (<i>Aspergillus niger</i> sourced) and Hexaammineruthenium (III) chloride
Power source	Two 1.5V alkaline AAA batteries
Battery life	More than 5,000 tests at 4 tests per day
Display type	Liquid Crystal Display (LCD)
Memory	500 results with time and date stamp
Average	7-, 14-, 30-, and 90-day averaging
Automatic shut off	2 minutes after last user action
Size	4.5" x 2.5" x 1.2"
Weight	2.8 oz. (without batteries)

Meter Operating Ranges	
Temperature	50°F–104°F (10°C–40°C)
Relative humidity	20%–80%
Hematocrit	30%–55%
Altitude	10,000 ft. (3,048 meters)
Unit of measurement	mg/dL
Control Solution Operating Range Temperature	68-104 °F (20–40 °C)

ASSURE PLATINUM[®] TEST STRIPS

Intended Use


Assure Platinum Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip when used with the Assure Platinum Blood Glucose Meter. Testing is done outside the body (*in vitro* Diagnostic Use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of, or screening for, diabetes mellitus and is not intended for neonates.



The Assure Platinum Test Strips come in a moisture-proof, light-protected bottle, and are designed to work with the Assure Platinum Blood Glucose Meter. The test strips are sensitive to moisture and light, so it is important that you keep the bottle sealed until you are ready to use the strips. Do not leave any test strips outside the test strip bottle while not in use. Replace the cap tightly after a test strip is removed from the bottle.

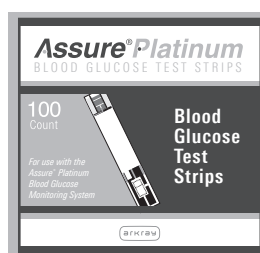
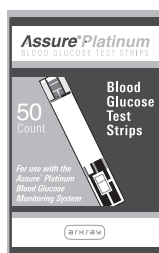
These test strips require only 0.5 μL of blood. Apply the application tip to the blood sample. The strip draws in the blood by capillary action. The blood glucose reacts with the enzyme on the test strip. This produces an electrical current proportional to the blood glucose level. The meter detects the current and converts it into a blood glucose reading. Assure Platinum Test Strips use glucose oxidase chemistry.

Storage and Handling

- Store test strip container in a cool, dry place between 39–86°F (4–30°C).
- Keep away from direct sunlight and heat. Do not freeze or refrigerate.
- Do not store or transfer the Assure Platinum® Test Strips outside of the original bottle.
- Do not bend, cut or alter an Assure Platinum Test Strip.
- As soon as you have removed a test strip, replace the cap securely on the bottle.
- When you first open the bottle, write the date on the bottle label. Use the test strips within 3 months of first opening the bottle.
- Do not use test strips beyond the expiration date ( Exp.) on the label.
- Always clean and dry hands before handling a test strip. Do not touch the sample application tip of the test strip.
- Do not re-use an Assure Platinum Test Strip.
- Only use Assure Platinum Test Strips with an Assure Platinum Blood Glucose Meter.

NOTE: Healthcare Professionals should wear gloves when testing patient.

IMPORTANT: Low or high blood glucose readings can indicate a potentially serious medical condition. If blood glucose reading is unusually low or high, or the patient/resident does not feel the way readings indicate, repeat the test using a new test strip. If result is still not consistent with symptoms, or if blood glucose result is less than 60 mg/dL or higher than 240 mg/dL contact the diabetes healthcare professional for advice.



ORDERING DETAILS

	ARKRAY Product Code#	Reimbursement #
Assure Platinum Test Strips 50-count	500050	08317-5000-50
Assure Platinum Test Strips 100-count	500100	08317-5001-00

WARNINGS AND PRECAUTIONS

- For *in vitro* Diagnostic Use.
- Never make significant changes to your diabetes control program or ignore physical symptoms without consulting with your healthcare professional.
- Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional immediately.
- Extremes in hematocrit may affect test results. Hematocrit levels less than 30% may cause falsely high readings. Hematocrit levels greater than 55% may cause falsely low readings.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic/hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with blood glucose meters.
- Patients undergoing oxygen therapy may yield false results.
- High levels of ascorbic acid may yield inaccurate results.
- Externally taken drug ephedrine will not interfere with blood glucose results when taken at therapeutic concentrations. However, abnormally high concentrations in blood may cause inaccurate results.

Healthcare Professionals: Please note additional limitations of procedure:

- Triglycerides at 3,300 mg/dL may significantly affect test results.
- Metabolites of icodextrin (maltose, maltotriose and maltotetraose) do not significantly affect test results.

Limitations of System

- The Assure Platinum® Blood Glucose Monitoring System is not designed to substitute pathology laboratory equipment and should not be used for the diagnosis of diabetes.
- Use only fresh capillary whole blood. Do not use serum or plasma or venous whole blood.
- Do not use the Assure Platinum Blood Glucose Monitoring System to test neonates. It has not been validated for neonatal use.
- Assure Platinum Test Strips may be used at altitudes up to 10,000 ft (3,048 m) without effect.

ASSURE® DOSE CONTROL SOLUTIONS

Intended Use

For use with Assure Platinum®, GLUCOCARD Vital® or ReliOn™ Prime Blood Glucose Meter and test strips as a quality control check to verify the accuracy of blood glucose test results. Control solutions are available in two levels – Normal (Level 1) and High (Level 2).

Summary

Assure Dose Control Solution contains a known amount of glucose that reacts with the test strips. Compare the control solution test result with the range printed on the test strip bottle label.

Storage and Handling

- Close the control solution bottle tightly and store at a temperature between 36–86 °F (2–30 °C).
- Keep away from direct sunlight and heat. Do not freeze.
- Use before the expiration date printed on the bottle.
- Use the Assure Dose Control Solution within 90 days (3 months) of first opening. It is recommended that you write the date of opening on the control solution bottle label (“Date Opened”) as a reminder to dispose of the opened solution after 90 days.
- Make sure your meter, test strips and control solution are at a temperature between 68–104 °F (20–40 °C) when performing a test.
- Always replace the cap immediately after use.
- Assure Dose Control Solution is not a cleaning solution. Do not clean your meter with Assure Dose Control Solution.

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use.

- Assure Dose Control Solution is not intended for human consumption. Do not drink.
- Only use with Assure Platinum, GLUCOCARD Vital or ReliOn™ Prime Blood Glucose Meter and Test Strips.
- To avoid contamination, NEVER touch tip of control solution bottle to test strip.
- Dye in control solution may stain clothing or surfaces.

IMPORTANT: If you do not set the meter in the control solution mode, the control solution result will NOT be valid. Using the control solution mode will also flag the result in memory. This prevents the result from being part of the averages.

Troubleshooting

If the result is outside the range printed on the test strip bottle, repeat the test. One or more of the following may cause an out-of-range result:

- The meter was not placed in control solution mode before adding solution. Refer to manual or test strip insert for more information.
- The control solution is expired or contaminated.
- The control solution was stored below 36°F (2°C) or above 86°F (30°C).
- The test strip was not stored correctly.
- The test strip was used after the expiration date on the bottle.
- The test strip bottle was open for more than 90 days (3 months).
- The test strip is inserted incorrectly.
- The meter has been damaged or has malfunctioned.
- The first drop of control solution was not discarded.
- The control solution is contaminated as the tip of the control solution bottle touched the test strip.

PLEASE NOTE: If your Assure® Dose Control Solution result continues to read outside the required range printed on the test strip label, the system may not be working correctly. DO NOT USE the system to test your blood glucose until the control solution result is within the acceptable range. If you are unable to resolve the problem or need assistance, please call Technical Customer Service at 800.818.8877, option 5, 24 hours a day, 7 days a week. Contact your diabetes healthcare professional if you are unable to reach Technical Customer Service.



**Assure® Dose Control
Solution - Normal
(Level 1)**



**Assure® Dose Control
Solution - High
(Level 2)**

ORDERING DETAILS

Assure Dose Control Solution
(Normal and High)

ARKRAY Product Code#
500006

Reimbursement #
08317-5000-06


Meter Operation and Set-Up

METER SET-UP

Before using the Assure Platinum® Meter for the first time, set the time and date. Do not perform a blood glucose test until you have performed meter set-up. In the set-up mode, there are menu options for audible beep, hypo warning, daylight savings time, time, date, backlight, and QC reminder.

Basic rules for meter set-up

Step 1: Press “M” button to turn meter on. The full screen layout will be briefly displayed followed by the memory.

Step 2: Press and hold the “M” button for two seconds. You have now entered set-up mode. The audible beep symbol  appears at the bottom of the display screen.

Step 3: The current setting will be displayed for each menu option as you scroll through the menu. Use the Back and Forward buttons to change setting.

Step 4: Press “M” button briefly to accept the setting and move to the next option.

Step 5: To exit set-up mode at any time and save all settings, press and hold the “M” button for more than two seconds. This will return you to the memory screen.

Step 6: Press the “M” button to turn meter off.

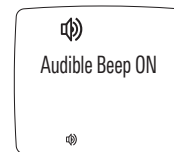
Setting the Audible Beep

The beep may be turned “On” (Diagram A) or “Off” (Diagram B).

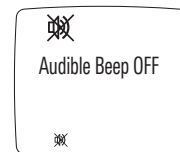
If turned “On”, the beep will sound when:

- Meter is turned on.
- Test has ended and the result is displayed.
- HYPO warning is turned on and blood glucose result is below HYPO setting.
- Meter starts to count down.

A.



B.

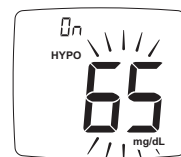


Setting the Hypoglycemic (HYPO) Warning

Set the HYPO Warning to remind someone to take action due to a low blood glucose result. You must take caution if the HYPO Warning is used in a multi-patient setting as each resident may have a different HYPO threshold.

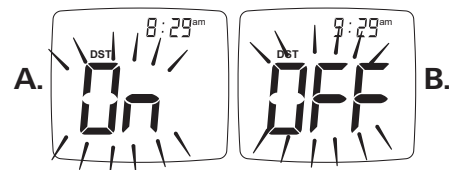
If the HYPO Warning is set to “On” (Diagram A), you will be prompted to select the value at which you wish the warning to sound. The value will flash to show that it can be changed. You may pick a value between 20–80 mg/dL.

A.



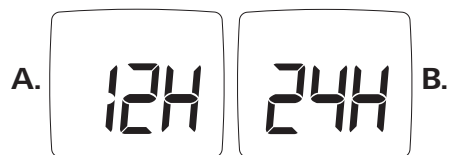
Setting the Daylight Savings Time

This meter has the function of switching from standard time to daylight saving time (DST). "ON" (Diagram A) or "OFF" (Diagram B) will blink.



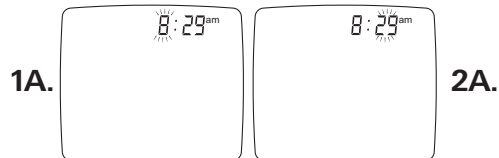
Setting the Time Format

The time can be displayed in either a 12-hour format (Diagram A) or a 24 hour format (military time) (Diagram B).



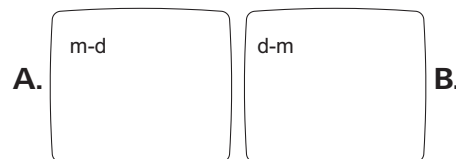
Setting the Time

The hour (Diagram 1A) and minute setting (Diagram 2A) will flash to indicate that it may be changed.



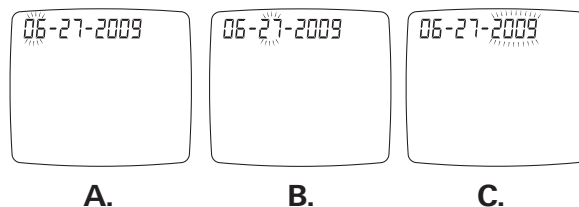
Setting the Date Format

The date can either be displayed in the month/day format (m-d) (Diagram A) or the international day/month format (d-m) (Diagram B).



Setting the Date

Set the month (Diagram A), day (Diagram B) and year (Diagram C).



Setting the Backlight Setting

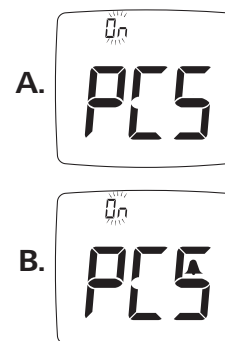
To save the battery life, the backlight level is pre-set not to come on. Select settings of "0," "5," "10," "15," and "100."


- 0 Backlight off.
- 5, 10, 15 Backlight will stay on for 5, 10 or 15 seconds.
- 100 Backlight will always stay on.



Setting the qcProGuard®/ QC Reminder

This can be set to remind someone to perform a control solution test. When set to "On" (Diagram A), the reminder will prompt you to do a control solution test every 24 hours. If a control test has not been performed within 24 hours of the previous test, PCS (Perform Control Solution test) will flash on the screen along with ▲ (Diagram B). PCS will flash three times and then disappear. The ▲ will stay on the screen and also mark a result in the memory mode.



NOTE: If PCS flashes when inserting strip, then enter control solution mode by pressing either the Back or Forward button when the apply blood symbol appears on the screen. PCS will not be on the screen. You will see a control solution bottle  at the top right of your screen.

BLOOD GLUCOSE TESTING

OBTAINING A DROP OF BLOOD

NOTE:

- We recommend that healthcare professionals use any auto-disabling, single-use safety lancet to obtain patient blood samples. These instructions are for the Assure Lance® Safety Lancet. Call Technical Customer Service at 800.818.8877, option 5 to find a distributor.
- We advise healthcare professionals to wear gloves during blood testing.
- Meter system must be at room temperature for testing.

SECTION

B

Step 1

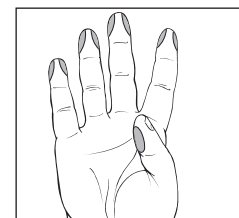
Wash patient's hands with soap and warm water.

Dry hands thoroughly. If alcohol wipes are used, make sure the area is dry before taking blood sample. Residual alcohol may lead to inaccurate readings.



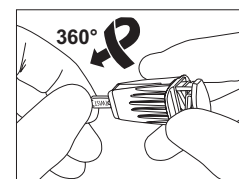
Step 2

Let the arm hang down for 10 to 15 seconds. (Holding the arm below the heart and massaging the wrist, palm and finger makes it easier to obtain a blood drop).



Step 3

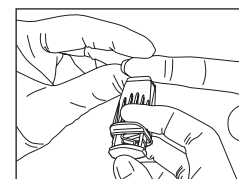
Choose a site on the side of a fingertip to minimize pain.



Step 4

Grasp the outer white edge of the Assure Lance Safety Lancet. Twist the protective cap 360° to remove.

Do not put your thumb on the top button while removing the cap; this prevents a misfire.



Step 5

Place lancet against side of fingertip. Press button firmly.

After use, discard in sharps container.

PERFORMING A BLOOD GLUCOSE TEST

CAUTION: To reduce the chance of infection

Before performing a blood glucose test, observe the following safety precautions:

- All components that come into contact with blood samples should be considered to be biohazards capable of transmitting viral diseases between patients and healthcare professionals.
- A new pair of clean gloves should be worn by the user before testing each patient.
- Wash hands thoroughly with soap and water before putting on a new pair of gloves and performing the next patient test.
- Use only an auto-disabling, single-use lancing device for each patient.
- The meter should be cleaned and disinfected after use on each patient.

CAUTION: Failure to follow instructions may cause inaccurate results.

Step 1

Remove Assure Platinum® Test Strip from the bottle. Immediately replace the bottle cap tightly.

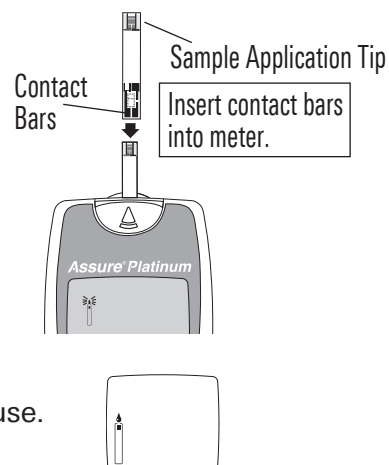
Insert test strip as shown in the diagram.

Meter will turn on automatically.

Verify that all symbols appear on the screen.

NOTE: If both PCS and ▲ appear on the screen, perform a control solution test.

The strip and flashing blood drop indicate the meter is ready for use.



Step 2

Obtain a blood sample. Touch the sample application tip at the end of the strip to the blood drop on your finger, using a 90° angle. Capillary action will pull the blood into the strip.

NOTE: Apply blood to test strip within 20 seconds of obtaining a blood sample. The meter will start to count down when it detects that blood has been applied. If meter does not start after adding the first blood drop, remove the test strip and test with a new test strip. Discard strip if meter does not start to count down.

IMPORTANT: The minimum sample volume is 0.5 µL. Smaller samples may not start the meter or can start the meter count down and provide an E13 error message. Ensure blood completely fills the reaction site.



Enough
Blood



Not Enough
Blood



Too Much
Blood

Step 3:

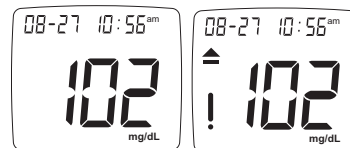
Meter will count down by showing “7”. The meter will show the result in 7 seconds.



NOTE: Results will be shown in units of mg/dL. Results will not show a decimal point.

Option: Flagging Test Result in Memory

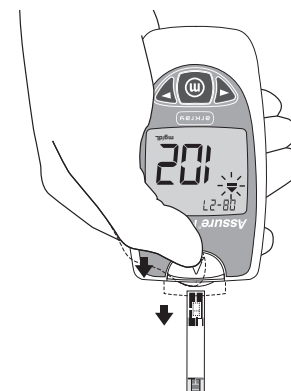
- Results may be marked with an “!” if you feel the result is incorrect or the test procedure was not followed correctly.
- Mark the test result with an “!” by pressing either the Forward or Back button after result is on screen. Marked results will not be included in the 7-, 14-, 30-, or 90-day averages.



NOTE: Healthcare Professionals: Record test result in patient's chart.

Step 4:

The flashing arrow reminds you to remove the test strip. Remove the test strip by holding the meter so that the test strip points down. Push the test strip release button forward. Dispose of test strip. The meter shuts off automatically when you remove the test strip.



PERFORMING A CONTROL SOLUTION TEST

You should check your meter and test strips using Assure® Dose Control Solutions (Normal-Level 1 and High-Level 2) to confirm the meter and test strips are working properly, or to check if you are testing correctly. Assure Dose 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 bottles have Assure Dose Control Solution ranges printed on the labels. Compare the result displayed on the meter to the Assure Dose Control Solution range printed on the test strip bottle. Before using a new meter or a new bottle of test strips, you should conduct a control solution test following the procedure with two different levels of control solutions (Normal-Level 1 and High-Level 2).

USE CONTROL SOLUTION

- To test your technique.
- Before testing with the meter for the first time.
- When you open a new bottle of test strips.
- When you suspect the meter or test strips may not be functioning properly.
- If the test results appear to be abnormally high or low or are not consistent with clinical symptoms.
- When the meter has been dropped or stored below 32°F (0°C) or above 122°F (50°C).
- The test strip bottle has been left open or has been exposed to light, temperatures below 39°F (4°C) or above 86°F (30°C), or humidity levels above 80%.
- Each time the batteries are changed.

SETTING THE QUALITY CHECK REMINDER

The qcProGuard quality check reminder can be set to remind someone to perform a control solution test.

When set to “On”, the reminder will prompt you to do a control solution test every 24 hours. If a control test has not been performed within 24 hours of the previous test, PCS (Perform Control Solution test) will flash on the screen along with ▲. PCS will flash three times and then disappear. The ▲ will stay on the screen and also mark a result in the memory mode.



WARNINGS AND PRECAUTIONS:

For *in vitro* Diagnostic Use.

- Assure Dose Control Solution is not intended for human consumption.
- Do not drink.
- Only use with Assure Platinum®, GLUCOCARD Vital® or ReliOn™ Prime Blood Glucose Meter and Test Strips.
- To avoid contamination, NEVER touch tip of control solution bottle to test strip!
- Dye in control solution may stain clothing or surfaces.

NOTE: Healthcare Professionals: Perform control solution tests in accordance with your state regulatory guidelines.

Step 1

Insert test strip as shown. The meter will turn on automatically. The full screen will come on for a moment. Make sure all symbols appear on the screen. The strip symbol and flashing blood drop will automatically be displayed.

NOTE: If both PCS and ▲ appear on the screen, perform a control solution test.

Step 2

Press the Back ◀ or ▶ Forward button one time to enter the control solution mode. A control solution bottle "b" will appear at the top right of the screen.

NOTE: If you do not enter the control solution mode, the control solution result will NOT be valid.

Using the control solution mode will also flag the result in memory. This prevents the result from being part of the averages. ⚡ will prompt you to apply control solution.

Step 3

Mix solution by gently inverting control solution bottle several times (do not shake). Remove the cap from the control solution bottle and place on flat surface. Squeeze the bottle and discard the first drop. Apply the second drop to the top of the clean cap.

Step 4

Bring meter and strip to drop. Test strip will draw up the solution. The meter will show result in 7 seconds.

Step 5

Compare the result to the range printed on the test strip bottle. Make sure the result is within the acceptable range. If the result falls within this range, the meter and test strip are working correctly.

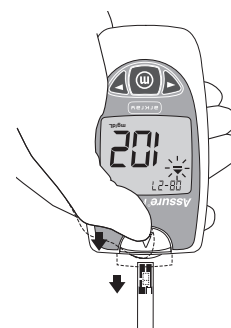
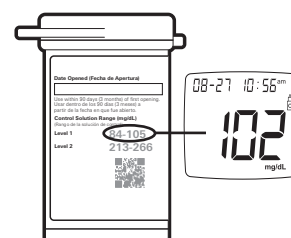
NOTE: Do not use system if control solution result is out of range.

NOTE: Healthcare Professionals: Record result in quality logbook.

Step 6

Remove the test strip by holding the meter so that the test strip points down. Push the strip release button forward. The test strip will fall out and meter will shut off automatically. Dispose of the used test strip. Wipe excess control solution from cap and replace cap on control solution bottle.

NOTE: Healthcare Professionals: Repeat Steps 1–6 with a second control solution.



METER MEMORY

The Assure Platinum® stores up to 500 test results. When more than 500 test results have been performed, the meter drops the oldest result each time you add a new result. When you recall test results from Memory, the most recent test result is always shown first. **Remove the test strip from meter before using Memory.**

NOTE: We do not recommend using the memory feature in a multi-patient setting. Results stored in the memory are not related to a specific patient.

RECALLING RESULTS

Step 1

Press the “M” button. The last result in memory will be shown. MEM will be shown in the upper left side of the screen. This screen is a stored result.

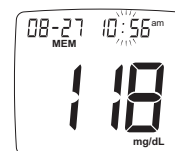
The meter will show the date and result number position (for example 001 for last result (Diagram A), 002 for second to last result (Diagram B), etc.). It will then show the date and time. These will alternate until you press the Back or Forward button.

Step 2

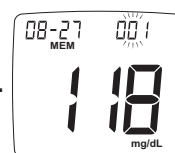
Continue to press either the Forward or Backward button to scroll through memory.

Step 3

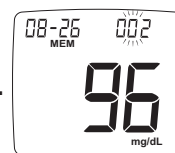
Press the “M” button to exit memory mode and turn meter off.



A.




B.



VIEWING 7-, 14-, 30-, AND 90-DAY AVERAGING

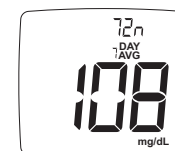
The following are NOT included in the glucose averages:

- Results marked  before using control solution.
- Results marked with ! when the test was performed.
- Results obtained when date and time have not been set.

NOTE: “LO” results are included as 20 mg/dL in the averages. “HI” results are included as 600 mg/dL in the averages.

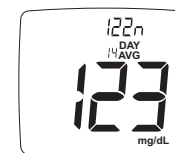
Step 1

While recalling results, press and hold the Forward and Backward buttons at the same time for two seconds. Meter will display 7-day average (7 DAY AVG). This can include 1-500 results. The number at the top, for example 72n, shows the number of tests that are included in the average.



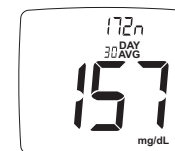
Step 2

Press the Forward button to show the 14-day average (14 DAY AVG). This can include 1–500 results. The number at the top, for example 122n, shows the number of tests that are included in the average.



Step 3

Press the Forward button to show the 30-day average (30 DAY AVG). This can include 1–500 results. The number at the top, for example 172n, shows the number of tests that are included in the average.



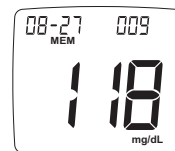
Step 4

Press the Forward button to show the 90-day average (90 DAY AVG). This can include 1–500 results. The number at the top, for example 450n, shows the number of tests that are included in the average.



Step 5

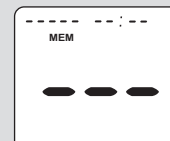
Press the “M” button to exit averaging mode. Press “M” button again to turn meter off.



SECTION

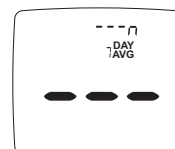
B

NOTE: If no results are stored in the memory or you are using the meter for the first time, the meter will show three bars.



7 Day Average Screen

If a test has not been done in the last 7 days, the meter will show the 7 Day Average screen with three bars. This means there are no results stored to make up the average.



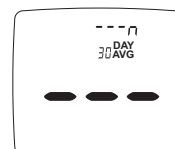
14 Day Average Screen

If a test has not been performed in the last 14 days, the meter will show the 14 Day Average screen with three bars. This means there are no results stored to make up the average.



30 Day Average Screen

If a test has not been done in the last 30 days, the meter will show the 30 Day Average screen with three bars. This means there are no results stored to make up the average.



90 Day Average Screen

If a test has not been done in the last 90 days, the meter will show the 90 Day Average screen with three bars. This means there are no results stored to make up the average.



INSERTING OR REPLACING THE BATTERY

To replace batteries:

Step 1

Turn meter off.*

Step 2

Press battery cover latch. Pull the battery cover up on the back of the meter.

Step 3

Remove the two used batteries.

Step 4

Insert two new AAA batteries.

Step 5

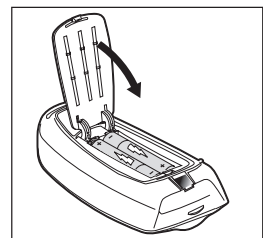
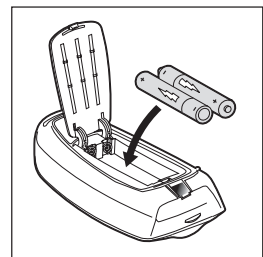
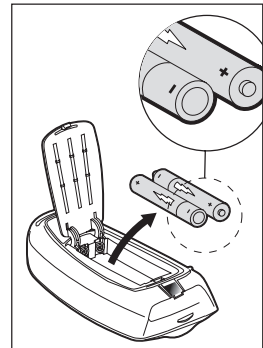
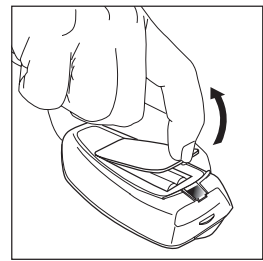
Close battery cover.

Step 6


E00 may be displayed. Check time and date.

Step 7

Dispose of batteries as per guidelines.



***NOTE:** Failure to turn meter off during battery replacement will result in lost time and date.

Battery life will decrease with backlighting. A flashing battery symbol  means the battery is low. Replace batteries as soon as possible. **Do not use rechargeable batteries.**

Replace batteries within one minute to avoid losing the time and date setting.

NOTE: To save battery power, the meter turns itself off two minutes after last use.

GUIDELINES FOR CLEANING AND DISINFECTING THE ASSURE PLATINUM® METER

To minimize the risk of transmitting blood-borne pathogens, the cleaning and disinfecting procedure should be performed as recommended in the instructions below.

The Assure Platinum® Blood Glucose Monitoring System may only be used for testing multiple patients when standard precautions and the manufacturer's disinfecting procedures are followed.

The meter should be cleaned and disinfected after use on each patient.

The cleaning procedure is needed to clean dirt, blood and other bodily fluids off the exterior of the meter before performing the disinfecting procedure. The disinfecting procedure is needed to prevent the transmission of blood-borne pathogens.

Always wear the appropriate protective gear, including disposable gloves. Select a wipe from the table below and carefully review the manufacturer's instructions.

Clean and disinfect the meter following step-by-step instructions in this QA/QC Reference Manual. Use caution as to not allow moisture to enter the test strip port, data port or battery compartment, as it may damage the meter.

ARKRAY has tested and validated the durability and functionality of the Assure Platinum meter with the most commonly used EPA-registered wipes. Our testing confirmed the wipes listed below will not damage the functionality or performance of the meter through 3,650 cleaning and disinfecting cycles. Please read the manufacturer's instructions before using their wipes on the meter. ARKRAY recommends using these wipes to clean and disinfect the Assure Platinum meter:

Manufacturer	Disinfectant Brand Name	EPA #
Clorox® Professional Products Company	Clorox® Healthcare Bleach Germicidal Wipes	67619-12
	Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	56392-8
Professional Disposables International, Inc. (PDI)	Super Sani-Cloth® Germicidal Disposable Wipes	9480-4
Metrex® Research	CaviWipes™	46781-8
Cambridge Sensors USA	Microdot® Bleach Wipe	69687-1

Clorox and Dispatch are trademarks or registered trademarks of Clorox. Sani-cloth is a trademark or registered trademark of PDI. Metrex and CaviWipes are trademarks or registered trademarks of Metrex. Microdot is a trademark or registered trademark of Cambridge Sensors USA, LLC.

Additional options for cleaning and disinfecting the Assure Platinum meter.

If you choose to follow Options 1 or 2 below, we recommend you create supporting documentation to justify your choice. Choosing a product not listed in the table above could shorten use life or affect performance of the Assure Platinum meter.

Option 1

- Obtain a commercially available EPA-registered disinfectant detergent or germicide wipe. A list of EPA registered disinfectants can be found at the following website:
www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants
- Carefully review the manufacturer's instructions.
- Remove wipe from the container and gently squeeze out excess liquid.
- Clean and disinfect the meter following step-by-step instructions listed below in this QA/QC Reference Manual.
- Use caution as to not allow moisture to enter the test strip port, data port or battery compartment, as it may damage the meter.

• Option 2

- Clean the outside of the blood glucose meter with a lint-free cloth dampened with soapy water or isopropyl alcohol (70-80%).
- Disinfect the meter by diluting 1mL of household bleach (5-6% sodium hypochlorite solution) in 9mL water to achieve a 1:10 dilution.
- Use a lint-free cloth dampened with the solution to thoroughly wipe down the meter.
- Use caution as to not allow moisture to enter the test strip port, data port or battery compartment, as it may damage the meter.

If you have any questions, please contact Technical Customer Service at 800.818.8877, option 5.

CLEANING AND DISINFECTING PROCEDURES

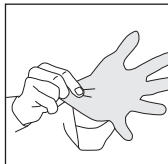
NOTE

Many wipes act as both a cleaner and disinfectant. If blood is visibly present on the meter, two wipes must be used; one wipe to clean and a second wipe to disinfect.

CLEANING

Step 1

Wear appropriate protective gear such as disposable gloves.



Step 2

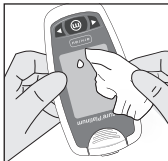
Open the cap of the disinfectant container and pull out 1 towelette and close the cap.



Step 3

Wipe surface of the meter to clean blood and other body fluids.

Carefully wipe around the test strip port by inverting the meter so that the test strip port is facing down. This prevents disinfectant liquid from entering the meter.

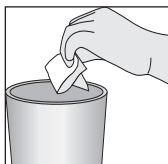


CAUTION

- Do not let liquid from the wipe saturate the test strip port, data port or battery compartments.

Step 4

Dispose of the used towelette in a trash bin. If blood is visible on the meter, it should be cleaned prior to each disinfection step.

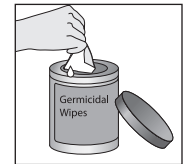


DISINFECTING

Step 5

Pull out 1 new towelette and wipe the entire surface of the meter horizontally and vertically to remove bloodborne pathogens.

Carefully wipe around the test strip port by inverting the meter so that the test strip port is facing down. This prevents disinfectant liquid from entering the meter.



CAUTION

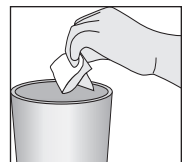
- Do not let liquid from the wipe saturate the test strip port, data port or battery compartments.

Step 6

Treated surface must remain wet for recommended contact time. Please refer to wipe manufacturer's instructions. **DO NOT WRAP THE METER IN A WIPE.**

Step 7

Dispose of the used towelette in a trash bin.



CLEANING AND DISINFECTING FAQ

If a blood glucose meter is assigned to an individual resident and not shared, does it still need to be cleaned and disinfected?

To ensure compliance ARKRAY recommends that blood glucose meters be cleaned and disinfected after each use. Each meter in use is subject to QC testing per the facility's policy.

Can cleaning and disinfecting be accomplished with one wipe?

Many wipes act as both a cleaner and disinfectant. If blood is visibly present on the meter, two wipes must be used; one wipe to clean and a second wipe to disinfect.

What will happen if a blood glucose meter is not cleaned and disinfected after use?

Per the CMS F-Tag 880 guideline, surveyors may issue a citation if they observe no cleaning and disinfecting of meters after a blood glucose test as they would not be in compliance with CMS F-Tag 880.

It is important that an LTC facility establish a program for infection control and identify a key individual responsible for the overall program oversight. The program should include addressing the cleaning and disinfecting of blood glucose meters along with other equipment and environmental surfaces. The program should involve establishing goals and priorities, planning, strategy implementation, post-surveillance and more. Additionally, staff roles and responsibilities should be identified and training should be documented. It is also important to provide education on infection control and the proper use of products. More information on establishing a comprehensive infection prevention and control program can be found in the CMS Infection Control Guidance Document.

F-TAG 880

The CMS has implemented phase 2 of cleaning and disinfecting standards in the facility assessment code 483.70

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INFECTION CONTROL REQUIREMENTS FOR BLOOD GLUCOSE MONITORING

What is the Centers for Medicare and Medicaid Services (CMS) F-Tag 880?

F-Tag 880 is an interpretive guideline for infection control programs in Long Term Care facilities. It is put in place to prevent, recognize and control the onset and spread of infection. F-Tag 880 is used for guidance by CMS Regional Offices and State Survey Agencies for [re-]certification and complaint investigations.

Does F-Tag 880 only apply to blood glucose meters?

No, F-Tag 880 applies to all resident care equipment and environmental surfaces, including blood glucose meters.

Why is Cleaning and Disinfecting of blood glucose meters such a high priority?

Blood glucose meters are at high risk of becoming contaminated with bloodborne pathogens such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV). Transmission of these viruses from resident to resident has been documented due to contaminated blood glucose devices. According to the Centers for Disease Control and Prevention, cleaning and disinfecting of meters between resident use can prevent the transmission of these viruses through indirect contact.

TROUBLESHOOTING

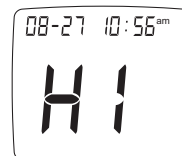
Display Screen

Please first read this section. If you still have questions, call Technical Customer Service at 800.818.8877, option 5 (24 hours a day, 7 days a week). Contact your healthcare professional if you cannot reach Technical Customer Service. Do not send your meter to ARKRAY or your local dealer without first calling to get approval to do so.

HI AND LO MESSAGES

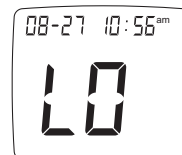
HI Message Your blood glucose level is more than 600 mg/dL.

Repeat test with new test strip. If this message shows again, contact your healthcare professional immediately!



LO Message Your blood glucose level is less than 20 mg/dL.

Repeat test with new test strip. If this message shows again, contact your healthcare professional immediately!



ERROR MESSAGES

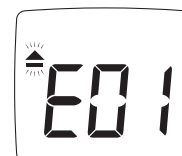
The battery has been replaced.

Check that the time and date are set correctly. (The time and date will be flashing). With the meter turned off, press and hold "M" button for two seconds to enter "check meter settings mode." Then confirm that the time and date are correct. If they are not correct, press and hold "M" button to enter set-up mode.



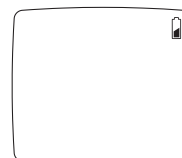
A used strip has been inserted. Or the meter is having a problem reading the strip.

Repeat test with new test strip.



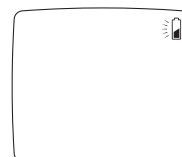
Battery power is getting low.

There is enough power for about 100 tests. Replace batteries soon.



Battery power low.

There is enough power for about 20 tests. Replace batteries soon.



The battery power is too low for testing.

Replace batteries.



Thermometer symbol.

The meter temperature is outside acceptable range of 41–113°F (5–45°C). Allow the meter and test strips to warm up or cool down for at least 30 minutes to adjust to new temperature.

**Test Strip Calibration Reading Error.**

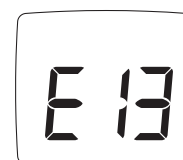
Meter detected abnormal signal of blanking on Assure Platinum® test strip. Remove the test strip and insert again.

**Corrupted Memory.**

Result cannot be obtained. Call Technical Customer Service at 800.818.8877, option 5.

**Not enough blood was added to test strip.**

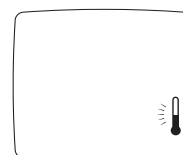
Retest with new test strip. Apply at least 0.5 µL of blood to sample application tip.

**QC Reminder.**

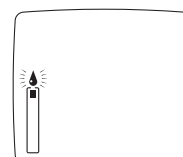
If the QC reminder is set to "On" in set-up mode, both PCS and ▲ will appear on the screen. PCS and alarm symbol act as a reminder to perform a control solution test every 24 hours.

**Flashing Thermometer Symbol.**

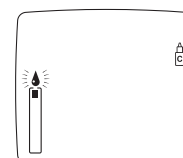
The room is outside the preferred temperature range of 50–104°F (10–40°C). Treat results obtained with caution. Repeat test where the temperature is within preferred range. Allow meter and strips at least 30 minutes to adjust to new temperature. The flashing thermometer will be shown during testing until meter is within preferred temperature range. These readings will show a thermometer when results are recalled from memory.

**Apply Blood Sample.**

The blood drop symbol flashes to show that the meter detects a test strip and is ready for the blood sample.

**Apply Control Solution.**


The blood drop symbol flashes to show that the meter has detected a test strip. If the control solution bottle icon is also on the screen, it is ready for you to apply control solution.



NOTE: For errors not listed, do not attempt to use meter. Contact Technical Customer Service at **800.818.8877, option 5**, 24 hours a day, 7 days a week.

TROUBLESHOOTING CONTROL SOLUTION PROCEDURE

If the control solution test result is out-of-range, check the following and repeat the test:

Check	Action
Did you do the test in control solution mode? Do you see the control solution bottle symbol  on the screen with the result?	If not, do the test again. Insert a test strip, press the Back or Forward button for control solution mode.  should appear on screen.
Have the test strips and/or control solution expired?	Make sure that test strips and control solutions are not past expiration date. This date is shown on bottle. Discard control solution and/or test strips 90 days after bottle is opened.
Were control solutions stored correctly (36–86°F) (2–30°C)?	If not, retest with new bottle of control solution.
Did you insert test strip firmly into meter?	Make sure test strip is inserted all the way into test strip port.
Were the test strips stored correctly (between 39–86°F (4–30°C))? Was the bottle cap replaced immediately after taking out a test strip?	If not, retest with a new bottle of test strips.
Is the test strip inserted properly?	Make sure that the test strip is inserted into the test strip port correctly.
Is the meter damaged? Does it show an error code?	If yes, contact Technical Customer Service at 800.818.8877, option 5.
Did you discard the first drop of control solution?	If not, do test again. Discard first drop of control solution.
Did you touch the tip of the control solution bottle to the test strip during use?	If yes, replace control solution.
Does your Control Solution result still read outside the range printed on the test strip bottle?	If yes, the system may not be working correctly. DO NOT USE the system to test your blood glucose until the control solution result is within range.

If you need help, please call Technical Customer Service at **800.818.8877**, option 5, 24 hours a day, 7 days a week. Contact your diabetes healthcare professional if you cannot reach Customer Service.

FREQUENTLY ASKED QUESTIONS

1. Can results vary between meters in side-by-side tests?

Yes. One meter is not a valid reference method for another meter. Readings would likely vary because of the many variables that can affect the reading including:

- The naturally uneven distribution of glucose in blood between sites
- The time that the blood drop is exposed to the environment
- Whether you had to apply extra pressure to obtain the blood sample
- Inherent 15 to 20% variability of BGMs from laboratory reference methods
- Size of sample
- User technique

Medical studies reveal that it is not uncommon to get differences between the same brand of test strips or between meters. Small variances are thought by many health professionals to be perfectly reasonable.¹

Solution: To confirm the accuracy of your meter, test results should be compared to those obtained from a laboratory.

2. Can the Assure Platinum® Meter results vary from the laboratory test results?

Yes. The test result you get with your meter should fall within 15% of the laboratory result.¹ However, the difference might exceed 20% on rare occasions because of the following important variables:

a. Plasma versus whole blood

While blood glucose meters test whole blood, laboratory blood glucose measurements are made either from a whole blood sample or from a blood plasma sample (blood with the red cells removed). Both methods are widely used, and neither is more “correct” than the other. However, the very nature of these two sample types produces slightly different glucose measurements from the sample blood specimen. Plasma measurements are, on average, about 12% higher than their whole blood counterparts.²

Solution: The Assure Platinum System is “plasma-referenced.” Assure Platinum results should fall within 15% to 20% of a laboratory result, which is based on testing a plasma sample. Although the Assure Platinum uses a whole blood sample, we have adjusted its internal calibration so that it converts results to match a plasma-referenced result. Assure Platinum results will be, on average, 12% higher than laboratory results based on whole blood testing. To compare Assure Platinum results with a whole blood referenced laboratory result, first multiply the laboratory result by 1.12. Then Assure Platinum results should fall within 15% to 20% of the adjusted laboratory result.

b. Capillary versus venous blood

The blood you use to test from the fingertip is capillary blood, while laboratories generally use venous blood. Unless the patient is in a fasting state, the blood sugar level of the capillary blood will be higher than that of the venous blood. Capillary blood glucose levels may be 20 to 70 mg/dL higher than venous blood glucose after food intake.³

c. Time test was performed

If the meter test is not done within 30 minutes of the laboratory test, it will result in variations in the readings as blood glucose levels can change quickly.

For example: Glucose levels of whole blood can drop up to 7 mg/dL each hour because of glycolysis if the samples are left at room temperature.

Solution: Assure that the lab test is performed within 30 minutes of the blood being drawn.

3. If testing is performed in extreme temperatures will it affect the test results obtained from the meter?

Yes. The meter is designed to be used within the following temperature range: 50–104°F (10–40°C). Tests will be accurate when performed within this range.

4. Can plasma or serum be used in the Assure Platinum® Meter?

No. The Assure Platinum Meter is designed to work with whole blood samples and Assure Dose Control Solutions only.

References:

1. "Self Monitoring of Blood Glucose," Diabetes Care, Volume 19, Supplement 1, Jan. 1996, pp. S562-S566.
2. Tietz NW. Fundamentals of Clinical Chemistry, 4th Edition; Burtis and Ashwood, 1996.
3. Caraway WT: Carbohydrates. In Teitz NW (ed.) Fundamentals of Clinical Chemistry. Philadelphia. WB Saunders Company.

PERFORMANCE CHARACTERISTICS FOR CONSUMERS

Assure Platinum® performance has been evaluated both in laboratory and clinical tests.

Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a laboratory method and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher. The chart below displays how often the Assure Platinum meter achieves this goal. The chart is based on a study done to see how well the Assure Platinum blood glucose meter compared to laboratory results.

Fingertip Results - Participant

For glucose results lower than 75 mg/dL, the percent (and number) of meter results that match the laboratory method within 15 mg/dL:	100% 6/6
For glucose results at 75 mg/dL or higher, the percent (and number) of meter results that match the laboratory method within 20%:	97% 92/95
Total number of patients in the study:	101

PERFORMANCE CHARACTERISTICS FOR HEALTHCARE PROFESSIONALS

Precision

Precision results indicate that on average you can expect a 2.2% variation from back-to-back testing across a 39 - 585 mg/dL glucose range. The table shows Coefficient of Variation (CV%) values for five glucose levels that cover the glucose range typical of persons with diabetes. Values are averages for three separate lots of test strips.

Mean Glucose Level (mg/dL)	n	SD (mg/dL)	CV%
39	100	1.12	2.90
102	100	2.31	2.28
142	100	3.24	2.28
219	100	6.10	2.78
289	100	6.34	1.63
585	100	9.20	1.57

Accuracy

Assure Platinum was assessed against the YSI Model 2300. Studies were conducted by Healthcare Professionals. The results below were obtained from subjects with Type 1 or Type 2 diabetes.

Assure Platinum	Professional
Slope	1.00
Y-Intercept	-2.33
Correlation coefficient (r)	0.99
Number of subjects	288
Range tested (mg/dL)	26-480 mg/dL

The tables below show how well the Assure Platinum Blood Glucose Monitoring System compared to the laboratory results.

Professional Fingerstick Accuracy*

Glucose results lower than 75 mg/dL (< 75 mg/dL)

Range differences in values between the laboratory results and the Assure Platinum® Blood Glucose Monitoring System	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/ dL
The number and percent of how many times the results fell within the ranges listed above	42/48 88%	48/48 100%	48/48 100%

Glucose results greater than or equal to 75 mg/dL (≥ 75 mg/dL)

Range differences in values between the laboratory results and the Assure Platinum Blood Glucose Monitoring System	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
The number and percent of how many times the results fell within the ranges listed above	127/240 53%	189/240 79%	231/240 96%	240/240 100%

* Acceptance criteria in ISO 15197: 2003 are that 95% of all differences in glucose values should be within 15 mg/dL for glucose values less than 75 mg/dL (top table) and within 20% for glucose values greater than 75 mg/dL (bottom table).

NOTE: When glucose meter results are compared to the laboratory results, difference values below 75 mg/dL are expressed in mg/dL, while those above 75 mg/dL are compared in percent.

U.S. Patent No. 6,916,410 B2

1 Definition and Diagnosis of Diabetes Mellitus and Intermediate Hyperglycaemia. World Health Organization, 2006.

2 Diabetes Care, Vol. 33 Jan; 1 S82-86, 2010.

In-Service Guide

Name of facility: _____

IN-SERVICE TRAINING

Assure Platinum® Blood Glucose Monitoring System: In-Service Training and Certificate

Instructor: Before signing checklist, the trainee must meet objectives listed below.

SECTION

C

1. Familiarization with components of the Assure Platinum Blood Glucose Monitoring System:

Meter: <ul style="list-style-type: none"><input type="checkbox"/> Features (strip release button, test strip port, etc.)<input type="checkbox"/> Serial Number<input type="checkbox"/> Storage<input type="checkbox"/> Cleaning and Disinfecting<input type="checkbox"/> Technical Customer Service Number	Test Strips: <ul style="list-style-type: none"><input type="checkbox"/> Lot Number<input type="checkbox"/> Expiration Date<input type="checkbox"/> Storage<input type="checkbox"/> Control Solution Range<input type="checkbox"/> Proper Strip Insertion<input type="checkbox"/> Handling	Control Solutions: <ul style="list-style-type: none"><input type="checkbox"/> Expiration Date<input type="checkbox"/> Acceptable Range<input type="checkbox"/> Test Procedure Safety Lancets: <ul style="list-style-type: none"><input type="checkbox"/> Usage / Activation<input type="checkbox"/> Disposal
---	---	---

2. Describe or Demonstrate:

<input type="checkbox"/> Initial Meter Set-Up		
Options:	Default:	Option:
Audible Beep	<input type="checkbox"/> On	<input type="checkbox"/> Off
Hypo Warning	<input type="checkbox"/> Off	<input type="checkbox"/> On
Daylight Savings Time	<input type="checkbox"/> Off	<input type="checkbox"/> On
Time Format	<input type="checkbox"/> 12H	<input type="checkbox"/> 24H
Date Format	<input type="checkbox"/> m-d	<input type="checkbox"/> d-m
Backlight Setting	<input type="checkbox"/> Off (0)	<input type="checkbox"/> On
qcProGuard®/QC Reminder	<input type="checkbox"/> Off (0)	<input type="checkbox"/> On

3. Additional Training In-service Completion:

- ☐ Assure ID® Safety Pen Needle Training
- ☐ Discharge Program Training
- ☐ Phazix® Pill Swallowing Gel

Instructor Name (Print)

Operator-Trainee Name (Print)

Date

Instructor Name (Signature)

Operator-Trainee Name (Signature)

Name of facility: _____

COMPETENCY CHECKLIST

Assure Platinum® Blood Glucose Monitoring System:

Operator _____

Date _____

Trainer _____

The Trainer should observe the Operator performing the following tasks:

- | | | |
|---|------------------------------|-----------------------------|
| 1. Select and prepare the fingerstick site correctly. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 2. Use lancet/lancing device correctly. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 3. Insert test strip into meter correctly. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 4. Apply blood to sample application tip correctly. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 5. Dispose of lancet correctly. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 6. Identify when to repeat test or check result with a laboratory test. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 7. Record result correctly. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 8. Follow facility protocol for quality control testing. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 9. Clean/disinfect meter correctly. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 10. Change battery. | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 11. Additional Product Training | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

Did the Operator perform each task correctly? ☐ YES ☐ NO

If yes, the Operator is now certified to use the Assure Platinum Blood Glucose Monitoring System. If no, retrain, perform tasks on list and document performance on competency checklist again.

SECTION

C

Name of facility: _____

INSTRUCTOR TRAINING RECORD

Assure Platinum® Blood Glucose Monitoring System

The healthcare professionals listed below have been trained to serve as trainers for the Assure Platinum Blood Glucose Monitoring System. They are qualified to perform initial training of operations, conduct performance reviews, and maintain records concerning operators.

ARKRAY Representative Name _____

[illegible]

To be used during the initial training on the Assure Platinum Blood Glucose Monitoring System by an ARKRAY Representative within the facility.

To be kept on file in the Nursing Unit and updated by Trainer.

Name of facility: _____

NURSE IN-SERVICE TRAINING RECORD

Assure Platinum® Blood Glucose Monitoring System

The healthcare professionals listed below have been trained to use the Assure Platinum Blood Glucose Monitoring System.

Trainer Name _____

[illegible]

To be used during the initial training on the Assure Platinum Blood Glucose Monitoring System by an ARKRAY Representative or Trainer within the facility.

To be kept on file in the Nursing Unit and updated by Trainer.

Name of facility: _____

SELF-TEST

Assure Platinum® Blood Glucose Monitoring System:

The following is a multiple choice self-test that is designed to test your proficiency in using the Assure® Platinum Meter. Answer the questions by circling the letter of the statement that is CORRECT. Check your answers against the correct answers, which are located at the end of the test. More than one answer may be acceptable on some questions.

If you respond incorrectly to any of the questions, make sure you study the section or talk to your instructor.

SECTION

C

1. The Assure Platinum Meter

- a. Uses reflectance technology
- b. Uses biosensor technology
- c. Stores up to 500 tests in memory
- d. Can be used with any brand of test strips

2. The Assure Platinum Test Strips

- a. Have a CODE chip that is packaged with every box of test strips
- b. Can be used with other meters besides the Assure Platinum
- c. Are not sensitive to light, moisture, and humidity
- d. Do not require you to code the meter; they are auto-coding

3. When obtaining a blood sample

- a. You should not wash the patient's hand
- b. Hang the patient's arm down below their heart for 10 to 15 seconds to increase blood flow
- c. You should lance the side of fingertip
- d. You should use the same site selection of the fingertip each time

4. When performing a test with control solutions

- a. Solutions should be applied to test strip before it is inserted into the meter
- b. The test strip must be in the meter before solutions are applied
- c. Use any brand of control solutions
- d. Press the "M" Button to enter control solution mode prior to applying solution to the test strip

5. Assure Dose Control Solutions

- a. Are for cleaning the meter
- b. Are used to verify that the test strips are reacting properly
- c. Are good for 90 days after opening
- d. Should be used if strips have been exposed to extremes in temperature, light, or humidity

6. When applying blood to the Assure Platinum Test Strips

- a. Smear the blood sample
- b. Apply it to the reaction site of the test strip
- c. Apply it to the sample application tip
- d. If meter does not start after adding the first blood drop, you may apply a second drop.

7. The Assure Platinum meter can be used with

- a. Whole blood
- b. Serum or plasma
- c. Neonatal blood samples
- d. Venous blood

8. The Assure Platinum meter should be cleaned and disinfected between patient tests to avoid cross-contamination? ☐ True ☐ False

9. Nurses who use the Assure Platinum meter to test patients should

- a. Wear gloves when cleaning the meter
- b. Test the meter with two control solutions
- c. Not rely on the memory or average features as they are not related to a specific patient
- d. Use a safety lancet, such as the Assure® Lance, to obtain a patient's blood sample

Name: _____

Date: _____

Score: _____

SECTION

C

Name of facility: _____

SELF-TEST

Assure Platinum® Blood Glucose Monitoring System

Answer Key:

- | | |
|------------|---------------|
| 1. b, c | 6. c |
| 2. d | 7. a |
| 3. b, c | 8. True |
| 4. b | 9. a, b, c, d |
| 5. b, c, d | |

SECTION

C

Name of facility: _____

METER TRACKING FORM

Active Meters Per Unit		Meter Serial Number	
		New	Replacement
	1		
	2		
	3		
	4		
	5		
	6		
	7		

SECTION

C

FIELD INSPECTION REPORT Assure Platinum® Blood Glucose Monitoring System:

Address: _____
Time: _____
Phone: _____

ARKRAY Representative Signature: _____

[illegible]

REGULATORY REVIEW AND GUIDELINES FOR QA/QC PROTOCOLS

COMPETENCY CHECKLIST

	Joint Commission on Accreditation of Healthcare	Clinical and Laboratory Standards Institute (CLSI) (Formerly NCCLS)	Clinical Laboratory Improvement Amendments (CLIA)
Personnel/ Training	<ul style="list-style-type: none"> • Staff members can describe or demonstrate their roles and responsibilities (HR.2.20) • Participate in ongoing in-services • Education is documented (HR.2.30) • Competence to perform job responsibilities is assessed, demonstrated, and maintained (HR.3.10) 	<ul style="list-style-type: none"> • Formal training and written examination 	<ul style="list-style-type: none"> • Follow manufacturer's instructions
Quality Assurance	<ul style="list-style-type: none"> • Current and complete policies are available to the person performing the test • Written policies and procedures for: specimen collection, identification, and required labeling; specimen preservation; instrument calibration; quality control and remedial action; equipment performance evaluation; test performance 	<ul style="list-style-type: none"> • Follow manufacturer's instructions for calibration • Written procedure manual • Manual contains principles of operation, reagents/ equipment, calibration, quality control, stepwise procedure, reporting results, procedure limitations, references, supplemental material, review and updates 	<ul style="list-style-type: none"> • Follow manufacturer's instructions
Quality Control	<ul style="list-style-type: none"> • Written quality control plan that specifies how procedures will be controlled • Performed at least as frequently as recommended by manufacturer • Should include two levels of control • Quality control procedures are performed at least once each day on each instrument used for resident testing (PC.16.50) 	<ul style="list-style-type: none"> • On each day of use, two controls (high and normal) should be performed per instrument • Each operator to perform a quality control prior to the first patient test of the day • Additional checks should be performed when a new bottle of strips is opened, each time a reagent lot is changed and to ensure the strips and meter are functioning properly 	<ul style="list-style-type: none"> • Follow manufacturer's instructions
Linearity/ Calibration	<ul style="list-style-type: none"> • Linearity not covered in the standards 	<ul style="list-style-type: none"> • Initially and as specified by manufacturer or as required by government or accrediting bodies 	<ul style="list-style-type: none"> • Follow manufacturer's instructions
Proficiency Training	<ul style="list-style-type: none"> • Not specified 	<ul style="list-style-type: none"> • Participate in program that meets accreditation, federal and state regulations 	<ul style="list-style-type: none"> • Not specified
Inspections	<ul style="list-style-type: none"> • Currently triennial (APP-5) 	<ul style="list-style-type: none"> • Not a certifying agency 	<ul style="list-style-type: none"> • Not subject to routine survey • Conducted only when authorized by the RO

SECTION

C

ARKRAY provides this checklist as a guideline only. These guidelines are subject to change by the regulating body at any time. Utilize this checklist in accordance with your facility's policy.

Addendums

PRODUCT ORDERING

ORDERING DETAILS	ARKRAY Product Code #	Reimbursement #
Assure Platinum® Meter	500001	08317-5000-01
Assure Platinum® Test Strips 50-count	500050	08317-5000-50
Assure Platinum® Test Strips 100-count	500100	08317-5001-00
Assure® Dose Control Solution (Normal-Level 1 and High-Level 2)	500006	08317-5000-06

WARRANTY

You are a valued customer of ARKRAY. It is important to us that you are satisfied with your Assure Platinum Blood Glucose Monitoring System.

ARKRAY warrants that your Assure Platinum Meter will be free from defects in materials and workmanship for a period of five years from the date of the original purchase. If during this time the meter does not work properly because of a defect in materials or workmanship, ARKRAY agrees to replace or repair, free of charge any and all parts proven to be defective and subject to warranty.

This warranty is in lieu of all other warranties, expressed or implied, including any implied warranty of merchantability or fitness for any purpose, other than stated herein.

This warranty does not apply to the performance of the Assure Platinum Meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. This warranty only applies to the original purchaser of the meter and/or its agents.

RETURNS

You must contact ARKRAY Technical Customer Service at **800.818.8877** option 5, 24 hours a day, 7 days a week before returning your meter. You will be instructed how to return the meter to ARKRAY. Returned meters without this authorization will not be accepted.

SECTION

D

SAMPLE POLICY AND PROCEDURES

NOTE: The following Sample Policies and Procedures are provided only as an example to help your facility establish your own policies and procedures. Your own policy may vary depending upon your facility's existing procedures. Please consult with your Director of Nursing for further direction.

SECTION

D

POLICY: INFECTION CONTROL

Purpose

The purpose of this guide is to ensure that correct cleaning and disinfecting of the Assure Platinum® Blood Glucose Monitoring System is followed to prevent the potential transmission of infectious organisms through the Assure Platinum Blood Glucose Monitoring System. A strong, consistent facility policy will provide lasting benefits to healthcare professionals and patients. Please consult with your nursing or infection control managers to determine your own stated policy.

Both the Centers for Disease Control (CDC) and Joint Commission (JCAHO) recommend that precautions be taken during all procedures and in all circumstances where there is a possibility of exposure to blood or any body fluid.

To assist you with the infection control process we suggest you use the following ideas to assist you in developing an Infection Control Policy and Procedure Guide for your Assure Platinum Blood Glucose Monitoring System. Remember, this is not designed to replace your policy, but to provide a guideline for blood glucose infection control procedures.

Protocol Notes

Personnel should review and follow their organization's principles of aseptic and infection control.

Personnel should prevent contamination of themselves and cross-contamination to patients and other staff by adhering to their organization's facility-wide infection control policy.

Level of Responsibility: RN/LPN

Equipment Needed:

- Assure Platinum Meter
- Assure Platinum Test Strips
- Auto-disabling, single-use safety lancet (we recommend the Assure Lance Safety Lancet)
- Gloves
- Prepared disinfectant
- Appropriate containers for contaminated disposable equipment/gowns

Procedure

1. Prepare for Testing

Wash hands thoroughly. Gather all of the supplies needed to perform a blood glucose test. Wear gloves and a gown according to organization's policy.

2. Perform the Test

Follow the instructions on how to perform a test with an Assure Platinum Meter (detailed in Section B of the QA/QC Manual).

3. Dispose of used test strip and lancet

Dispose of the used Assure Platinum Test Strip and lancet after the test is performed in the appropriately marked containers or follow your facility's printed policy of disposal for this type of matter.

4. Clean and Disinfect

5. Dispose of used gloves or garments in appropriate containers.

GUIDELINES FOR CLEANING AND DISINFECTING THE ASSURE PLATINUM® METER

To minimize the risk of transmitting blood-borne pathogens, the cleaning and disinfecting procedure should be performed as recommended in the instructions below.

The Assure Platinum Blood Glucose Monitoring System may only be used for testing multiple patients when standard precautions and the manufacturer's disinfecting procedures are followed.

The meter should be cleaned and disinfected after use on each patient.

The cleaning procedure is needed to clean dirt, blood and other bodily fluids off the exterior of the meter before performing the disinfecting procedure. The disinfecting procedure is needed to prevent the transmission of blood-borne pathogens.

Always wear the appropriate protective gear, including disposable gloves. Select a wipe from the table below and carefully review the manufacturer's instructions.

Clean and disinfect the meter following step-by-step instructions in this QA/QC Reference Manual. Use caution as to not allow moisture to enter the test strip port, data port or battery compartment, as it may damage the meter.

ARKRAY has tested and validated the durability and functionality of the Assure Platinum meter with the most commonly used EPA-registered wipes. Our testing confirmed the wipes listed below will not damage the functionality or performance of the meter through 3,650 cleaning and disinfecting cycles. Please read the manufacturer's instructions before using their wipes on the meter. ARKRAY recommends using these wipes to clean and disinfect the Assure Platinum meter:

Manufacturer	Disinfectant Brand Name	EPA #
Clorox® Professional Products Company	Clorox® Healthcare Bleach Germicidal Wipes	67619-12
	Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	56392-8
Professional Disposables International, Inc. (PDI)	Super Sani-Cloth® Germicidal Disposable Wipes	9480-4
Metrex® Research	CaviWipes™	46781-8
Cambridge Sensors USA	Microdot® Bleach Wipe	69687-1

Clorox and Dispatch are trademarks or registered trademarks of Clorox. Sani-cloth is a trademark or registered trademark of PDI. Metrex and CaviWipes are trademarks or registered trademarks of Metrex. Microdot is a trademark or registered trademark of Cambridge Sensors USA, LLC.

Additional options for cleaning and disinfecting the Assure Platinum meter.

If you choose to follow Options 1 or 2 below, we recommend you create supporting documentation to justify your choice. Choosing a product not listed in the table above could shorten use life or affect performance of the Assure Platinum meter.

Option 1

- Obtain a commercially available EPA-registered disinfectant detergent or germicide wipe. A list of EPA registered disinfectants can be found at the following website:
www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants
- Carefully review the manufacturer's instructions.
- Remove wipe from the container and gently squeeze out excess liquid.
- Clean and disinfect the meter following step-by-step instructions listed below in this QA/QC Reference Manual.
- Use caution as to not allow moisture to enter the test strip port, data port or battery compartment, as it may damage the meter.

• Option 2

- Clean the outside of the blood glucose meter with a lint-free cloth dampened with soapy water or isopropyl alcohol (70-80%).
- Disinfect the meter by diluting 1mL of household bleach (5-6% sodium hypochlorite solution) in 9mL water to achieve a 1:10 dilution.
- Use a lint-free cloth dampened with the solution to thoroughly wipe down the meter.
- Use caution as to not allow moisture to enter the test strip port, data port or battery compartment, as it may damage the meter.

If you have any questions, please contact Technical Customer Service at 800.818.8877, option 5.

CLEANING AND DISINFECTING PROCEDURES

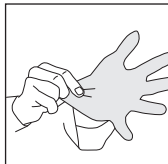
NOTE

Many wipes act as both a cleaner and disinfectant. If blood is visibly present on the meter, two wipes must be used; one wipe to clean and a second wipe to disinfect.

CLEANING

Step 1

Wear appropriate protective gear such as disposable gloves.



Step 2

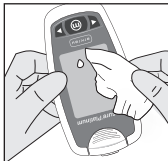
Open the cap of the disinfectant container and pull out 1 towelette and close the cap.



Step 3

Wipe surface of the meter to clean blood and other body fluids.

Carefully wipe around the test strip port by inverting the meter so that the test strip port is facing down. This prevents disinfectant liquid from entering the meter.

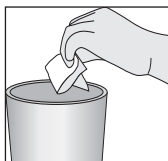


CAUTION

- Do not let liquid from the wipe saturate the test strip port, data port or battery compartments.

Step 4

Dispose of the used towelette in a trash bin. The meter should be cleaned prior to each disinfection step.

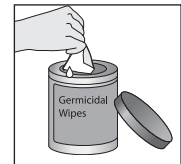


DISINFECTING

Step 5

Pull out 1 new towelette and wipe the entire surface of the meter horizontally and vertically to remove bloodborne pathogens.

Carefully wipe around the test strip port by inverting the meter so that the test strip port is facing down. This prevents disinfectant liquid from entering the meter.



CAUTION

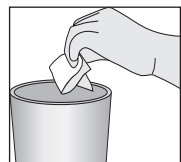
- Do not let liquid from the wipe saturate the test strip port, data port or battery compartments.

Step 6

Treated surface must remain wet for recommended contact time. Please refer to wipe manufacturer's instructions. **DO NOT WRAP THE METER IN A WIPE.**

Step 7

Dispose of the used towelette in a trash bin.



POLICY: PERFORMING A BLOOD GLUCOSE TEST WITH THE ASSURE PLATINUM® METER

Patients who require daily administration of insulin or oral hypoglycemic agents will have:

- Glucose levels monitored using the Assure Platinum Blood Glucose Meter in accordance with a physician's order. When no physician's order is present, registered nurse should monitor at least daily.
- Fasting serum blood glucose test performed as ordered by the physician.

Patients with diet-controlled diabetes mellitus will have:

- Glucose levels monitored using the Assure Platinum Blood Glucose Meter in accordance with a physician's order. When no physician's order is present, registered nurse should monitor at least weekly.
- Fasting serum blood glucose test performed as ordered by the physician.

Level of Responsibility: RN/LPN

Equipment Needed:

- Assure Platinum Blood Glucose Meter
- Assure Platinum Test Strips
- Safety Lancet
- Gloves
- Alcohol Wipe

Procedure:

Consult manufacturer's direction for additional information regarding the use of the Assure Platinum Blood Glucose Meter.

1. Verify physician's order
2. Assemble equipment
3. Identify the resident
4. Explain procedure
5. Provide privacy
6. Wash hands
7. Insert a test strip to turn the meter on.
8. Put on non-sterile gloves.
9. Cleanse area that is to be punctured (side of fingertip) with an alcohol swab. Allow area to dry.
10. Obtain blood sample
 - a. Follow manufacturer's directions for preparing lancet. Do not touch sterile point.
 - b. Lightly hold lancet assembly against skin and lance the area.
 - c. Obtain a blood sample (a hanging drop of blood).
 - d. Dispose lancet according to facility procedure.
11. Apply blood to test strip.
 - a. Verify that the bottle of test strips has not expired and/or the bottle has not been opened for longer than 90 days. Discard the bottle of test strips if it has expired and/or has been opened for more than 90 days.
 - b. Touch the sample application tip at the end of the strip to the blood drop on your finger. Capillary action will pull the blood into the strip. Do not smear the blood and do not place blood on top of the reaction zone.

- c. Await result. Result will appear in 7 seconds.
 - d. Record result in patient's chart.
 - e. Dispose of strip according to local guidelines.
12. Remove gloves.
13. Wash hands.

Aftercare:

- Clean and disinfect Assure Platinum® Blood Glucose Meter between patient tests (Refer to Policy: Cleaning the Assure Platinum Meter).
- Return blood glucose meter and test strip bottle to proper place.
- Dispose of lancet into a sharps (puncture-resistant) container for soiled needles/syringes. DO NOT recap or reuse needle.
- Place used alcohol swab, test strip and gloves in infectious waste container.

POLICY: QUALITY CONTROL TESTING ON ASSURE PLATINUM® METER

Quality control testing using the Assure® Dose Control Solution will be performed to examine the performance of the Assure Platinum Blood Glucose Monitoring System.

The Assure Dose® Control Solution checks if the meter and test strips are working correctly as a system and if you are testing correctly.

Perform a Control Solution Test:

- Before testing with the Assure Platinum System for the first time.
- When you open a new bottle of test strips.
- Whenever you suspect the meter or test strips may not be functioning properly.
- If test results appear to be abnormally high or low or are not consistent with clinical symptoms.
- The test strip bottle has been left open or has been exposed to light, temperatures below 39°F (4°C) or above 86°F (30°C), or humidity levels above 80%.
- To check your technique.
- When the Assure Platinum Meter has been dropped or stored below 32°F (0°C) or above 122°F (50°C).
- Each time the batteries are changed.

IMPORTANT: Depending on state regulations, control solution testing may be required on a daily basis. Please check with your local inspector's regulations or facility procedures.

IMPORTANT:

- Assure Dose Control Solution is not intended for human consumption. Do not drink.
- Only use with Assure Platinum Blood Glucose Meter and Assure Platinum Test Strips.
- To avoid contamination NEVER touch the tip of the bottle to the test strip!
- Dye in control solution may stain clothing or surfaces.
- Store the control solution between 36–86°F (2–30°C).
- Keep away from direct sunlight and heat. Do not freeze.
- Use before the expiration date printed on bottle.
- Use the control solution within 90 days (3 months) of first opening. It is recommended that you write the date of opening on the control solution bottle label ("Date Opened") as a reminder to dispose of the opened solution after 90 days.
- Always replace the cap immediately after use.
- Assure Dose Control Solution is not a cleaning solution. Do not clean your meter with control solution.

Level of Responsibility: RN/LPN

Equipment Needed:

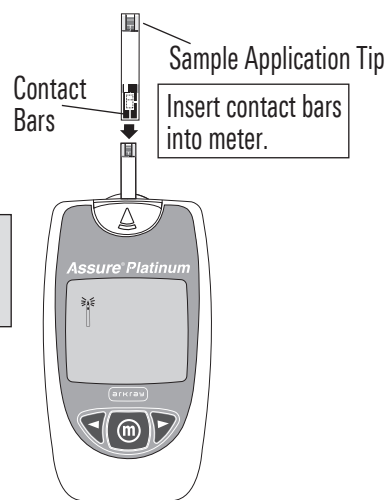
- Assure Dose Control Solution (Normal and High)
- Assure Platinum Test Strips
- Assure Platinum Meter
- Record Sheet


Procedure:

Consult manufacturer's direction for additional information regarding the use of the Assure Platinum® Blood Glucose Meter.

1. Wash hands.
2. Insert a test strip as shown in diagram. The meter will turn on automatically. The full screen will come on for a moment. Make sure all symbols appear on the screen (see page 2). The strip symbol and flashing blood drop will automatically be displayed.

NOTE: If both PCS and ▲ appear on the screen, perform a control solution test.



3. Press the ◀ or ▶ button one time to enter the control solution mode. You will see a control solution bottle () at the top right of the screen.

Using the control solution mode will also flag the result in memory. This prevents the result from being part of the averages.

"  " will prompt you to apply the control solution.

NOTE: If you do not enter the control solution mode, the control solution result will NOT be valid.

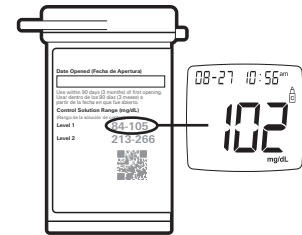


4. Mix control solution by gently inverting control solution bottle several times (do not shake). Remove the cap from the control solution bottle. Place cap on flat surface. Squeeze the bottle and discard the first drop. Apply the second drop to the top of the clean cap.

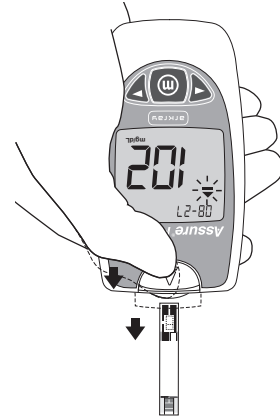


5. Bring meter and strip to drop. Test strip will draw up the solution. The meter will show result in 7 seconds.

6. Compare the result to the range printed on the test strip bottle. Make sure the result is within the acceptable range. If the result falls within this range, the meter and test strip are working correctly. Do not use system if control solution result is out of range.



7. Remove the test strip by holding the meter so that the test strip points down. Push the strip release button forward. The test strip will fall out and meter will shut off automatically. Dispose of the used test strip.



Note: Repeat steps 1–7 with a second control solution. Do not use system if control solution is out of range.

Aftercare:

- Clean and disinfect Assure Platinum® Blood Glucose Meter.
- Return blood glucose meter, control solution, and test strip bottle to proper place.
- Record results in the quality log book.

POLICY: MAINTAINING THE ASSURE PLATINUM® METER

Level of Responsibility: RN/LPN

Changing the Battery

The Assure Platinum uses two AAA alkaline batteries. They allow 5,000 tests with four tests per day. Battery life will decrease with backlighting. A flashing battery symbol means the battery is low. Replace batteries as soon as possible. Do not use rechargeable batteries. Discard used batteries as per local guidelines.

Replace batteries within one minute to avoid losing the time and date setting.

NOTE: To save battery power, the meter turns itself off 2 minutes after last use.

Equipment Needed:

- Two AAA alkaline batteries

To replace batteries:

Step 1

Turn meter off.*

Step 2

Press battery cover latch. Pull the battery cover up on the back of the meter.

Step 3

Remove the two used batteries.

Step 4

Insert two new AAA batteries.

Step 5

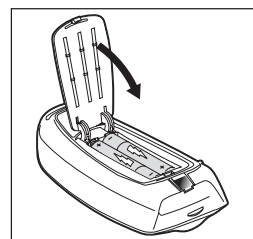
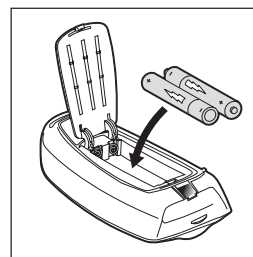
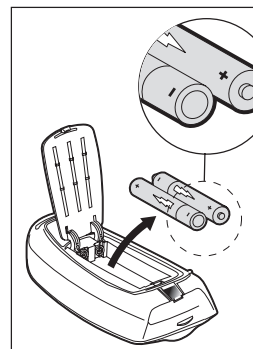
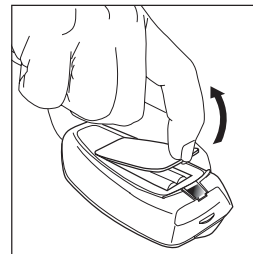
Close battery cover.

Step 6

E00 may be displayed. Check time and date.

Step 7

Dispose of batteries as per guidelines.



***NOTE:** Failure to turn meter off during battery replacement will result in lost time and date.

SECTION

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Technical Customer Service, 800.818.8877, option 5
24 hours a day, 7 days a week

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