

Assure[®] Titanium

BLOOD GLUCOSE MONITORING SYSTEM

Quality Assurance/ Quality Control

(QA/QC) Reference Manual



arkray

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Introduction

Important Health-Related Information

- The Assure Titanium Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (*in vitro* diagnostic use). Although fresh capillary whole blood samples are used for measurement, displayed results are equivalent to plasma glucose levels.
- The Assure Titanium Blood Glucose Monitoring System is intended for multiple-patient use in professional healthcare settings.
- After each use, healthcare personnel should change gloves.
- The Assure Titanium Blood Glucose Meter is designed to minimize code-related errors in monitoring by using the no-coding function.
- The glucose in the blood sample reacts with special chemicals on the test strip to produce a small electrical current. The Assure Titanium Blood Glucose Meter converts this electrical current to a glucose concentration.
- The Assure Titanium Blood Glucose Meter should be used only with the Assure Titanium Blood Glucose Test Strips.
- For accurate test results, allow the Assure Titanium Blood Glucose Meter, Assure Titanium Blood Glucose Test Strips and Assure Control-Control Solution to adjust to the surrounding temperature (46-86°F (8-30°C)) and relative humidity (10 to 90%) for 30 minutes before testing blood glucose.
- For questions or concerns, contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.

This comprehensive manual has been designed to provide you with a thorough reference source for the Assure Titanium 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.

Limitations

- For point-of-care use only.
- *In vitro* diagnostic use.
- **Not for** Alternative Site Testing (AST).
- **Do not** use the Assure Titanium Blood Glucose Monitoring System for screening or diagnosis of diabetes.
- **Not indicated for** use in patients undergoing tight glycemic control.
- **Do not** use the Assure Titanium Blood Glucose Monitoring System to test neonates. The Assure Titanium Blood Glucose Monitoring System has not been validated for neonatal use.
- **Do not** use at altitudes higher than 10,000 ft (3048 m) above sea level.
- Use only Assure Titanium Blood Glucose Test Strips for testing with the Assure Titanium Blood Glucose Meter.

Specifications

Product Specifications	
Measurement range	10-600 mg/dL
Sample size	Minimum 0.5 μ L
Test time	7 seconds
Sample type	Fresh capillary whole blood*
Calibration	Plasma-equivalent
Assay method	Electrochemical; Glucose oxidase (GO; <i>Aspergillus niger</i>): 1.5-1.9 IU Hexaammineruthenium (III) chloride: 10-12 μ g
Battery life	5,000 tests
Power	Two 1.5 V alkaline AAA batteries (disposable)
Memory	1,000 test results
Size	4.7 x 2.4 x 1.2 inch (119.5 x 60.0 x 28.8 mm)
Weight	4.1 oz (115 g) with batteries

* Although fresh capillary whole blood samples are used for measurement, displayed results are equivalent to plasma glucose levels.

Operating Ranges	
Temperature	46-104°F (8-40°C)
Relative humidity	10-90%
Altitude	10,000 ft (3,048 meters)
Hematocrit	10-70%
Calibration	Plasma-equivalent

Assure Titanium Blood Glucose Monitoring System (BGMS)


System Components

a. Assure Titanium Blood Glucose Meter

b. Batteries

- Check all the components after opening the Assure Titanium Blood Glucose Monitoring System package.
- The Assure Titanium Quick Reference Guide (QRG) and User Manual (UM) are available online. To access the Titanium QRG and UM, please visit: Lp.arkrayusa.com/assuretitanium.
- Assure Titanium test strips are necessary but not included.
- Assure Control-Control Solutions (Level 2 and Level 3) are necessary but not included.
- Target range for the 2 levels of Control solutions:
 - Level 2 (Normal): 130 mg/dL \pm 11% (116 - 144 mg/dL)
 - Level 3 (High): 360 mg/dL \pm 11% (321 - 399 mg/dL)
- *Control range is assigned for each Lot of test strips by measuring control solution with test strips after Lot correction. Please refer to the test strip vial label for the actual values for each specific lot.
- Control solution can be ordered separately. Please contact ARKRAY Technical Customer Service: 800.818.8877, 24 hours a day, 7 days a week.

Inserting or Replacing the Batteries

The Assure Titanium Blood Glucose Meter uses two 1.5 V alkaline AAA batteries. Before using the meter, check the battery compartment and insert batteries if empty. When the  appears on the screen 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 lose their charge.

Step 1

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

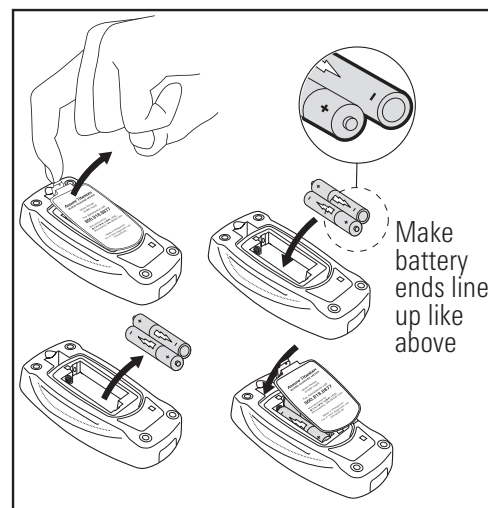
Step 2

Remove the used batteries. Insert two new AAA batteries and ensure the batteries are inserted firmly.

Step 3

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

Dispose of the used batteries according to your local environmental regulations.

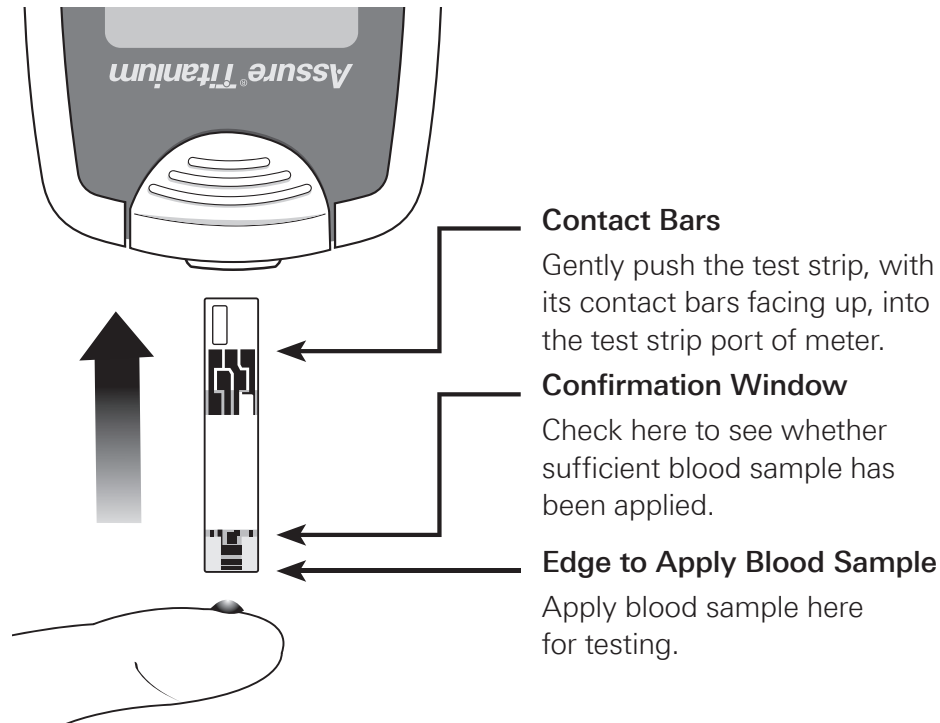


NOTE:

- Removing the meter batteries will not affect your stored results. However, meter settings may need to be reset.
- See page 4 in the “Meter Operation and Setup” section.

Assure Titanium Blood Glucose Test Strips

The Assure Titanium Blood Glucose Monitoring System measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied at the confirmation window edge of the test strip.



NOTE:

- All components that come into contact with blood samples should be considered biohazardous, capable of transmitting viral diseases between patients and healthcare professionals.

- Assure Titanium Blood Glucose Test Strips should be used only with fresh capillary whole blood samples.
- **Do not** reuse test strips.
- **Do not** use Assure Titanium Blood Glucose Test Strips beyond the expiration date. This may cause inaccurate results.
- **Do not** use test strips beyond six months (180 days) after opening the vial. Record the discard date (six months from the day the vial was opened) on the vial label.
- Store test strips in a cool and dry place at a temperature of 34-86°F (1-30°C), 10-90% RH. Avoid storing test strips in direct sunlight.
- Store test strips only in their original vial.
- Close the vial tightly after taking out a test strip and use the test strip immediately.
- Handle test strips only with clean and dry hands using protective gears such as disposable gloves.
- **Do not** bend, cut or alter test strips in any way.
- For detailed storage and usage information, refer to the Assure Titanium Blood Glucose Test Strip package insert.

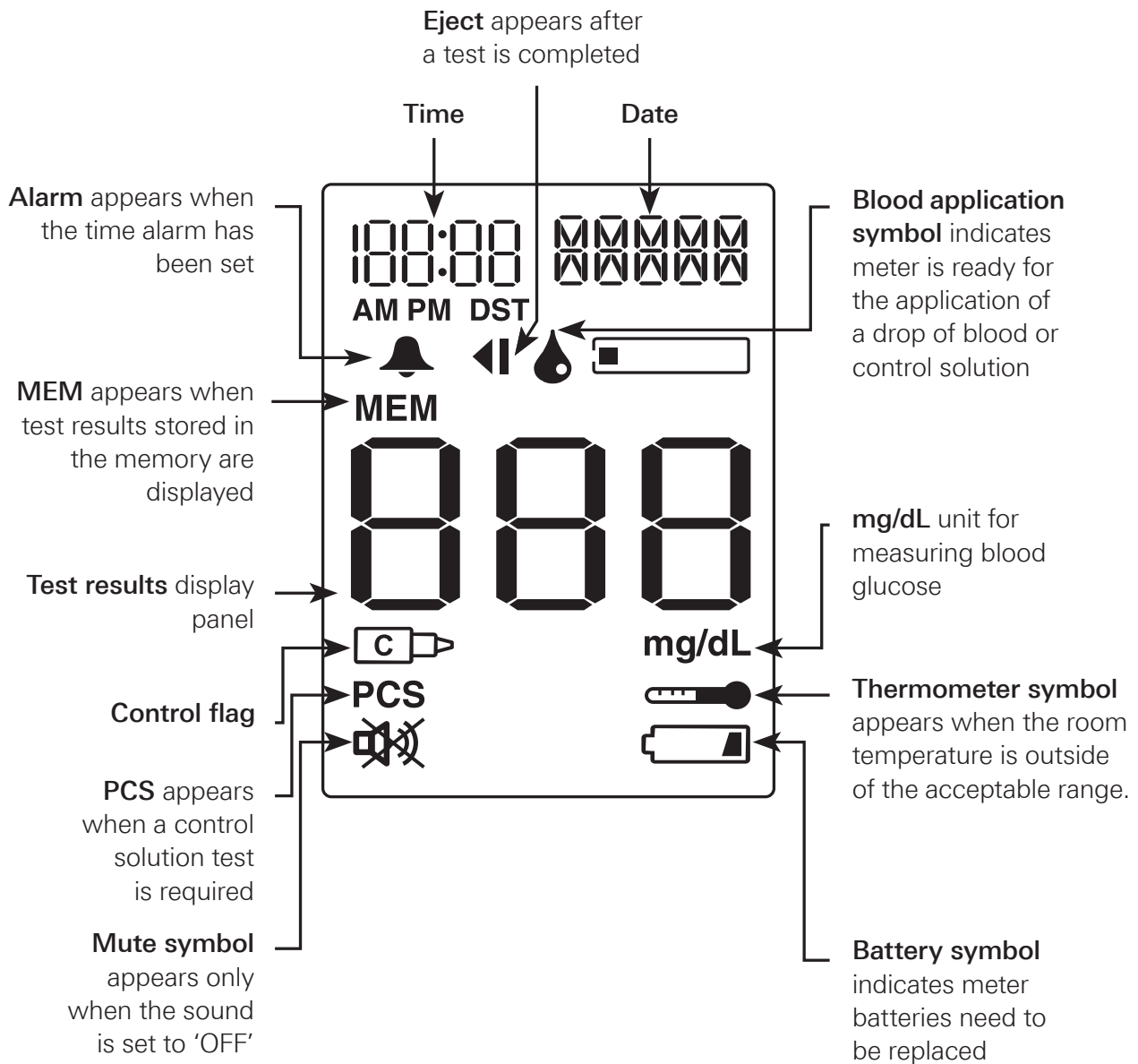
Assure Titanium Blood Glucose Meter

SECTION

B



Assure Titanium Blood Glucose Meter Display



NOTE:


- It is recommended to check that 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 Titanium Blood Glucose Meter is preset and fixed in mg/dL.

Meter Operation and Setup





Meter Setup

You should check and update the meter-settings such as time and date before using your meter or after changing the meter batteries.

Entering and Exiting Set-up Mode





Press and hold the  button for three seconds to enter the set-up mode. While setting up the meter, current settings will appear on the screen.

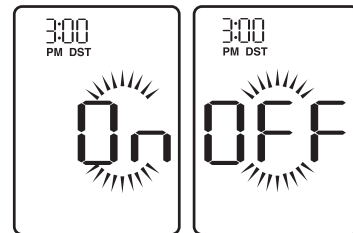
To save your settings and exit from the set-up mode, press and hold the  button for three seconds again.

- Press  or  to scroll through settings.
- Press and hold  or  to quickly scroll through numbers.




Adjusting the Date and Time

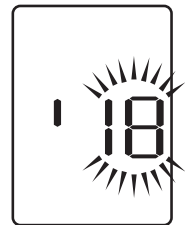
Step 1 Setting Daylight Savings Time (DST)

Press  and 'On' will flash on the screen. Press  or  to turn 'On' or 'OFF' daylight savings time function. Press  to confirm your selection and progress to the next step.






Step 2 Setting the Year

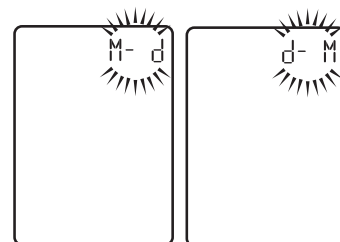
Press  or  until the correct year appears. After setting the year, press  to confirm your selection and progress to the next step.



Step 3 Setting the Date Format

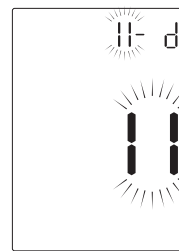
The date can either be displayed in month/day format (M-d) or day/month format (d-M).

Press  or  to select preferred format, press  to confirm your selection and progress to the next step.



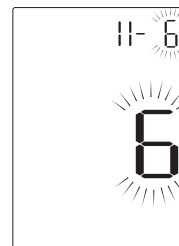
Step 4 Setting the Month

A number indicating the month will be flashing on the screen. Press or until the correct month appears. Press to confirm your selection and progress to the next step.



Step 5 Setting the Day

A number indicating the day will be flashing on the screen. Press or until the correct day appears. Press to confirm your selection and progress to the next step.

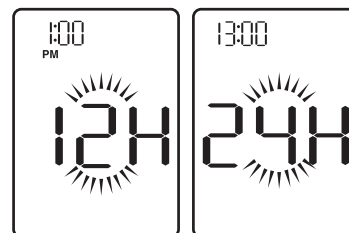


NOTE:

- Steps 4 and 5 are reversed for d-M date format.

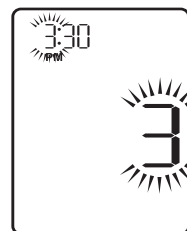
Step 6 Setting the Time Format

The meter can be set in the 12-hour (AM/PM) or 24-hour format. Press or to select a format. The AM/PM is not displayed in the 24-hour format. Press to confirm your selection and progress to the next step.



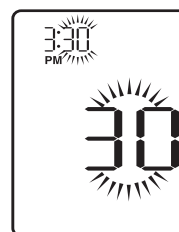
Step 7 Setting the Hour

Press or until the correct hour appears, then press to confirm your selection and progress to the next step.



Step 8 Setting the Minute

Press or until the correct minute appears, then press to confirm your selection and return to the main set up screen.



Setting the Sound On/Off

Step 1

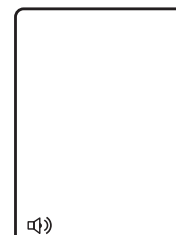
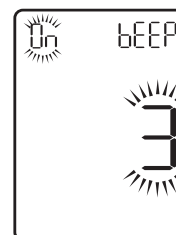
Press and then . 'On' and a number will flash on the screen. Press or to select the sound level. Press to confirm your selection.

A setting of '1' is the quietest and '3' the loudest. When set to '0' the sound will be turned off and will appear on the screen.

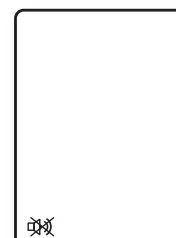
If turned 'On', the beep will sound:

- When you press and/or or to turn on the meter or to set the alarm.
- When the test strip is inserted in the meter
- When the blood sample or control solution sample is absorbed into the test strip, and the test starts.
- When the test result is displayed.
- At the time of a preset alarm.
- Disinfection timer function is in use.

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



Audible Beep ON



Audible Beep OFF

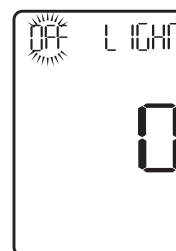
NOTE:

- Symbol is displayed only when the sound is set to 'OFF'.






Setting the Backlight

Press and then . The current setting will be flashing on the screen. Press or to select the backlight 'On' duration (0, 5, 10, 15 or 100), then press to confirm your selection.




- A setting of '0' means the backlight is off.
- A setting of '100' means the backlight will always be on.
- A setting of '5', '10' or '15' means the backlight will stay on for 5, 10 or 15 seconds respectively.






Setting the Alarm(s)

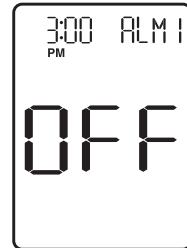
Five customizable alarms can be set. Press  and then , then the current setting will be flashing on the screen. Press  or  to select 'On' or 'OFF' for the alarm, then press  to confirm your selection.

If 'OFF' is selected, you will return to the main alarm screen.




If 'On' is selected, a number for "hour" will flash on the screen. Press  or  until the correct hour appears, then press  to confirm your selection.

A number for minutes will now be flashing on the screen. Press  or  until the correct minutes appear, then press  to confirm your selection. Repeat these steps to set any additional alarms.

Once complete, press and hold  for three seconds to save your settings and turn the meter off.



NOTE:

- The AM/PM option can be verified when you press  or  to select the appropriate time.
- When any of the five alarms is set,  will always be displayed.
- The alarms will not beep if the meter sound is set to 'OFF'.

Performing a Control Solution Test

The Assure Titanium Blood Glucose Meter has a 24-hour QC Lockout feature which helps ensure that proper QC testing is conducted. To release the QC lockout, testing with both Assure Control Level 2 and Level 3 Control Solutions is required. The Assure Control-Control Solutions contain known amounts of glucose and are used to check that the meter and test strips are working properly.

Assure Control-Control Solutions are necessary for control solution testing, but not included. Assure Control-Control Solutions can be ordered separately through your local sales representative or distributor. For detailed storage and usage information, refer to the Assure Control-Control Solutions package insert.



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

Before using a new meter or new vial of test strips, and every 24 hours to avoid QC lockout, conduct a control solution test using Assure Control-Control Solutions.

CAUTION:

- Keep the control solution away from skin and eyes. Contact may cause irritation.
- **Do not** drink the control solution.

NOTE:

- Use Assure Control-Control Solutions only.
- Check the expiration dates printed on the bottle. When you first open a control solution bottle, record the open date in the space provided on the label. **Do not** use control solutions beyond their discard date (date opened plus three months (90 days)).
- Make sure your meter, test strips and control solutions are at room temperature for 30 minutes before testing. Control solution tests must be done at 46-86°F (8-30°C).
- For accurate test results, allow the Assure Titanium Blood Glucose Meter, Assure Titanium Blood Glucose Test Strips and Assure Control-Control Solution to adjust to the surrounding temperature 46-86°F (8-30°C) and relative humidity 10 to 90% for 30 minutes before testing blood glucose.
- Close the control solution bottle tightly and store at a temperature of 36-86°F (2-30°C).

Use Assure Control-Control Solution When:

- You want to practice the test procedure, instead of using blood.
- You use the meter for the first time.
- You have opened a new vial of test strips, and with every new lot of test strips.
- Every 24 hours to release QC Lockout.
- You suspect the meter or test strips are not working properly.
- The meter has been dropped or damaged.
- The test results do not reflect how the patient feels.
- The results appear to be abnormally high, low, or are not consistent with the patient's clinical symptoms.


Assure Control-Control Solution Testing

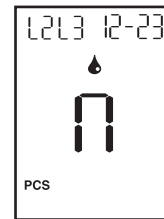
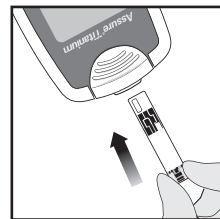
NOTE:

- To release QC Lockout: When PCS appears on the screen when the meter is turned on, control solution tests have to be performed first with both Level 2 and Level 3 control solutions. After inserting the test strip, use the ◀ and ▶ buttons to select the appropriate control solution level.
- To perform a control solution test at any other time and to reset the QC Lockout timer: When PCS does not appear on the screen, insert a test strip and then press and hold the center button for one second. The meter will be ready for a control solution test. Use the ◀ and ▶ buttons to select the appropriate control solution level.
- Control solution can be run at any time and the meter will auto-detect it as a control solution test. However, you must follow the above steps in order to reset the QC Lockout timer.
- After selecting control solution level and performing control solution test, the control solution level associated with that test cannot be changed.

Step 1

Remove an Assure Titanium Blood Glucose Test Strip from the test strip vial and close the vial. Gently push the test strip into the meter's test strip port, with the contact bars facing up, until the meter beeps.

Be careful not to bend the test strip while pushing it in. The  symbol will be displayed on the screen.



Step 2


Gently invert the Assure Control-Control Solution bottle several times before each test.

Step 3

Remove the cap and discard the first one or two drops. Apply one drop of control solution to the control solution cap.



Step 4

After the  symbol appears on the screen, touch the edge of the test strip to the control solution until the meter beeps.



NOTE:

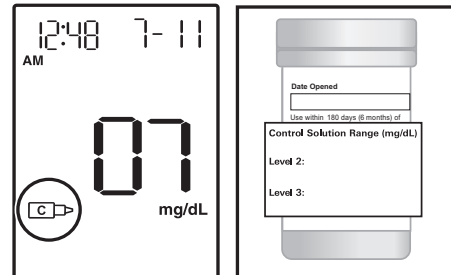
- The meter will switch off if the control solution sample is not applied within five minutes of the symbol appearing on the screen. If the meter turns off, remove the test strip, reinsert it, and start from Step 2.

Step 5

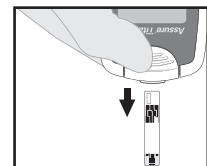
A test result will appear after the meter counts down from 7 to 1. The meter will automatically detect the test sample as a control solution and mark the test result as a control solution test.

Control solution test results are stored in the meter's memory.

Compare your control test results with the appropriate control solution range printed on the test strip vial. If the result falls within the specified range, you may use the meter and test strips to test the patient's blood sample.

**Step 6**

Remove the used test strip from the meter's test strip port. The meter will turn off automatically. Used test strips should be discarded safely in disposable containers.

**CAUTION:**

- The ranges printed on the test strip vial are for Assure Control-Control Solutions only. They do not have any connection to the patient's blood glucose level.
- If the meter does not automatically detect and mark the control solution test result as a control solution test, do not use the meter and contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.

Comparing the Control Solution Test Results

The test result of each control solution test should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur due to the following factors:

Situations	Actions
<ul style="list-style-type: none"> • If the control solution bottle was not gently inverted several times • If the meter, test strip or the control solution were exposed to high or low temperatures • If the test strip is past the expiration date • If the first one or two drops of the control solution were not discarded or the top of the cap was not wiped clean • If the meter is not functioning properly 	Repeat the control solution test.
<ul style="list-style-type: none"> • If the control solution is past the expiration date printed on the bottle • If the control solution is past its discard date (the date the bottle was opened plus three months (90 days) • If the control solution is contaminated 	Discard the used control solution and repeat the test using a new bottle of control solution.

NOTE:

- If results continue to fall outside the range printed on the test strip vial, the test strip and meter may not be working properly. Do not use your system and contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.

PCS (QC Lockout)

PCS (QC lockout) is a feature that will lock out users, once every 24 hours, from performing a blood glucose test until a control solution test is performed to confirm that meter yields correct results.

NOTE:

- When **PCS** appears on the screen when the meter is turned on, control solution tests must be performed first with both Level 2 and Level 3 control solutions as per steps on page 13 in the "Performing a Control Solution" section. The **PCS** symbol stays on the screen until both Level 2 and Level 3 control solution tests have been performed.
- If a blood glucose test is performed without conducting control solution tests, E0 will appear until control solution testing is conducted.

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 biohazardous, 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 blood glucose 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. See page 20 in the "Cleaning and Disinfecting" section in this manual.

For more information, please refer to the following guidelines:

1. CDC: "Biosafety in Microbiological and Biomedical Laboratories (BMBL)" www.cdc.gov/labs/BMBL.html
2. CLSI. M29-A3: Protection of laboratory workers from occupationally acquired infections. (Ed. 4) Wayne, PA: Clinical Laboratory Standards Institute.

Preparing the Lancing Device

You will need a lancing device in order to collect a blood sample. Only an auto-disabling, single use lancing device should be used. The auto-disabling, single use lancing device can be purchased from your sales representative or distributor.

Please read the instructions provided by the lancing device manufacturer before using their lancing device.

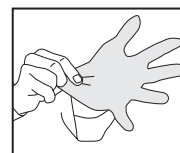
Step 1

Users as well as patients should wash hands and the sample site with soap and warm water. Rinse and dry thoroughly. This is important because contaminants on the skin may affect results.

If alcohol wipes are used, make sure the area is dry before taking a blood sample.


Residual alcohol may lead to inaccurate readings.

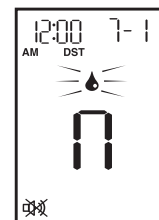
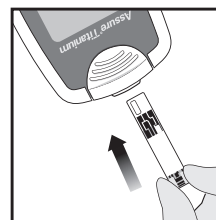
Wear appropriate protective gear such as disposable gloves.



Preparing the Meter and Test Strip

Step 2

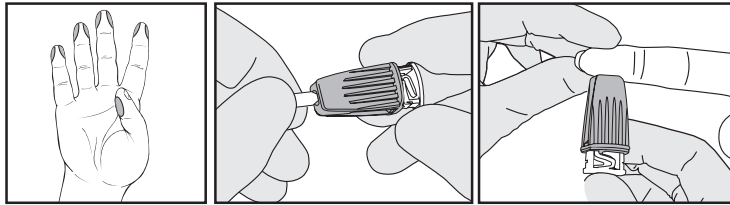
Remove an Assure Titanium Blood Glucose Test Strip from the test strip vial and close the vial. Push the test strip gently into the meter's test strip port, with the contact bars facing upwards, until the meter automatically turns on and the  symbol appears.



Obtaining and Applying the Blood Sample


Step 3

Obtain a blood sample using a lancing device. Place the lancing device against the fingertip and activate. The best puncture sites are areas on the middle or ring fingers.



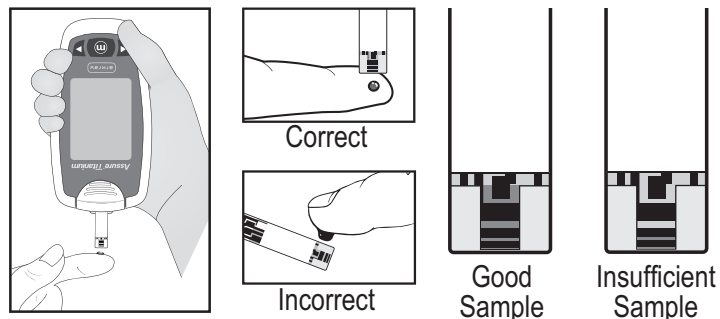
Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 μ L is needed to fill the confirmation window.

Step 4

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

If the confirmation window is not filled because of abnormal viscosity or insufficient volume, an E3 message may appear.

It is recommended that the application of the blood sample to the test strip be performed vertical to the sample site as shown in the diagram.



SECTION

E

Step 5

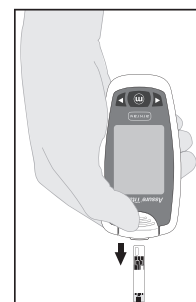
The test result will appear after the meter counts down from 7 to 1. The result will be automatically stored in the meter's memory.

NOTE:

- Results stored in the memory are not related to a specific patient.

Step 6

Point the meter downward to discard the test strip safely in a disposable container by sliding the Test Strip Ejector on the top of the meter. Once the test strip is removed, the meter will automatically turn off immediately.



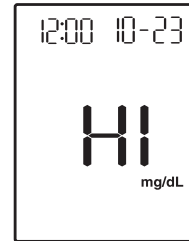
'HI' and 'Lo' Messages

The meter displays results between 10-600 mg/dL.

'HI' Message

'HI' appears when the blood glucose level is greater than 600 mg/dL and indicates severe hyperglycemia (much higher than normal glucose levels).

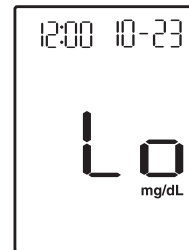
If 'HI' is displayed again upon retesting, please follow your standard of care practice or contact your emergency response team immediately.



'Lo' Message

'Lo' appears when a test result is less than 10 mg/dL and indicates severe hypoglycemia (very low glucose levels).

If 'Lo' is displayed again upon retesting, please follow your standard of care practice or contact your emergency response team immediately.



NOTE:

- If HI or Lo results are displayed but are not consistent with the patient's clinical symptoms, please contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.

Meter Memory


The Assure Titanium Blood Glucose Meter can save up to 1,000 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.



NOTE:

- Meter memory can be used to check the results when they need to be verified, such as when the results cannot be immediately recorded. However, we **do not** recommend using the memory feature as results stored in the memory are not related to a specific patient.

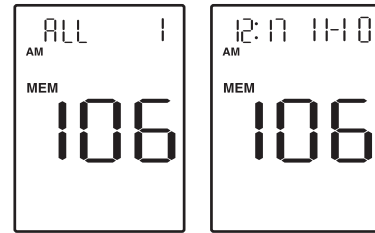
Viewing Test Results

Step 1


Press  to turn the meter on. 'ALL' will be displayed on the screen with the total number of results recorded through that point in time.


Press  or  to choose between 'ALL' or control solution 'CNTL' measurement results.

'MEM' will be shown on the left of the screen above the result. This means it is a stored result.



Step 2

Press  after selecting either 'ALL' or 'CNTL' as appropriate.

Then press  to scroll through the test results, starting from the most recent and ending with the oldest.

The test date and the recorded time will display at the top of the screen. The display alternates between 'date and time' and 'ALL' / 'CNTL' with the test result number.

NOTE:

- When viewing 'ALL' test results, the most recent test result will appear.
- The control solution test results are saved separately in the 'CNTL' menu and are not included under 'ALL'.

Step 3

Press  to return to the results seen previously.

After reviewing the stored test results, press  for three seconds to turn off the meter.

Cleaning and Disinfecting

- To minimize the risk of transmission of bloodborne pathogens, the cleaning and disinfection procedure should be performed as recommended in the instructions below.
- After disinfection, users should remove gloves and wash hands before testing the next patient.
- The cleaning procedure is needed to clean dirt as well as blood and other body fluids on the exterior of the meter before performing the disinfection procedure.
- The disinfection procedure is needed to prevent transmission of bloodborne pathogens.
- The meter should be cleaned and disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.

NOTE:

- The robustness studies were designed to simulate three years of multiple-patient use.
- We recommend cleaning and disinfecting the meter after the use on each patient. We have validated a total of 10,950 cleaning and disinfecting cycles (10,950 cleaning and 10,950 disinfection cycles) to represent the cleaning and disinfecting over the use life of the Assure Titanium Blood Glucose Meter. 1 cleaning and 1 disinfection cycle per each use * 10 uses per day * 365 days per year * 3 years = 10,950 cleaning and 10,950 disinfection cycles.

- We have validated **PDI® Super Sani-Cloth® Germicidal Disposable Wipe** for disinfecting the Assure Titanium Blood Glucose Meter. It has been shown to be safe for use with the meter. This disinfectant is available commercially in towelette form. In addition to the Assure Titanium Blood Glucose Monitoring System instruction, please read the instructions provided by the manufacturer of **PDI® Super Sani-Cloth® Germicidal Disposable Wipe** before using it.
- Only one cleaning/disinfecting solution should be used on the device for the life of the device as the effect of using more than one cleaner/disinfectant interchangeably has not been evaluated.

SECTION

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Name	PDI® Super Sani-Cloth® Germicidal Disposable Wipe
Manufacturer	Professional Disposables International, Inc. Phone: 845-365-1700 Website: www.pdihc.com
EPA registration	9480-4
Active ingredients	n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethylethylbenzyl ammonium chlorides: 0.25% n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides: 0.25% Isopropyl Alcohol: 55.0%
Contact time	2 minutes



- Only the disinfectant product listed within this user manual may be used on the Assure Titanium Blood Glucose Meter.

NOTE:

- The disinfectant product can be purchased from your medical distributor or directly from the manufacturer.
- It can also be purchased from online retailers (e.g., Amazon.com).

Infection Prevention during Blood Glucose Monitoring and Insulin Administration
<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>

Cleaning and Disinfecting Procedures

CAUTION

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

NOTE:

- Two disposable wipes will be needed for each cleaning and disinfecting procedure; one wipe for cleaning, and a second wipe for disinfecting.

Cleaning

Step 1

Secure the data port cover to prevent cleaning/disinfectant fluid entering the meter.

Step 2

Wear appropriate protective gear such as disposable gloves.

Step 3

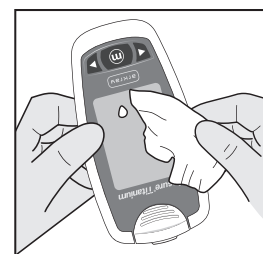
Open the cap of the disinfectant container and pull out one towelette and close the cap.

Step 4

Hold the meter with the test strip port facing downward to prevent liquid from entering the meter during cleaning and disinfection procedure.

Wipe the entire surface of the meter three times horizontally and three times vertically using one towelette 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.



Step 5

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

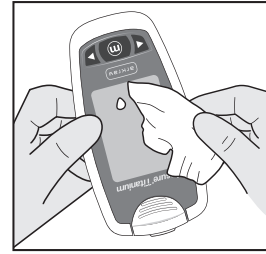
Disinfecting

Step 6

Hold the meter with the test strip port facing downward to prevent liquid from entering the meter during cleaning and disinfection procedure.

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

Continue to carefully wipe around the test strip port with test strip port facing downward to prevent liquid from entering the meter.



CAUTION

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

Step 7

The Disinfectant Countdown Timer (dct) may be used to monitor disinfectant timing.

Press and hold ◀ or ▶ for three seconds to activate the dct.

Press ◀ or ▶ to select the appropriate timer (1, 2, 3, 4 or 5 minutes). For PDI® Super Sani-Cloth® Germicidal Disposable Wipes, set the timer for 2 minutes. Press (m) to start the countdown timer. The meter will beep two times at the end of the countdown and shut off automatically.

Step 8

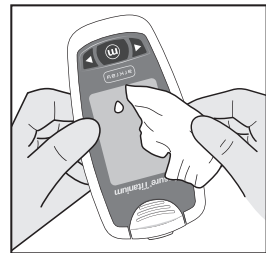
Dispose of the used towelette in a trash bin.

Step 9

Allow exteriors to remain wet for the corresponding contact time for the disinfectant. See page 20.

Step 10

Dry the meter with a clean paper towel.



After disinfection, dispose of user's gloves and wash hands before proceeding to the next patient.

NOTE:








- If any deterioration signs appear after cleaning or disinfecting, please stop using the system and contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.
- If the inscriptions on the exterior of the meter have been removed.
- If the color of the meter has changed or faded.
- If cracks or roughness develop on the meter.
- If a part of the segment on the meter display does not flash.
- Physical signs of deterioration include:
 - Cloudy or cracked meter lens.
 - Cracked meter case.
 - Debris under meter lens.
 - Meter display missing components.
 - Serial number or other back label information is unreadable.
 - The product identification (logo) is unreadable.
- Performance signs of deterioration include:
 - Meter buttons not working properly.
 - Meter doesn't register test strip, control solution or blood sample.
 - Meter turns off unexpectedly.






CAUTION

- Please note only the PDI® Super Sani-Cloth® Germicidal Disposable Wipe has been tested with the Assure Titanium Blood Glucose Meter at the time of printing this manual. Contact the manufacturer or distributor for recent updates.
- Never immerse the meter or hold it under running water as this will cause damage to the meter.


Troubleshooting

Troubleshooting Messages

Message	What it means	What to do
	Battery has been replaced.	Press  to enter set-up mode and verify date and time are correct.
	Measurement of blood sample during QC lock.	Remove the used test strip and perform control solution test with a new test strip.
	<ul style="list-style-type: none"> The contact bars of the test strip are dirty. A used test strip is inserted into the meter. A different type of test strip is inserted into the meter. 	Repeat the test with a new Assure Titanium Blood Glucose Test Strip.
	There is a problem inside the meter.	Contact ARKRAY Technical Customer Service at 800.818.8877 (24 hours a day, 7 days a week).
	<ul style="list-style-type: none"> The test strip touched blood again after the test started. The test strip inside the meter moved during testing. The blood sample was not correctly drawn into the test strip. There was not enough blood added to the test strip. 	Repeat the test with a new test strip.
	The battery is almost dead. Test results and changes made in the setup mode are not stored in the memory.	Replace the battery.

Message	What it means	What to do
	<ul style="list-style-type: none"> An abnormal sample has been detected. The contact bars of the test strip are dirty An incorrect sample type was used. 	Use a new test strip. Repeat measurement with fresh capillary whole blood sample drawn from the fingertip.
	<ul style="list-style-type: none"> The operating environment is not correct for testing. There was a sharp change in the surrounding temperature. 	Leave the meter and test strips somewhere where the temperature is 46-104°F (8-40°C) and relative humidity is 10-9% for at least 30 minutes. Remove the test strip and insert a new test strip back into the test strip port. Test the patient's/ resident's blood glucose only after the error and the thermometer symbol has disappeared. If the error still appears on the screen, contact ARKRAY Technical Customer Service at 800.818.8877 (24 hours a day, 7 days a week).
	There is a problem with the measurement unit of the meter.	Contact ARKRAY Technical Customer Service at 800.818.8877 (24 hours a day, 7 days a week).
	There is a problem with the communications unit of the meter.	Contact ARKRAY Technical Customer Service at 800.818.8877 (24 hours a day, 7 days a week).
	The meter could not detect the surrounding temperature correctly.	Contact ARKRAY Technical Customer Service at 800.818.8877 (24 hours a day, 7 days a week).

NOTE

- If the thermometer symbol () appears, the surrounding temperature is too high or too low, or the meter has not adjusted to the surrounding temperature. In this case, leave the meter and the test strips where the temperature is 46-104°F (8-40°C) and a relative humidity of 10-90% for at least 30 minutes. Test a blood sample only after the meter adapts to the environment for more than 30 minutes and the 'thermometer' symbol disappears.
- If any of the error messages persist, please contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.

General Troubleshooting

The display is blank even after inserting a test strip.

- Check that 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 (Assure Titanium Blood Glucose Test Strip).
- Check if the batteries are inserted correctly.
- Replace the batteries.

The test does not start even after applying the blood sample on the test strip.

- Check if the confirmation window is filled adequately.
- Repeat the test after inserting a new test strip.

The test result does not match the way the patient feels.

- Check to make sure the test strip has not expired.
- Repeat the test after inserting a new test strip.
- Perform control solution test.

NOTE

- If a problem is not resolved, please contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.

Performance Characteristics

The performance of the Assure Titanium Blood Glucose Monitoring System has been evaluated in laboratory and clinical tests.

Information regarding the performance characteristics below is intended for healthcare professionals.

Accuracy

The Assure Titanium Blood Glucose Monitoring System is calibrated to yield results equivalent to plasma glucose concentrations.

In total, capillary blood samples from 396 patients were measured and the results were compared to the YSI Model 2300 Glucose Analyzer, a lab instrument (comparator method). The tables below show differences in glucose values between the Assure Titanium Blood Glucose Meter and the YSI method.

	Results obtained by healthcare professionals	
	Nursing/Skilled Nursing Facility	Endocrinology Clinic
Slope	0.98	0.98
Correlating 'r'	0.99	0.99
Intercept	3.24	2.83
Number of Samples	130	266
Range Tested	29.0 - 405.5 mg/dL	43.7 - 492.5 mg/dL

The performance of this device has not been evaluated in pediatric populations.

Nursing/Skilled Nursing Facility

Accuracy results for glucose concentrations <75 mg/dL

Difference range between the true blood glucose level and the Assure Titanium Blood Glucose Monitoring System result	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
The percent (and number) of samples for which the difference between the Assure Titanium Blood Glucose Meter and the YSI comparator method were within the difference range shown in the top row	1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	0/1 (0.0%)

Accuracy results for glucose concentrations ≥75 mg/dL

Difference range between the true blood glucose level and the Assure Titanium Blood Glucose Monitoring System result	Within ± 5%	Within ± 10%	Within ± 12%	Within ± 15%	Within ± 20%	Exceeds ± 20%
The percent (and number) of samples for which the difference between the Assure Titanium Blood Glucose Meter and the YSI comparator method were within the difference range shown in the top row	80/129 (62.0%)	122/129 (94.6%)	125/129 (96.9%)	128/129 (99.2%)	129/129 (100%)	0/129 (0.0%)

SECTION

G

Endocrinology Clinic

Accuracy results for glucose concentrations <75 mg/dL

Difference range between the true blood glucose level and the Assure Titanium Blood Glucose Monitoring System result	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
The percent (and number) of samples for which the difference between the Assure Titanium Blood Glucose Meter and the YSI comparator method were within the difference range shown in the top row	17/26 (65.4%)	25/26 (96.2%)	26/26 (100%)	26/26 (100%)	0/26 (0.0%)

Accuracy results for glucose concentrations ≥75 mg/dL

Difference range between the true blood glucose level and the Assure Titanium Blood Glucose Monitoring System result	Within ± 5%	Within ± 10%	Within ± 12%	Within ± 15%	Within ± 20%	Exceeds ± 20%
The percent (and number) of samples for which the difference between the Assure Titanium Blood Glucose Meter and the YSI comparator method were within the difference range shown in the top row	163/240 (67.9%)	224/240 (93.3%)	230/240 (95.8%)	235/240 (97.9%)	240/240 (100%)	0/240 (0.0%)

The tables above show that 390 samples (27 + 363) of the 396 samples met the defined acceptance criteria.

NOTE

- When glucose meter results are compared to the laboratory results, differences below 75 mg/dL are expressed in mg/dL, while those greater than or equal to 75 mg/dL are expressed in percent.

Precision

Precision studies were performed in a laboratory using the Assure Titanium Blood Glucose Monitoring System.

Within Run Precision		
Average Blood Glucose Level	Test Strip Lot	%CV
30 – 50 mg/dL	1	2.6
	2	2.9
	3	2.4
51 – 110 mg/dL	1	2.1
	2	2.1
	3	2.4
111 – 150 mg/dL	1	2.2
	2	2.0
	3	2.3
151 – 250 mg/dL	1	3.1
	2	1.9
	3	2.4
251 – 400 mg/dL	1	3.1
	2	2.3
	3	2.7

Intermediate Precision	
Average Control Solution Glucose Level	%CV
42.4 mg/dL	1.9
87.0 mg/dL	1.6
129.3 mg/dL	1.4
254.7 mg/dL	1.5
360.6 mg/dL	2.1

Warranty Information

Warranty

The manufacturer warrants that the Assure Titanium Blood Glucose Meter shall be free of defects in material and workmanship in normal use for a period of three 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 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: 800.818.8877, 24 hours a day, 7 days a week.

Meters returned without this authorization will not be accepted.

Name of facility: _____

In-service Training and Certification

Assure Titanium Blood Glucose Monitoring System

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

1. Familiarization with components of the Assure Titanium 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 Test 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
---	--	--

*Actual blood sampling is not required.

2. Describe or Demonstrate:

Initial Meter Set-Up	
<input type="checkbox"/> Lot Number	<input type="checkbox"/> Time Format
<input type="checkbox"/> Expiration Date	<input type="checkbox"/> Date Format
<input type="checkbox"/> Storage	<input type="checkbox"/> Audible Sound
	<input type="checkbox"/> Backlight
	<input type="checkbox"/> Alarms

Instructor Name (Print)

Operator-Trainee Name (Print)

Date

Instructor Name (Signature)

Operator-Trainee Name (Signature)

Date

3. Additional Training In-service Completion:

<ul style="list-style-type: none"><input type="checkbox"/> Assure ID® Safety Pen Needle Training<input type="checkbox"/> Discharge Program Training<input type="checkbox"/> Assure PT Care PT/INR Monitoring System

Name of facility: _____

Competency Checklist

Assure Titanium Blood Glucose Monitoring System

Operator _____

Date _____

Trainer _____

The Trainer should observe the Operator performing the following tasks:

- Follow facility protocol for quality control testing..... YES NO
- 1. Change battery. YES NO
- 2. Select and prepare the fingerstick site correctly..... YES NO
- 3. Use safety lancet device correctly.* YES NO
- 4. Dispose of safety lancet correctly. YES NO
- 5. Insert test strip into meter correctly. YES NO
- 6. Apply blood to sample-application tip correctly. YES NO
- 7. Record result correctly. YES NO
- 8. Identify when to repeat test or check result with a laboratory test. YES NO
- 9. Perform control solution test correctly..... YES NO
- 10. Access control solution test in memory. YES NO
- 11. Clean/disinfect meter correctly..... YES NO

** Actual blood sampling is not required.*

Did the Operator perform each task correctly? YES NO

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

Name of facility: _____

Self-Test

Assure Titanium Blood Glucose Monitoring System

The following is a multiple choice self-test that is designed to test your proficiency in using the Assure Titanium Blood Glucose Monitoring System. 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.

1. The Assure Titanium Blood Glucose Meter stores up to _____ tests in the memory.

- a. 200
- b. 50
- c. 500
- d. 1,000

2. The Assure Titanium Blood Glucose Test Strips

- a. May be reused.
- b. Can be used with other meters besides the Assure Titanium Blood Glucose Monitoring System.
- c. Are sensitive to light, moisture and humidity.
- d. Has a confirmation window used to determine if a sufficient amount of blood sample has been applied.

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 the fingertip.
- d. You should use the same site selection of the fingertip each time.

4. When performing a test with control solutions

- a. Any brand of control solutions may be used.
- b. The test strip must be in the meter before solutions are applied.
- c. A clean tissue or cloth may be used to wipe the first 1 or 2 drops of control solution from the top of the cap.
- d. Compare the result displayed on the meter to the range printed on the test strip bottle.

5. Assure Titanium Control Solutions

- a. Are used 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 test strips have been exposed to extremes in temperature, light or humidity.

6. When applying blood to the Assure Titanium Blood Glucose Test Strips

- a. Smear the blood sample.
- b. Apply it to the narrow end of the test strip until the meter beeps.
- c. The test result will appear after the meter counts down from 7 to 1.
- d. You may apply a second blood drop if meter does not start after adding the first drop.

7. The Assure Titanium Blood Glucose Meter can be used with

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

8. The Assure Titanium Blood Glucose Monitoring System should be cleaned and disinfected between patient tests to avoid cross-contamination.

- TRUE FALSE

9. Nurses who use the Assure Titanium Blood Glucose Monitoring System 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.

10. The Assure Titanium Blood Glucose Meter uses 2 AAA batteries.

- TRUE FALSE

Name: _____

Date: _____

Score: _____

Self-Test Key

Assure Titanium Blood Glucose Monitoring System

Answer Key

- | | |
|------------|---------------|
| 1. d | 6. b, c |
| 2. c, d | 7. a |
| 3. b, c | 8. True |
| 4. b, c, d | 9. a, b, c, d |
| 5. b, c, d | 10. True |

Name of facility: _____

Meter Tracking Form

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

Sample Policies 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.

Policy: Infection Control

Purpose

The purpose of this guide is to ensure that correct cleaning and disinfecting of the Assure Titanium® Blood Glucose Monitoring System is followed to prevent the potential transmission of infectious organisms through the Assure Titanium 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 Titanium 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 Titanium Meter
- Assure Titanium Test Strips
- Single use, auto-disabling 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 Titanium Meter (detailed in the "Performing a Blood Glucose Test" section).

3. Dispose of used test strip and safety lancet

Dispose of the used Assure Titanium test strip and safety 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.

Procedure: Cleaning and Disinfecting

CAUTION

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

NOTE:

- Two disposable wipes will be needed for each cleaning and disinfecting procedure; one wipe for cleaning and a second wipe for disinfecting.

Cleaning

Step 1

Secure the data port cover to prevent cleaning/disinfectant fluid entering the meter.

Step 2

Wear appropriate protective gear such as disposable gloves.

Step 3

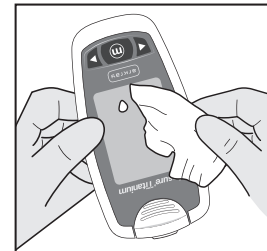
Open the cap of the disinfectant container and pull out one towelette and close the cap.

Step 4

Hold the meter with the test strip port facing downward to prevent liquid from entering the meter during the disinfection procedure.

Wipe the entire surface of the meter three times horizontally and three times vertically using one towelette 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.



Step 5

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

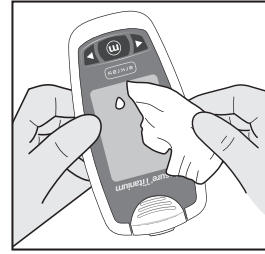
Disinfecting

Step 6

Remove a new towelette from the container.

Hold the meter with the test strip port facing downward to prevent liquid from entering the meter during cleaning and disinfection procedure.

Continue to carefully wipe around the test strip port with test strip port facing downward to prevent liquid from entering the meter.



Step 7

The Disinfectant Countdown Timer (dct) may be used to monitor disinfectant timing.

Press and hold ◀ or ▶ for three seconds to activate the dct.

Press ◀ or ▶ to select the appropriate timer (1, 2, 3, 4 or 5 minutes). For PDI® Super Sani-Cloth® Germicidal Disposable Wipes, set the timer for 2 minutes. Press Ⓜ to start the countdown timer. The meter will beep two times at the end of the countdown and shut off automatically.

Step 8

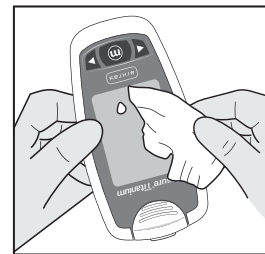
Dispose of the used towelette in a trash bin.

Step 9

Allow exteriors to remain wet for the corresponding contact time for the disinfectant. See page 20.

Step 10

Dry the meter with a clean paper towel.



After disinfection, dispose of user's gloves and wash hands before proceeding to the next patient.

CAUTION

- Please note only the PDI® Super Sani-Cloth® Germicidal Disposable Wipe has been tested with the Assure Titanium Blood Glucose Meter at the time of printing this manual. Contact the manufacturer or distributor for recent updates.
- Never immerse the meter or hold it under running water as this will cause damage to the meter.

NOTE:

- If any deterioration signs appear after cleaning or disinfecting, please stop using the system and contact ARKRAY Technical Customer Service at 800.818.8877 at any time.
- If the inscriptions on the exterior of the meter have been removed.
- If the color of the meter has changed or faded.
- If cracks or roughness develop on the meter.
- If a part of the segment on the meter display does not flash.
- Physical signs of deterioration include:
 - Cloudy or cracked meter lens.
 - Cracked meter case.
 - Debris under meter lens.
 - Meter display missing components.
 - Serial number or other back label information is unreadable.
 - The product identification (logo) is unreadable.
- Performance signs of deterioration include:
 - Meter buttons not working properly.
 - Meter doesn't register test strip, control solution or blood sample.
 - Meter turns off unexpectedly.

More information is available at:

www.cdc.gov/injection-safety/hcp/infection-control/

Policy: Quality Control and Assurance Testing

The Assure Titanium Blood Glucose Meter has a 24-hour QC Lockout feature which helps ensure that proper QC testing is conducted. To release the QC lockout, testing with both Assure Control Level 2 and Level 3 Control Solutions is required. The Assure Control-Control Solutions contain known amounts of glucose and are used to check that the meter and test strips are working properly.

Assure Control-Control Solutions are necessary for control solution testing, but not included. Assure Control-Control Solutions can be ordered separately through your local sales representative or distributor. For detailed storage and usage information, refer to the Assure Control-Control Solutions package insert.



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

Before using a new meter or new vial of test strips, and every 24 hours to avoid QC lockout, conduct a control solution test using Assure Control-Control Solutions.

CAUTION:

- Keep the control solution away from skin and eyes. Contact may cause irritation.
- **Do not** drink the control solution.

NOTE:

- Use Assure Control-Control Solutions only.
- Check the expiration dates printed on the bottle. When you first open a control solution bottle, record the open date in the space provided on the label. **Do not** use control solutions beyond their discard date (date opened plus three months (90 days)).
- Make sure your meter, test strips and control solutions are at room temperature for 30 minutes before testing. Control solution tests must be done at 46-86°F (8-30°C).
- For accurate test results, allow the Assure Titanium Blood Glucose Meter, Assure Titanium Blood Glucose Test Strips and Assure Control-Control Solution to adjust to the surrounding temperature 46-86°F (8-30°C) and relative humidity 10 to 90% for 30 minutes before testing blood glucose.
- Close the control solution bottle tightly and store at a temperature of 36-86°F (2-30°C).

Use Assure Control-Control Solution When:

- You want to practice the test procedure, instead of using blood.
- You use the meter for the first time.
- You have opened a new vial of test strips, and with every new lot of test strips.
- Every 24 hours to release QC Lockout.
- You suspect the meter or test strips are not working properly.
- The meter has been dropped or damaged.
- The test results do not reflect how the patient feels.
- The results appear to be abnormally high, low, or are not consistent with the patient's clinical symptoms.


NOTE:

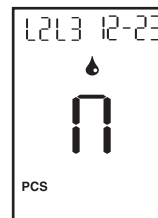
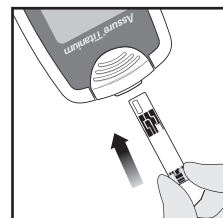
- To release QC Lockout: When PCS appears on the screen when the meter is turned on, control solution tests have to be performed first with both Level 2 and Level 3 control solutions. After inserting the test strip, use the ◀ and ▶ buttons to select the appropriate control solution level.
- To perform a control solution test at any other time and to reset the QC Lockout timer: When PCS does not appear on the screen, insert a test strip and then press and hold the center button for one second. The meter will be ready for a control solution test. Use the ◀ and ▶ buttons to select the appropriate control solution level.
- Control solution can be run at any time and the meter will auto-detect it as a control solution test. However, you must follow the above steps in order to reset the QC Lockout timer.
- After selecting control solution level and performing control solution test, the control solution level associated with that test cannot be changed.

Procedure: Performing a Control Solution Test

Step 1

Remove an Assure Titanium Blood Glucose Test Strip from the test strip vial and close the vial. Gently push the test strip into the meter's test strip port, with the contact bars facing up, until the meter beeps.

Be careful not to bend the test strip while pushing it in. The  symbol will be displayed on the screen.



Step 2


Gently invert the Assure Control-Control Solution bottle several times before each test.

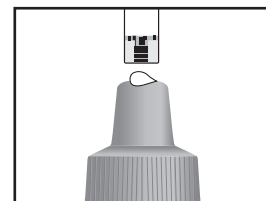
Step 3

Remove the cap and discard the first one or two drops. Apply one drop of control solution to the control solution cap.



Step 4

After the  symbol appears on the screen, touch the edge of the test strip to the control solution until the meter beeps.

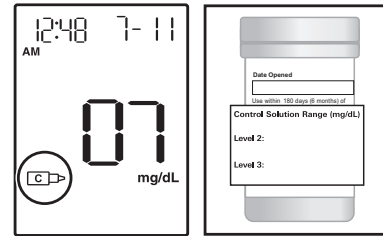


NOTE:

- The meter will switch off if the control solution sample is not applied within five minutes of the symbol appearing on the screen. If the meter turns off, remove the test strip, reinsert it, and start from Step 2.

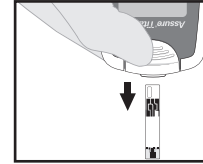
Step 5

A test result will appear after the meter counts down from 7 to 1. The meter will automatically detect the test sample as a control solution and mark the test result as a control solution test. Control solution test results are stored in the meter's memory. Compare your control test results with the appropriate control solution range printed on the test strip vial. If the result falls within the specified range, you may use the meter and test strips to test the patient's blood sample.



Step 6

Remove the used test strip from the meter's test strip port. The meter will turn off automatically. Used test strips should be discarded safely in disposable containers.



CAUTION:

- The ranges printed on the test strip vial are for Assure Control-Control Solutions only. They do not have any connection to the patient's blood glucose level.
- If the meter does not automatically detect and mark the control solution test result as a control solution test, do not use the meter and contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.

Comparing the Control Solution Test Results

The test result of each control solution test should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur due to the following factors:

Situations	Actions
<ul style="list-style-type: none"> • If the control solution bottle was not gently inverted several times • If the meter, test strip or the control solution were exposed to high or low temperatures • If the test strip is past the expiration date • If the first one or two drops of the control solution were not discarded or the top of the cap was not wiped clean • If the meter is not functioning properly 	Repeat the control solution test.
<ul style="list-style-type: none"> • If the control solution is past the expiration date printed on the bottle • If the control solution is past its discard date (the date the bottle was opened plus three months (90 days)) • If the control solution is contaminated 	Discard the used control solution and repeat the test using a new bottle of control solution.

NOTE:

- If results continue to fall outside the range printed on the test strip vial, the test strip and meter may not be working properly. Do not use your system and contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.

PCS (QC Lockout)

PCS (QC lockout) is a feature that will lock out users, once every 24 hours, from performing a blood glucose test until a control solution test is performed to confirm that meter yields correct results.

NOTE:

- When **PCS** appears on the screen when the meter is turned on, control solution tests must be performed first with both Level 2 and Level 3 control solutions as per steps on page 27 in the “Cleaning and Disinfecting” section. The **PCS** symbol stays on the screen until both Level 2 and Level 3 control solution tests have been performed.
- If a blood glucose test is performed without conducting control solution tests, E0 will appear until control solution testing is conducted.

Policy: Monitoring Blood Glucose in Patients

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

- Glucose levels monitored using the Assure Titanium 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 Titanium 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 Titanium Glucose Meter
- Assure Titanium Test Strips
- Safety Lancet
- Gloves
- Alcohol Wipe

Procedure: Performing a Blood Glucose Test

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

1. Verify physician's order
2. Assemble equipment
3. Identify the resident
4. Explain procedure

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 biohazardous, 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 blood glucose 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. See page 20 in the "Cleaning and Disinfecting" section in this manual.

For more information, please refer to the following guidelines:

5. CDC: "Biosafety in Microbiological and Biomedical Laboratories (BMBL)" www.cdc.gov/labs/BMBL.html
6. CLSI. M29-A3: Protection of laboratory workers from occupationally acquired infections. (Ed. 4) Wayne, PA: Clinical Laboratory Standards Institute.

Preparing the Lancing Device

You will need a lancing device in order to collect a blood sample. Only an auto-disabling, single use lancing device should be used. The auto-disabling, single use lancing device can be purchased from your sales representative or distributor.

Please read the instructions provided by the lancing device manufacturer before using their lancing device.

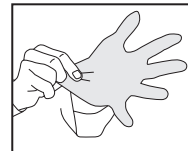
Step 1

Users as well as patients should wash hands and the sample site with soap and warm water. Rinse and dry thoroughly. This is important because contaminants on the skin may affect results.

If alcohol wipes are used, make sure the area is dry before taking a blood sample.


Residual alcohol may lead to inaccurate readings.

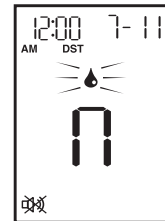
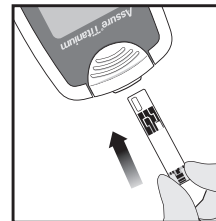
Wear appropriate protective gear such as disposable gloves.



Preparing the Meter and Test Strip

Step 2

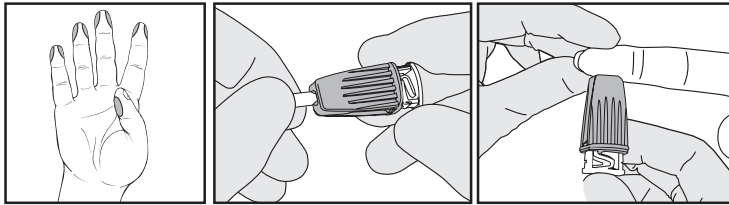
Remove an Assure Titanium Blood Glucose Test Strip from the test strip vial and close the vial. Push the test strip gently into the meter's test strip port, with the contact bars facing upwards, until the meter automatically turns on and the  symbol appears.




Obtaining and Applying the Blood Sample

Step 3

Obtain a blood sample using a lancing device. Place the lancing device against the fingertip and activate. The best puncture sites are areas on the middle or ring fingers. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 μL is needed to fill the confirmation window.

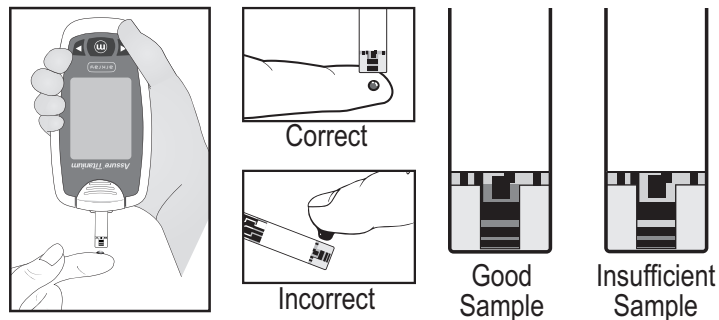


Step 4

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

If the confirmation window is not filled because of abnormal viscosity or insufficient volume, an E3 message may appear.

It is recommended that the application of the blood sample to the test strip be performed vertical to the sample site as shown in the diagram.



Step 5

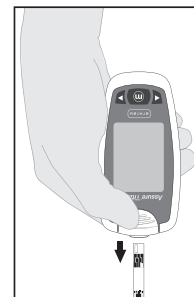
The test result will appear after the meter counts down from 7 to 1. The result will be automatically stored in the meter's memory.

NOTE:

- Results stored in the memory are not related to a specific patient.

Step 6

Point the meter downward to discard the test strip safely in a disposable container by sliding the Test Strip Ejector on the top of the meter. Once the test strip is removed, the meter will automatically turn off immediately.



'HI' and 'Lo' Messages

The meter displays results between 10-600 mg/dL.

'HI' Message

'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 follow your standard of care practice or contact your emergency response team immediately.



'Lo' Message

'Lo' appears when a test result is less than 10 mg/dL and indicates severe hypoglycemia (very low glucose levels).

If 'Lo' is displayed again upon retesting, please follow your standard of care practice or contact your emergency response team immediately.



NOTE:

- If HI or Lo results are displayed but are not consistent with the patient's clinical symptoms, please contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.


Meter Memory

The Assure Titanium Blood Glucose Meter can save up to 1,000 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.

NOTE:

- Meter memory can be used to check the results when they need to be verified, such as when the results cannot be immediately recorded. However, we **do not** recommend using the memory feature as results stored in the memory are not related to a specific patient.

Policy: Maintaining Assure Titanium BGMS

The Assure Titanium Blood Glucose Meter uses two 1.5 V alkaline AAA batteries. Before using the meter, check the battery compartment and insert batteries if empty. When the  appears on the screen 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 lose their charge.

Procedure: Inserting or Replacing the Batteries

Step 1

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

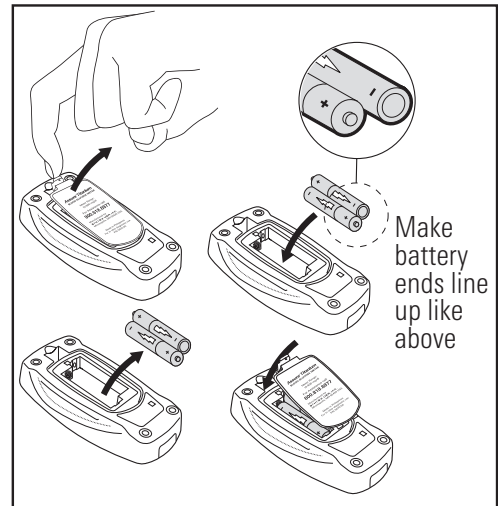
Step 2

Remove the used batteries. Insert two new AAA batteries and ensure the batteries are inserted firmly.

Step 3

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

Dispose of the used batteries according to your local environmental regulations.



NOTE:

- Removing the meter batteries will not affect your stored results. However, meter settings may need to be reset.
- See the “Assure Titanium Blood Glucose Monitoring System (BGMS)” section.

Notes:

Notes:

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