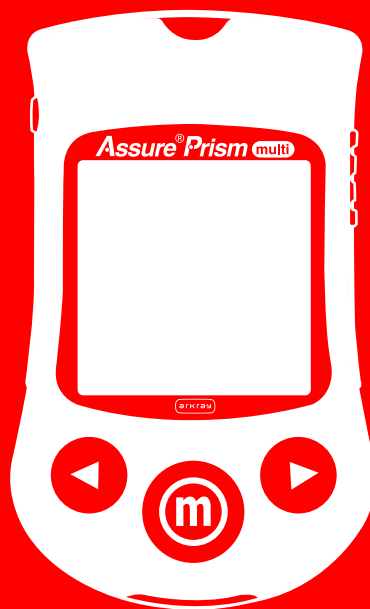


# ASSURE<sup>®</sup> PRISM MULTI

+ BLOOD GLUCOSE MONITORING SYSTEM



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



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



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# Introduction

The Assure® Prism multi Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh and calf.

Alternative site testing should be used only during steady-state blood glucose conditions. The system is intended for use outside the body (*in vitro*) and is intended for multiple-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only to be used with an auto-disabling, single-use lancing device. It is not intended for use on neonates and is not intended for the diagnosis or screening of diabetes.

This comprehensive manual has been designed to be a thorough reference source for the Assure Prism multi Blood Glucose Monitoring System and includes:

- Product operations
- Training and in-services
- Guidelines for policies and procedures
- Quality Assurance/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 certification programs and agencies.

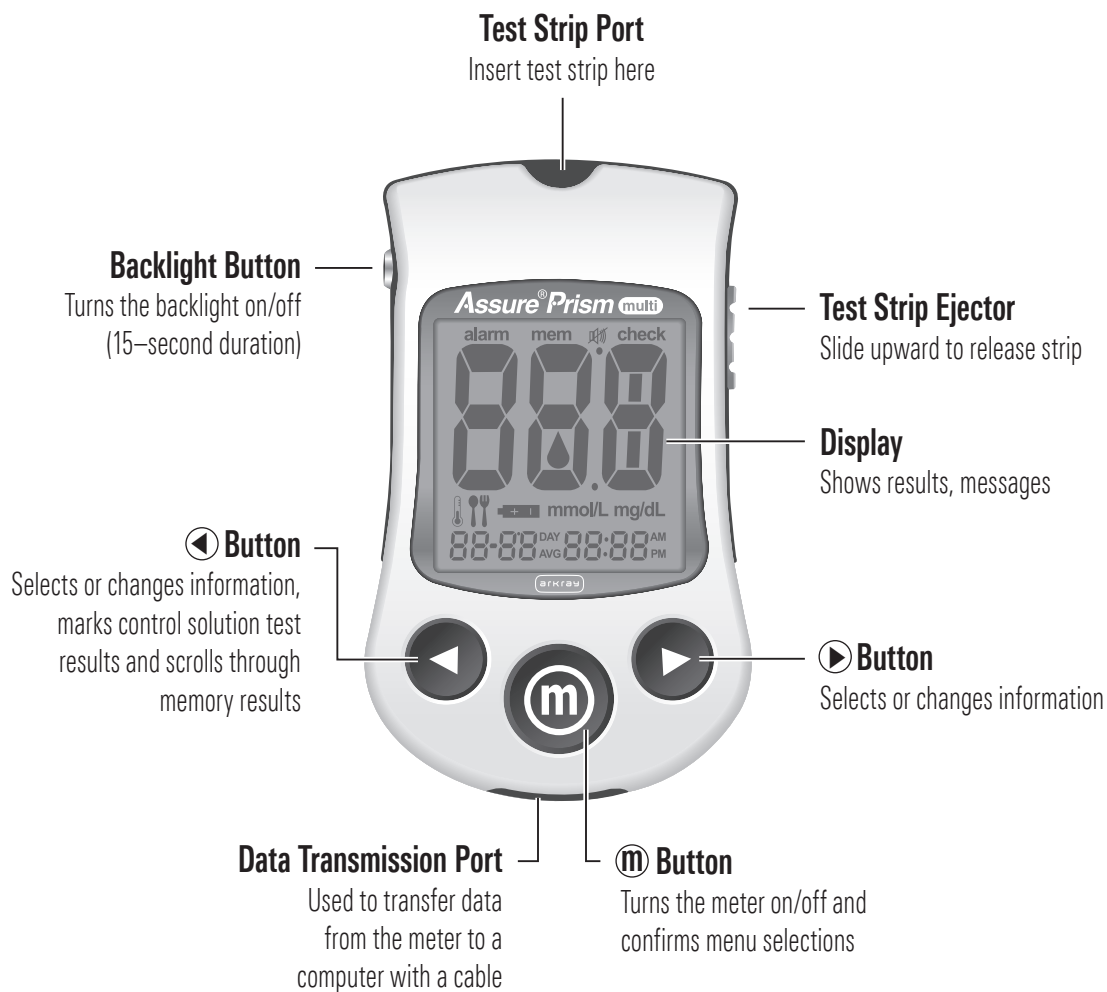
We trust that this Quality Assurance/Quality Control manual will provide you with the needed support tools for your blood glucose monitoring program. If you have any questions after receiving the manual, please call ARKRAY's Technical Customer Service Department at 800.818.8877, option 5, 24 hours a 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 Prism multi Blood Glucose Monitoring System, Assure Prism multi Test Strips or Assure Prism Control Solution. Please see the instructions included with each product for additional detail.

# System Components

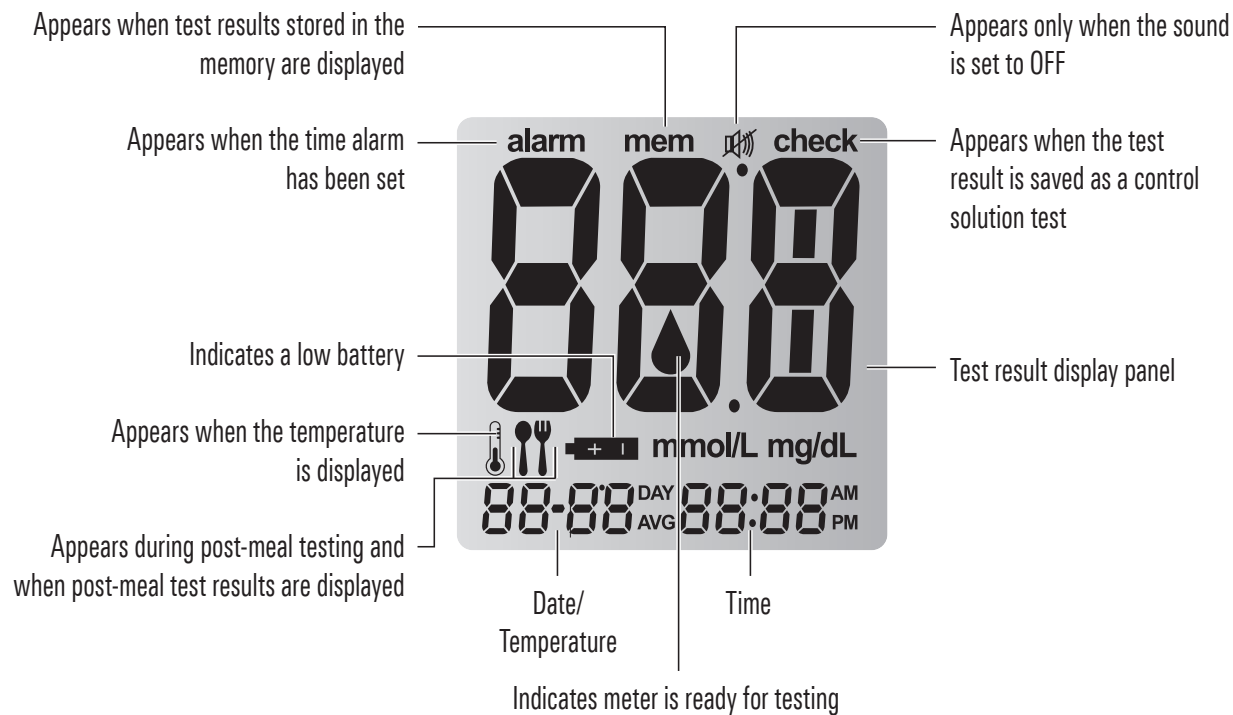
## ASSURE® PRISM MULTI BLOOD GLUCOSE METER



### ORDERING DETAILS

ARKRAY Product Code # 530001    NDC # 08317-5300-01

## METER DISPLAY SCREEN



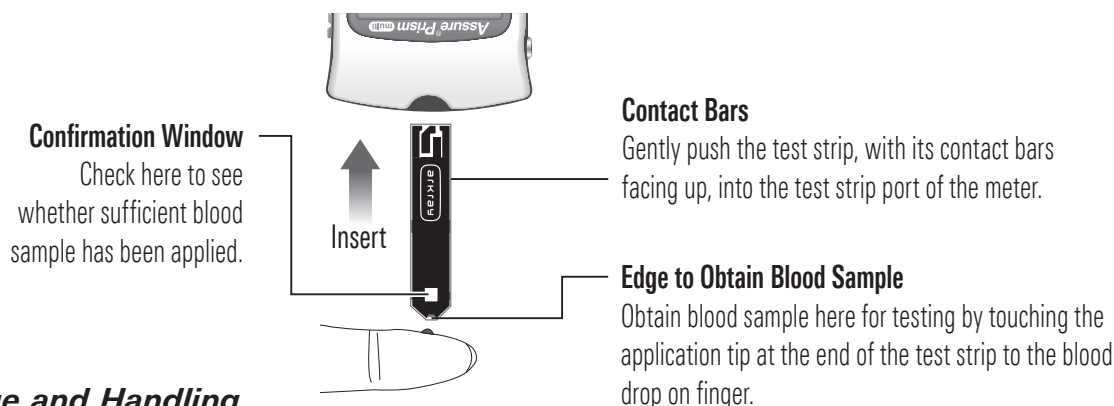
### NOTE

- 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® Prism multi Blood Glucose meter is preset and fixed in mg/dL.



## ASSURE® PRISM MULTI TEST STRIPS

The Assure Prism multi Blood Glucose Test Strips are for use with the Assure Prism multi Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites (forearm, palm, thigh and calf). Alternative site testing should be used only during steady-state blood glucose conditions. The Assure Prism multi Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with auto-disabling, single-use lancing device. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.



### Storage and Handling

- Store unused test strips only in their original bottle/box.
- Store test strips in a cool and dry place between 34-86°F (1-30°C).
- Keep the test strips away from direct sunlight and heat.
- Do not freeze test strips.
- Close bottle cap tightly immediately after taking out a test strip.
- Use the test strip immediately after taking it out of the bottle/individual wrap.
- Handle test strips only with clean, dry hands.
- Do not bend, cut or alter the test strips in any way.
- Do not force a test strip into the meter. Gently push it into the meter's test strip port.
- Apply only fresh capillary whole blood to the test strip.
- Use all of the test strips within the expiration date printed on the test strip bottle/box label.
- Do not use the expired test strips and dispose the expired test strips immediately because using test strips past the expiration dates can produce incorrect test results.
- If the test strips are used and stored according to its storage and handling methods, test strips in new, unopened bottle/boxes, test strips in bottle/boxes that have been opened can be used until the expiration date printed on the test strip bottle/box label.

### UNEXPECTED RESULTS

- Low or high blood glucose readings can indicate a potentially serious medical condition. If the blood glucose reading is unusually low or high, or symptoms do not match the test result, repeat the test using a new test strip.
- If the result is still not consistent with the symptoms observed or if blood glucose result is less than 60 mg/dL or higher than 240 mg/dL consult your patients healthcare provider.

## Warnings and Precautions

- Alternative site and fingertip results may differ significantly due to rapid changes in the glucose level after meals or exercise, hypoglycemic symptoms, or effects of drugs such as insulin. AST testing should only be conducted under steady-state blood glucose conditions. Use a fingertip sample if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.
- Test strips are for single use only. Do not reuse.
- If the test strip does not absorb the blood sample properly, please contact Technical Customer Service at 800.818.8877, option 5, 24 hours a day, 7 days a week.
- For instructions on how to obtain samples from alternative sites, please refer to the AST section of the User Manual for your meter.

### Alternative Site Blood Sampling (forearm, palm, thigh, calf)

Select a clean, soft and fleshy sample site free of visible veins and hair and away from bones. Gently massage the sample site to increase blood circulation to minimize differences between fingertip and alternative site test results. Place auto-disabling, single-use lancing device against the sample site. Press the release button. Massage the site to obtain a round drop (at least 0.5 µL) of blood. Apply test strip tip to blood sample.

### Limitations

- An abnormally high or low red blood cell count (hematocrit level over 60% or below 20%) may produce inaccurate results.
- Inaccurate results may occur in severely hypotensive (having low blood pressure) individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with the Assure® Prism multi Blood Glucose Monitoring System.
- Severe dehydration (excessive water loss) may cause falsely low results. If you believe your resident is suffering from severe dehydration, consult their physician immediately.
- There is no effect from altitudes of up to 10,000 ft (3,000 m) above sea level.
- Interferences: Acetaminophen, ascorbic acid (vitamin C), uric acid and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurate high results.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- Dispose used test strips in a proper waste container, according to your local waste authority.
- Not for neonatal use and not for screening or diagnosis of diabetes.

### Ordering Details

Product Description	ARKRAY Product Code#	NDC#
Assure Prism multi Test Strips 50 count	530050	08317-5300-50
Assure Prism multi Test Strips 100 count	530100	08317-5301-01
Assure Prism multi Test Strips – Foil-wrapped 50-count	532050	08317-5320-50

## ASSURE® PRISM CONTROL SOLUTION

The Assure Prism Control Solutions are red in color. The Assure Prism Control Solutions are for use with the Assure Prism multi Meter and Assure Prism multi Test Strips to check that the meter and test strips are working together properly and that you are performing the test correctly.

### Storage and Handling

Store the Assure Prism Control Solutions at temperatures between 46-86°F/8-30°C, tightly capped the bottle. It must be kept at room temperature (68-77°F/20-25°C) at least 30 minutes before testing to obtain correct results. Do not refrigerate or freeze the control solution.

### Warnings and Precautions

- Assure Prism Control Solutions are for *in vitro* diagnostic use only.
- Use Assure Prism Control Solutions only with the Assure Prism multi Meter and test strips.
- Do not swallow or inject the control solution.
- Check the expiration date shown on the bottle label. Do not use if expired.
- Do not use beyond 3 months (90 days) after opening the bottle. Record the discard date (3 months from the day the bottle was opened) on the bottle label.
- If the control solution test results are outside the range printed on the test strip bottle/box, do not use the system to test blood until you have resolved the problem.
- Control solution, meter and test strips must be stored at room temperature (68-77°F/20-25°C) at least 30 minutes before testing.
- The control solution contains a dye that may stain clothes.

### CAUTION

- The control solution ranges printed on the test strip bottle/box are for the Assure Prism Control Solutions only. These ranges are used to check the meter and test strip performance.
- **These are not recommended ranges for blood glucose level.**

### Recommended Control Solution Use

- You want to practice the test procedure, using the control solution instead of blood
- You use the Assure Prism multi Meter for the first time
- You begin using a new bottle or box of individually wrapped test strips
- You suspect that the meter or the test strips are not working properly
- You think the test results are inaccurate or they do not reflect how the patient feels
- If the meter has been dropped or damaged

### Ordering Details

#### Product Description

#### ARKRAY Product Code#

#### NDC#

Assure Prism Control Solution – Level 1 and 2

530006

08317-5300-06

## METER SPECIFICATIONS






For additional information refer to the Assure® Prism multi Blood Glucose Monitoring System User Manual.

Product Specifications	
Test strips	Assure Prism multi Blood Glucose Test Strips
Measurement range	20–600 mg/dL
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two 3.0 lithium batteries (disposable, type CR2032)
Memory	500 test results
Size	3.66 x 2.20 x 0.83 inch (93 x 56 x 21 mm)
Weight	2.10 oz (59.6 g) with batteries

Operating Ranges	
Temperature	50–104°F (10–40°C)
Relative humidity	10–90%
Hematocrit	20–60%
Altitude	10,000 ft (3,048 meters)
Unit of measurement	mg/dL



# Meter Operation and Set-up

## METER SET-UP

You should check and update the meter settings such as time and date before using your meter or after changing the meter batteries. Press and hold the  button for 3 seconds to enter the SET mode. Whenever you want to complete the settings and exit from the SET mode, press and hold the  button for 3 seconds again. Press  or  to reach the accurate value. Press and hold  to scroll faster.





### *Adjusting the Date and Time*

#### Step 1: Entering the SET Mode

Press and hold the  button for 3 seconds. After all the segments flash across the screen, SET will be displayed on the screen. Press the  button again to progress to the next step.






#### Step 2: Setting the Year

Press  or  until the correct year appears. Press and hold  button to scroll through the numbers quickly. After setting the year, press the  button to confirm your selection and progress to the next step.






#### Step 3: Setting the Month

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






#### Step 4: Setting the Date

Press  or  until the screen displays the correct date. Press the  button to confirm the date and progress to the next step.






#### Step 5: Setting the Time Format

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






#### Step 6: Setting the Hour

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




#### Step 7: Setting the Minute


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



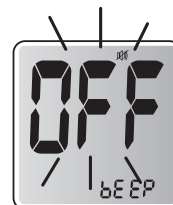
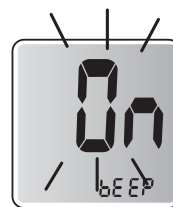
### Step 8: Setting the Sound On/OFF

On pressing ◀ or ▶, the screen will display On or OFF. Press the  button to confirm the selection.



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

- When you press the  button and/or ▶ button to turn on the meter or to set the alarm.
- When the test strip is inserted in the meter.
- When the blood or control solution sample is absorbed into the test strip and the test starts.
- When the test result is displayed.

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



#### NOTE

-  symbol is displayed only when the sound is set to OFF.
- At any stage, press the  button for 3 seconds to exit SET mode and turn off the meter.
- Press and hold ◀ button to quickly scroll through the numbers.

#### NOTE

- In a multi-patient setting, we do not recommend using the memory feature including post-meal alarms, pre-set blood glucose or averaging. Results stored in the memory are not related to a specific patient.

## PERFORMING A BLOOD GLUCOSE TEST

### CAUTION

**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 and capable of transmitting viral diseases between patients and healthcare professionals.
- Before testing each patient, a new pair of clean gloves should be worn by the user.
- 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.
- After use on each patient, the meter should be cleaned and disinfected. Refer to the Cleaning and Disinfection section in this manual.

SECTION

B

For more information, please refer to the following guidelines:

1. "Biosafety in Microbiological and Biomedical Laboratories (BMBL)", [www.cdc.gov/biosafety/publications/bmbl5/](http://www.cdc.gov/biosafety/publications/bmbl5/)
2. "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.

### ***Preparing the Lancing Device***

A lancing device is needed 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 medical distributor or by telephone from the manufacturer.

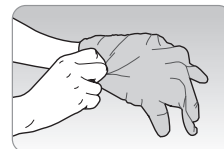
**Please read the instructions provided by the lancing device manufacturer before using the device.**

#### **Step 1**

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

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

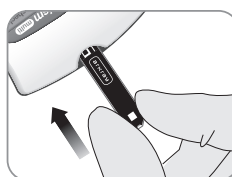
Wear appropriate protective gear such as disposable gloves.




### ***Preparing the Meter and Test Strip***

#### **Step 2**

With the contact bars facing up, insert a test strip into the meter's test strip port.



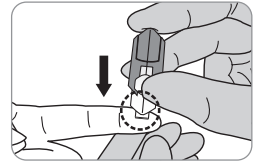
Push the test strip gently into the test strip port until the meter automatically turns on and the  symbol appears.



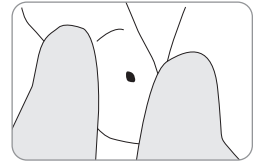
## Applying the Blood Sample

### Step 3


Obtain a blood sample using a lancing device. Place the lancing device against the sampling site in the direction of the arrow. 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 microliter is needed to fill the confirmation window.

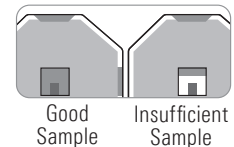
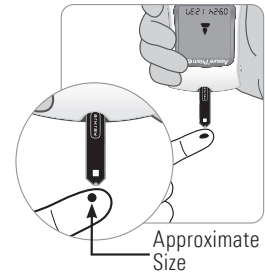


### Step 4


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

If the confirmation window is not filled in time because of abnormal viscosity or insufficient volume, an Er4 message may appear.

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



### NOTE

- The meter will switch off if the blood sample is not applied within 2 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

The test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory.

### Step 6

Slide the ejector button on the right side of the meter to safely discard used test strips in a disposable container.

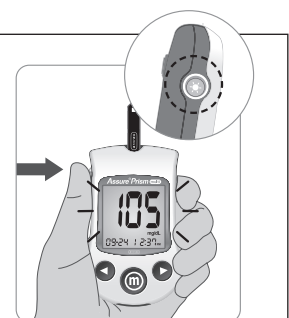
If the test strip is removed, the meter will automatically turn off after 3 seconds.



### Turning On the Backlight

When the meter is on, pressing the backlight button powers on the display backlight.

The backlight will turn off after 15 seconds or when you press the backlight button again.





## PERFORMING A CONTROL SOLUTION TEST

You should check your meter and test strips using Assure® Prism Control Solutions (Level 1 and 2). Assure Prism 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 or individually wrapped test strip box have Assure Prism Control Solution ranges printed on the labels\*. Compare the result displayed on the meter to the Assure Prism Control Solution range printed on the test strip bottle or individually wrapped test strip box. Before using a new meter or a new bottle or box of test strips, you should conduct a control solution test following the procedure with two different levels of control solutions (Level 1 and 2).



SECTION

B

\* For the individually wrapped test strips, Assure Prism Control Solution ranges are printed on the boxes.

### NOTE

- Use Assure Prism Control Solutions only.
- Check the expiration dates printed on the bottle. When you first open a control solution bottle, record the discard date (**date opened plus three [3] months**) in the space provided on the label.
- Make sure your meter, test strips and control solutions are at room temperature before testing. Control solution tests must be done at room temperature 68–77°F (20–25°C).
- Before using the control solution, shake the bottle, discard the first 1 or 2 drops and wipe the top of the control solution cap clean.
- Close the control solution bottle tightly and store at a temperature of 46–86°F (8–30°C).


### You should do a control solution test:

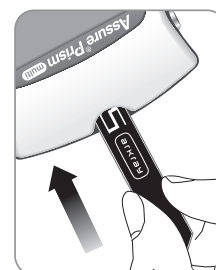
- To practice the test procedure using the control solution instead of blood.
- When using the meter for the first time.
- Whenever a new bottle or box of individually wrapped test strips is opened.
- If the meter or test strips do not function properly.
- If the patient's symptoms are inconsistent with the blood glucose test result and you feel that the meter or test strips are not working properly.
- If the meter is dropped or damaged.

### Assure Prism Control Solution Testing

#### Step 1

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

Gently push the test strip into the test strip port until the meter beeps. Be careful not to bend the strip while pushing it in. The  symbol will be displayed on the screen.



#### Step 2

Shake the Assure Prism Control Solution bottle well before each test.

#### Step 3

Remove the cap and squeeze the bottle to discard the first 1 or 2 drops. Apply one drop of control solution to the top of the control solution cap.



#### Step 4

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



#### NOTE

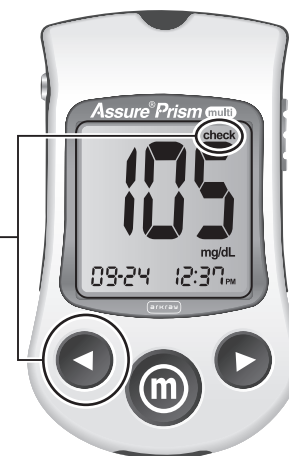
- The meter will switch off if the control solution sample is not applied within 2 minutes of the ▲ symbol appearing on the screen. If the meter turns off, remove the test strip, reinsert, and start from step 2.

#### Step 5

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

After your control solution result appears on the display, press ◀ for 3 seconds until “check” appears on the display.

When “check” is displayed, the result is stored in the meter’s memory but it is not included in the averages.



***Compare the result displayed on the meter to the range printed on the test strip bottle or box of individually wrapped test strips. If the result falls within the specified range, you are ready to use the meter and test strips to test with blood.***

#### 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 safely discarded in disposable containers.



#### CAUTION

- The ranges printed on the test strip bottle or box of individually wrapped test strips are for the Assure® Prism Control Solutions only. They do not have any connection to blood glucose level.

#### NOTE

- Assure Prism Control Solution can be purchased from your local supplier or pharmacy. If they do not stock it, contact ARKRAY Technical Customer Service at 800.818.8877, option 5, 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 bottle or box of individually wrapped test strips. 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"> <li>When the control solution bottle was not shaken well.</li> <li>When the meter, test strip or the control solution were exposed to high or low temperatures.</li> <li>When the first drop of the control solution was not discarded or the top of the cap was not wiped clean.</li> <li>When the meter is not functioning properly.</li> </ul>	Repeat the control solution test.
<ul style="list-style-type: none"> <li>When the control solution is past the expiration date printed on the bottle.</li> <li>When the control solution is past its discard date (the date the bottle was opened plus three [3] months).</li> <li>When the control solution is contaminated.</li> </ul>	Discard the used control solution and repeat the test using a new bottle of control solution.

If results continue to fall outside the range printed on the test strip bottle or box of individually wrapped test strips, the test strip and meter may not be working properly. Do not use your system and contact Technical Customer Service at **800.818.8877**, option 5, 24 hours a day, 7 days a week.

## METER MEMORY

The Assure® Prism multi Blood Glucose Meter can save up to 500 test results with time, date and temperature. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

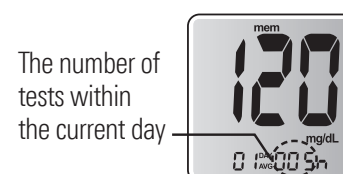
### NOTE

- In a multi-patient setting, we do not recommend using the memory feature including post-meal alarms, pre-set blood glucose or averaging. Results stored in the memory are not related to a specific patient.

## Viewing Test Results

### Step 1

Press the ► or Ⓜ button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1-day average value and the number of the test results saved within the current day.

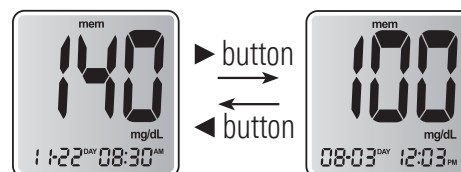


### Step 2

Use the ◀ button to scroll through the test results, starting from the most recent and ending with the oldest. The test date and the recorded temperature will display alternately.

Press the ► to return to the results seen previously.


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



### NOTE

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

## INSERTING OR REPLACING THE BATTERIES

The Assure® Prism multi Blood Glucose Meter uses two 3.0 V lithium batteries. Before using the meter, check the battery compartment and insert batteries if empty. When the  symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible. The test results may not be saved if the batteries run out.

### Step 1

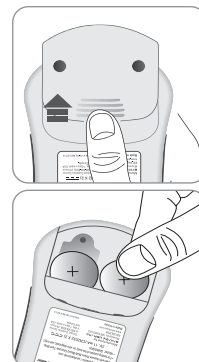
Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.

### Step 2

To remove the used batteries, place your finger under each battery and pull upward. Insert two new batteries with the + side facing up and make sure 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.



### NOTE

- Removing the meter batteries will not affect your stored results. You may, however, need to reset your meter settings.

## CLEANING AND DISINFECTING THE METER

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

**The meter should be cleaned and disinfected after use on each patient.** The Assure Prism multi Blood Glucose Monitoring System may only be used for testing multiple patients when standard precautions and the manufacturer's disinfection procedures are followed.

The **cleaning** procedure is needed to clean dirt, blood and other bodily fluids off the exterior of the meter before performing the disinfection procedure.

The **disinfecting** procedure is needed to prevent the transmission of blood borne pathogens.

Only wipes with EPA registration numbers listed below have been validated for use in cleaning and disinfecting the meter. Any disinfectant product containing these EPA registration numbers may be used on this device. These EPA registration numbers can be found on the EPA website. Wipes with EPA registration numbers not listed below should not be used to clean and disinfect the Assure Prism multi Meter. Please read the manufacturer's instructions carefully before using their wipes on the 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 Wipe	9480-4
Metrex® Research	CaviWipes1™	46781-13

Clorox and Dispatch are trademarks or registered trademarks of Clorox. Sani-cloth is a trademark or registered trademark of PDI. Metrex and CaviWipes1 are trademarks or registered trademarks of Metrex.

### ***Guidelines for Cleaning and Disinfecting the Assure® Prism multi Blood Glucose Monitoring System (BGMS)***

#### **NOTE**

- Do not get fluids inside the meter through the test strip port, data port or battery compartment.
- Never immerse the meter or hold it under running water because it will damage the meter.
- Two disposable wipes will be needed for each cleaning and disinfecting procedure; one wipe for cleaning and a second wipe for disinfecting.

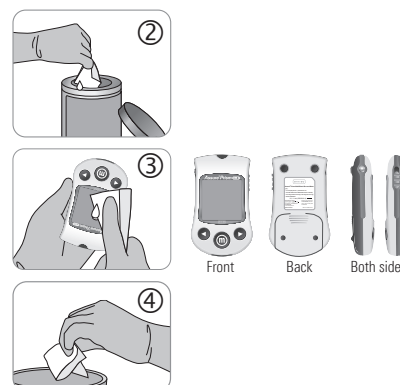
#### **Cleaning**

**Step 1:** 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 the entire surface of the meter 3 times horizontally and 3 times vertically using 1 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 4:** Properly dispose of the used towelette.



## NOTE

- No actual drying of the meter is necessary before starting the disinfecting procedure.

## SECTION

# B

### Disinfecting (The meter should be cleaned prior to disinfection.)

**Step 5:** Open the towelette container and pull out 1 towelette and close the lid.



**Step 6:** Wipe the entire surface of the meter 3 times horizontally and 3 times vertically to remove blood-borne 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.



**Step 7:** Properly dispose of the used towelette.



**Step 8:** Treated surface must remain wet for recommended contact time. Please refer to the Assure Prism multi BGMS User Manual for hepatitis B contact times. For all other contact times, refer to wipe manufacturers' instructions. **DO NOT WRAP THE METER IN A WIPE.** Once contact time is complete, wipe meter dry.



**Step 9:** After disinfection, the user's gloves should be removed and thrown away. Wash hands before proceeding to the next patient.



If any of the following deterioration signs appear after cleaning or disinfecting, please stop using the system and contact Technical Customer Service at 800.818.8877, option 5, 24 hours a day, 7 days a week.

- When the inscriptions on the exterior of the meter have been removed.
- When the color of the meter has changed or faded.
- When cracks or roughness develop on the meter.
- When a part of the segment on the meter display does not flash.

#### More information is available at:

- [www.cdc.gov/injectionsafety/blood-glucose-monitoring.html](http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html)

## 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?**

No, each time the cleaning and disinfecting procedure is performed two wipes are needed. One wipe to clean the meter and a second wipe to disinfect the meter.

**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.

LTC facilities are required to 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

## 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.

**More information is available at:**

- [www.cdc.gov/injectionsafety/blood-glucose-monitoring.html](http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html)

## TROUBLESHOOTING

### Display Screen Messages

**Please read this section first. 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.

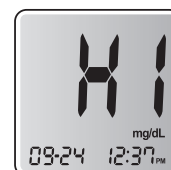
#### HI and Lo Messages

The meter displays results between 20–600 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).

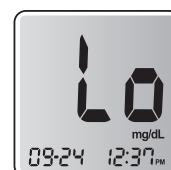
If “HI” is displayed again upon retesting, please contact the patient’s healthcare provider immediately.



##### Lo Message

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

If “Lo” is displayed again upon retesting, please contact the patient’s healthcare provider immediately.



#### NOTE

- If messages for hyperglycemia or hypoglycemia are displayed, even if the patient does not have those conditions, please contact Technical Customer Service at **800.818.8877**, option 5, 24 hours a day, 7 days a week.

### Error Messages

#### Er1: A used test strip was inserted.

Repeat the test with a new test strip.



#### Er2: The blood or control solution sample was applied before the ▲ symbol appeared.

Repeat the test with a new test strip and wait until the ▲ symbol appears before applying the blood or control solution sample.



#### Er4: The blood sample has abnormally high viscosity or insufficient volume.

Repeat the test with a new test strip.



#### Er5: This error message may appear when the wrong blood glucose test strip is used instead of an Assure® Prism multi Blood Glucose Test Strip.

Repeat the test with an Assure Prism multi Blood Glucose Test Strip.



#### Er6: There is a problem with the meter.

Do not use the meter. Contact Technical Customer Service at **800.818.8877**, option 5, 24 hours a day, 7 days a week.






**HIF: The temperature during the test was above the operating range.**

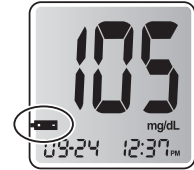
Move to an area where the temperature is within the operating range (50–104°F/10–40°C) and repeat the test after the meter and test strips have reached a temperature within the operating range.

**LoF: The temperature during the test was below the operating range.**

Move to an area where the temperature is within the operating range (50–104°F/10–40°C) and repeat the test after the meter and test strips have reached a temperature within the operating range.

**Low batteries.**

If the  symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible. The test results may not be saved if the batteries run out.

**NOTE**

- If the error messages persist, please contact Technical Customer Service at **800.818.8877**, option 5, 24 hours a day, 7 days a week.

**General Troubleshooting**

Problem	Troubleshooting
The display is blank even after inserting a test strip.	<ul style="list-style-type: none"> <li>• Check whether the test strip is inserted with the contact bars facing up.</li> <li>• Check if the test strip has been inserted completely into the test strip port.</li> <li>• Check if the appropriate test strip was used.</li> <li>• Check if the batteries are inserted with the "+" side facing up.</li> <li>• Replace the batteries.</li> </ul>
The test does not start even after applying the blood sample to the test strip tip.	<ul style="list-style-type: none"> <li>• Check if the confirmation window is filled completely.</li> <li>• Repeat the test after inserting a new test strip.</li> </ul>
The patient's test result does not match their symptoms.	<ul style="list-style-type: none"> <li>• Repeat the test after inserting a new test strip.</li> <li>• Check the expiration date of the test strip.</li> <li>• Perform control solution test.</li> </ul>

**NOTE**

- If the problem is not resolved, please contact Technical Customer Service at **800.818.8877**, option 5, 24 hours a day, 7 days a week.

# Regulatory Review and Guidelines for QA/QC Protocols

## COMPETENCY CHECKLIST

	Joint Commission on Accreditation of Healthcare Organizations (JCAHO)	Clinical and Laboratory Standards Institute (CLSI) (Formerly NCCLS)	Clinical Laboratory Improvement Amendments (CLIA)
<b>Personnel/Training</b>	<ul style="list-style-type: none"> <li>• Staff members can describe or demonstrate their roles and responsibilities (HR.2.20).</li> <li>• Participate in ongoing in-services.</li> <li>• Education is documented (HR.2.30).</li> <li>• Competence to perform job responsibilities is assessed, demonstrated, and maintained (HR.3.10).</li> </ul>	<ul style="list-style-type: none"> <li>• Formal training and written examination.</li> </ul>	<ul style="list-style-type: none"> <li>• Follow manufacturer's instructions.</li> </ul>
<b>Quality Assurance</b>	<ul style="list-style-type: none"> <li>• Current and complete policies are available to the person performing the test.</li> <li>• 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.</li> </ul>	<ul style="list-style-type: none"> <li>• Follow manufacturer's instructions for calibration.</li> <li>• Written procedure manual.</li> <li>• Manual contains principles of operation, reagents/equipment, calibration, quality control, stepwise procedure, reporting results, procedure limitations, references, supplemental material, review and updates.</li> </ul>	<ul style="list-style-type: none"> <li>• Follow manufacturer's instructions.</li> </ul>
<b>Quality Control</b>	<ul style="list-style-type: none"> <li>• Written quality control plan that specifies how procedures will be controlled.</li> <li>• At the least, perform as frequently as recommended by manufacturer.</li> <li>• Should include two levels of control solution.</li> <li>• At the least, quality control procedures are performed once each day on each instrument used for resident testing (PC.16.50).</li> </ul>	<ul style="list-style-type: none"> <li>• On each day of use, two control solutions (Level 1 and 2) should be performed per instrument.</li> <li>• Prior to the first test of the day, each operator is to perform a quality control test.</li> <li>• Additional checks should be performed when:               <ul style="list-style-type: none"> <li>• A new bottle/box of test strips is opened.</li> <li>• Each time a reagent lot is changed.</li> <li>• To ensure the test strips and meter are functioning properly.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Follow manufacturer's instructions.</li> </ul>
<b>Linearity/Calibration</b>	<ul style="list-style-type: none"> <li>• Linearity not covered in the standards.</li> </ul>	<ul style="list-style-type: none"> <li>• Initially and as specified by manufacturer or as required by government or accrediting bodies.</li> </ul>	<ul style="list-style-type: none"> <li>• Follow manufacturer's instructions.</li> </ul>
<b>Proficiency Training</b>	<ul style="list-style-type: none"> <li>• Not specified.</li> </ul>	<ul style="list-style-type: none"> <li>• Participate in program that meets accreditation, federal and state regulations.</li> </ul>	<ul style="list-style-type: none"> <li>• Not specified.</li> </ul>
<b>Inspections</b>	<ul style="list-style-type: none"> <li>• Currently triennial (APP-5).</li> </ul>	<ul style="list-style-type: none"> <li>• Not a certifying agency.</li> </ul>	<ul style="list-style-type: none"> <li>• Not subject to routine survey.</li> <li>• Conducted only when authorized by the RO.</li> </ul>

**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.**

SECTION

C

# ACCURACY AND PRECISION STUDIES

## Performance Characteristics

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

**ACCURACY:** The Assure Prism multi Blood Glucose Monitoring System is calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the Assure Prism multi Blood Glucose Monitoring System was tested by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a lab instrument.

The results below were obtained by diabetic patients at clinic centers.

	Obtained by Healthcare Professionals	Obtained by Lay Users
<b>Slope</b>	1.017	1.022
<b>Y-intercept</b>	-7.39 mg/dL	-8.31 mg/dL
<b>Correlation coefficient(r)</b>	0.992	0.992
<b>Number of samples</b>	122	118
<b>Range tested</b>	40-577 mg/dL	58-577 mg/dL

## Accuracy

### Results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
11/11 (100%)	11/11 (100%)	11/11 (100%)

### Results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
47/111 (42%)	89/111 (80%)	109/111 (98%)	111/111 (100%)

## Precision

Studies were performed in a laboratory using the Assure Prism multi Blood Glucose Monitoring System.

### Within Run Precision

Blood avg.*	41.4 mg/dL	SD = 1.8 mg/dL
Blood avg.*	79.6 mg/dL	SD = 2.8 mg/dL
Blood avg.*	129.8 mg/dL	CV = 2.6%
Blood avg.*	201.9 mg/dL	CV = 3.1%
Blood avg.*	349.6 mg/dL	CV = 2.7%

### Total Precision

Control avg.*	36.2 mg/dL	SD = 1.3 mg/dL
Control avg.*	117.0 mg/dL	CV = 2.3%
Control avg.*	321.8 mg/dL	CV = 2.4%

\*This study shows that there could be variation of up to 3.1%.

## ALTERNATIVE SITE TESTING EVALUATION

Comparison of results using various alternative site testing with the results of YSI measurements.

Alternative site test results for glucose concentration < 75 mg/dL			
	Within $\pm$ 5 mg/dL	Within $\pm$ 10 mg/dL	Within $\pm$ 15 mg/dL
<b>Fingertip</b>	2/2 (100%)	2/2 (100%)	2/2 (100%)
<b>Forearm</b>	2/2 (100%)	2/2 (100%)	2/2 (100%)
<b>Palm</b>	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
<b>Thigh</b>	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
<b>Calf</b>	1/2 (50.0%)	2/2 (100%)	2/2 (100%)

Alternative site test results for glucose concentration $\geq$ 75 mg/dL				
	Within $\pm$ 5%	Within $\pm$ 10%	Within $\pm$ 15%	Within $\pm$ 20%
<b>Fingertip</b>	34/56 (60.7%)	51/56 (91.1%)	55/56 (98.2%)	56/56 (100%)
<b>Forearm</b>	32/56 (57.1%)	52/56 (92.9%)	56/56 (100%)	56/56 (100%)
<b>Palm</b>	31/56 (55.4%)	52/56 (92.9%)	54/56 (96.4%)	56/56 (100%)
<b>Thigh</b>	27/56 (48.2%)	44/56 (78.6%)	54/56 (96.4%)	56/56 (100%)
<b>Calf</b>	24/56 (42.9%)	43/56 (76.8%)	53/56 (94.6%)	56/56 (100%)

# Addendums

## PRODUCT ORDERING

Product Description	ARKRAY Product Code #	NDC #
Assure® Prism multi Meter Blood Glucose Meter	530001	08317-5300-01
Assure Prism multi Test Strips 50 count	530050	08317-5300-50
Assure Prism multi Test Strips 100 count	530100	08317-5301-01
Assure Prism multi Test Strips - Foil wrapped 50 count	532050	08317-5320-50
Assure Prism Control Solution – Level 1 and 2	530006	08317-5300-06

## WARRANTY

### Manufacturer's Warranty

ARKRAY USA, Inc. warrants that the Assure Prism multi Blood Glucose Monitoring System shall be free of defects in material and workmanship in normal use for a period of three (3) years. The meter must have been subjected to normal use. The warranty does not cover improper handling, tampering, use, or service of the meter. Any claim must be made within the warranty period.

The ARKRAY USA, Inc. company will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty. As a matter of warranty policy, ARKRAY USA, Inc. will not reimburse the consumer's purchase price.

### Obtaining Warranty Service

To obtain warranty service, you must return the defective meter or meter part along with proof of purchase to ARKRAY USA, Inc.

Do not send your meter or meter parts to ARKRAY without first calling to get approval to do so. Technical Customer Service may be reached at **800.818.8877**, option 5, 24 hours a day, 7 days a week.

SECTION

D

Name of facility: \_\_\_\_\_

## IN-SERVICE TRAINING AND CERTIFICATION

### Assure® Prism multi Blood Glucose Monitoring System

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

#### 1. Familiarization with components of the Assure Prism multi Blood Glucose Monitoring System:

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

\*Actual blood sampling is not required.

#### 2. Describe/Demonstrate:

<b>Initial Meter Set-Up Options</b> <ul style="list-style-type: none"><li><input type="checkbox"/> Audible Beep</li><li><input type="checkbox"/> Time Format</li><li><input type="checkbox"/> Date Format</li></ul>
---

\_\_\_\_\_  
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"><li><input type="checkbox"/> Assure ID Safety Pen Needle Training</li><li><input type="checkbox"/> Discharge Program Training</li><li><input type="checkbox"/> Phaxix® Pill Swallowing Gel</li></ul>
--

SECTION

E

Name of facility: \_\_\_\_\_

## COMPETENCY CHECKLIST

Assure® Prism multi Blood Glucose Monitoring System

Operator \_\_\_\_\_

Date \_\_\_\_\_

Trainer \_\_\_\_\_

The Trainer should observe the Operator performing the following tasks:

- |   |  |
|---|--|
| 1. Follow facility protocol for quality control testing.                | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 2. Change battery.  | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 3. Select and prepare the fingerstick site correctly.                   | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 4. Use lancet/lancing device correctly.*                                | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 5. Dispose of lancet correctly.   | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 6. Insert test strip into meter correctly.                              | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 7. Apply blood to sample-application tip correctly.                     | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 8. Record result correctly.   | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 9. Identify when to repeat test or check result with a laboratory test. | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 10. Perform control solution test correctly.                            | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 11. Save control solution test correctly.                               | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 12. Clean/disinfect meter correctly.                                    | <input type="checkbox"/> YES <input type="checkbox"/> 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 Prism multi Blood Glucose Monitoring System. If no, perform tasks on list and document performance on competency checklist again.

SECTION

E

Name of facility: \_\_\_\_\_

## INSTRUCTOR TRAINING RECORD

# Assure® Prism multi Blood Glucose Monitoring System

The healthcare professionals listed below have been trained to serve as Trainers for the Assure Prism multi 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 Prism multi 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: \_\_\_\_\_

## SELF-TEST

### Assure® Prism multi Blood Glucose Monitoring System

The following is a multiple choice self-test that is designed to test your proficiency in using the Assure Prism multi 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 Prism multi Blood Glucose Meter stores up to \_\_\_\_\_ tests in the memory.**

- a. 200
- b. 50
- c. 500
- d. 10

**2. The Assure Prism multi Blood Glucose Test Strips**

- a. May be reused.
- b. Can be used with other meters besides the Assure Prism multi 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 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 tip of the cap.
- d. Compare the result displayed on the meter to the range printed on the test strip bottle or box of individually wrapped test strips.

**5. Assure Prism 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® Prism multi 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 5 to 1.
  - d. You may apply a second blood drop if meter does not start after adding the first drop.
- 7. The Assure Prism multi Blood Glucose Meter can be used with**
- a. Whole blood.
  - b. Serum or plasma.
  - c. Neonatal blood samples.
  - d. Venous blood.
- 8. The Assure Prism multi Blood Glucose Monitoring System should be cleaned and disinfected between patient tests to avoid cross-contamination?**
- ☐ True    ☐ False
- 9. Nurses who use the Assure Prism multi 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 Prism multi Blood Glucose Meter uses four 3.0V lithium batteries**
- ☐ True    ☐ False

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Score: \_\_\_\_\_

## SELF-TEST

Assure® Prism multi Blood Glucose Monitoring System

### Answer Key

- |            |               |
|------------|---------------|
| 1. c       | 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. False     |

SECTION

E

Name of facility: \_\_\_\_\_

## METER TRACKING FORM

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

SECTION

F



## FIELD INSPECTION REPORT Assure® Prism multi Blood Glucose Monitoring System:

Address: \_\_\_\_\_ Time: \_\_\_\_\_ Phone: \_\_\_\_\_

ARKRAY Representative Signature: \_\_\_\_\_

[illegible]

## 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

# F



# POLICY: INFECTION CONTROL

## Purpose

The purpose of this guide is to ensure that correct cleaning and disinfecting of the Assure® Prism multi Blood Glucose Monitoring System is followed to prevent the potential transmission of infectious organisms through the Assure Prism multi 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 Prism multi 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 Prism multi Meter
- Assure Prism multi Test Strips
- Lancet or lancing device (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 Prism multi Meter (detailed in Section B of the QA/QC Manual).

### 3. Dispose of used test strip and lancet

Dispose of the used Assure Prism multi 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.

## CLEANING AND DISINFECTING THE METER

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

**The meter should be cleaned and disinfected after use on each patient.** The Assure® Prism multi Blood Glucose Monitoring System may only be used for testing multiple patients when standard precautions and the manufacturer's disinfection procedures are followed.

### *Cleaning and Disinfection*

The **cleaning** procedure is needed to clean dirt, blood and other bodily fluids off the exterior of the meter before performing the disinfection procedure.

The **disinfecting** procedure is needed to prevent the transmission of blood borne pathogens.

Only wipes with EPA registration numbers listed below have been validated for use in cleaning and disinfecting the meter. Any disinfectant product containing these EPA registration numbers may be used on this device. These EPA registration numbers can be found on the EPA website. Wipes with EPA registration numbers not listed below should not be used to clean and disinfect the Assure Prism multi Meter. Please read the manufacturer's instructions carefully before using their wipes on the meter.

Manufacturer	Disinfectant Brand Name	EPA #
Clorox® Professional Products Company	Clorox Healthcare Bleach Germicidal Wipes	67619-12
	Dispatch® Hospital Cleaner Disinfectant Towels and Bleach	56392-8
Professional Disposables International, Inc. (PDI)	Super Sani-Cloth® Germicidal Disposable Wipe	9480-4
Metrex® Research	CaviWipes1™	46781-13

- A list of Environmental Protection Agency (EPA) registered disinfectants effective against HIV, hepatitis B and hepatitis C viruses can be found at the following website:

**[www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants](http://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants)**

Go to **[www.arkrayusa.com/diabetes-management/disinfect](http://www.arkrayusa.com/diabetes-management/disinfect)** for the most up-to-date information on approved cleaning and disinfecting procedures and materials for ARKRAY meters. If you have any questions, please contact our Technical Customer Service department at **800.818.8877**, option 5, 24 hours a day, 7 days a week.

### *Cleaning and Disinfecting Procedures*

#### **NOTE**

- Do not get fluids inside the meter through the test strip port, data port or battery compartment.
- Never immerse the meter or hold it under running water because it will damage the meter.
- Two disposable wipes will be needed for each cleaning and disinfecting procedure; one wipe for cleaning and a second wipe for disinfecting.

**More information is available at:**

- [www.cdc.gov/injectionsafety/blood-glucose-monitoring.html](http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html)

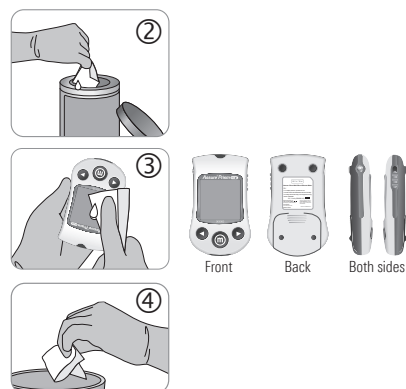
## Cleaning

**Step 1:** Wear appropriate protective gear such as disposable gloves.

**Step 2:** Open the towelette container and pull out 1 towelette and close the lid.

**Step 3:** Wipe the entire surface of the meter 3 times horizontally and 3 times vertically using 1 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 4:** Properly dispose of the used towelette.



### NOTE

- No actual drying of the meter is necessary before starting the disinfecting procedure.

## Disinfecting (The meter should be cleaned prior to disinfection.)

**Step 5:** Open the towelette container and pull out 1 towelette and close the lid.

**Step 6:** Wipe the entire surface of the meter 3 times horizontally and 3 times vertically to remove blood-borne 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.

**Step 7:** Properly dispose of the used towelette.

**Step 8:** Treated surface must remain wet for recommended contact time. Please refer to the Assure Prism multi BGMS User Manual for hepatitis B contact times. For all other contact times, refer to wipe manufacturers' instructions. **DO NOT WRAP THE METER IN A WIPE.** Once contact time is complete, wipe meter dry.

**Step 9:** After disinfection, the user's gloves should be removed and thrown away. Wash hands before proceeding to the next patient.



If any of the following deterioration signs appear after cleaning or disinfecting, please stop using the system and contact Technical Customer Service at 800.818.8877, option 5, 24 hours a day, 7 days a week.

- When the inscriptions on the exterior of the meter have been removed.
- When the color of the meter has changed or faded.
- When cracks or roughness develop on the meter.
- When a part of the segment on the meter display does not flash.

## POLICY: PERFORMING A BLOOD GLUCOSE TEST WITH THE ASSURE® PRISM MULTI METER

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

- Glucose levels monitored using the Assure Prism multi 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 Prism multi 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 Prism multi Blood Glucose Meter
- Assure Prism multi Test Strips
- Safety Lancet
- Gloves
- Alcohol Wipe

**Procedure:**

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

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

### ***Preparing the Lancing Device***

A lancing device is needed 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 medical distributor or by telephone from the manufacturer.

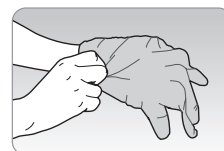
**Please read the instructions provided by the lancing device manufacturer before using the device.**

#### **Step 1**

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

If alcohol wipes are used, make sure the area is dry before taking 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

With the contact bars facing up, insert a test strip into the meter's test strip port.



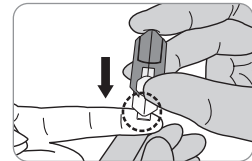
Push the test strip gently into the test strip port until the meter automatically turns on and the ▲ symbol appears.



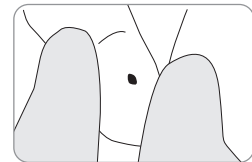
## Applying the Blood Sample

### Step 3

Obtain a blood sample using a lancing device. Place the lancing device against the sampling site in the direction of the arrow. 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 microliter is needed to fill the confirmation window.

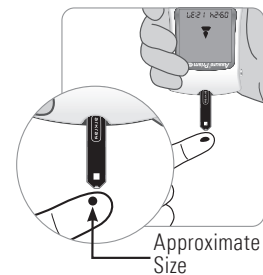


### Step 4

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

If the confirmation window is not filled in time because of abnormal viscosity or insufficient volume, an Er4 message may appear.

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



### NOTE

- The meter will switch off if the blood sample is not applied within 2 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

The test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory.

### Step 6

Slide the ejector button on the right side of the meter to safely discard used test strips in a disposable container.

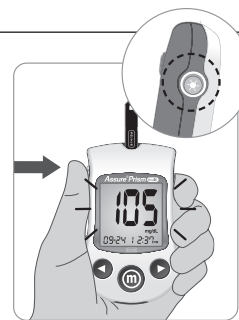
If the test strip is removed, the meter will automatically turn off after 3 seconds.



### ***Turning On the Backlight***

When the meter is on, pressing the backlight button powers on the display backlight.

The backlight will turn off after 15 seconds or when you press the backlight button again.



## POLICY: QUALITY CONTROL TESTING ON ASSURE® PRISM MULTI METER

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

The Assure Prism 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 Prism multi Blood Glucose Monitoring 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 Prism multi 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 Prism Control Solution is not intended for human consumption. Do not drink.
- Only use with Assure Prism multi Blood Glucose Meter and Assure Prism multi 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 35–86°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 Prism Control Solution is not a cleaning solution. Do not clean your meter with control solution.

**Level of Responsibility:** RN/LPN

### Equipment Needed:

- Assure Prism Control Solution (Normal and High)
- Assure Prism multi Test Strips
- Assure Prism multi Meter
- Record Sheet

## Assure® Prism Control Solution Testing

### Step 1

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

Gently push the test strip into the test strip port until the meter beeps. Be careful not to bend the strip while pushing it in. The ▲ symbol will be displayed on the screen.



### Step 2

Shake the Assure Prism Control Solution bottle well before each test.

### Step 3

Remove the cap and squeeze the bottle to discard the first 1 or 2 drops. Apply one drop of control solution to the top of the control solution cap.



### Step 4

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



#### NOTE

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

### Step 5

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

After your control solution result appears on the display, press ◀ for 3 seconds until "check" appears on the display.

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

**Compare the result displayed on the meter to the range printed on the test strip bottle or box of individually wrapped test strips. If the result falls within the specified range, you are ready to use the meter and test strips to test with blood.**



### 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 safely discarded in disposable containers.



#### CAUTION

- The ranges printed on the test strip bottle or box of individually wrapped test strips are for the Assure® Prism Control Solutions only. They do not have any connection to blood glucose level.

#### NOTE


- Assure Prism Control Solution can be purchased from your local supplier or pharmacy. If they do not stock it, contact ARKRAY Technical Customer Service at 800.818.8877, option 5, 24 hours a day, 7 days a week.



## POLICY: MAINTAINING THE ASSURE PRISM MULTI METER

**Level of Responsibility:** RN/LPN

### INSERTING OR REPLACING THE BATTERIES

The Assure Prism multi Blood Glucose Meter uses two 3.0 V lithium batteries. Before using the meter, check the battery compartment and insert batteries if empty. When the  symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible. The test results may not be saved if the batteries run out.

#### Step 1

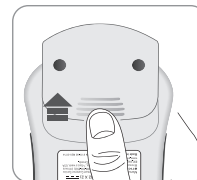
Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.

#### Step 2

To remove the used batteries, place your finger under each battery and pull upward. Insert two new batteries with the + side facing up and make sure 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.



#### NOTE

- Removing the meter batteries will not affect your stored results. You may, however, need to reset your meter settings.

SECTION

F





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**ARKRAY USA**

5182 West 76th Street  
Minneapolis, MN 55439 U.S.A  
800.818.8877  
[www.arkrayusa.com](http://www.arkrayusa.com)

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