

# ASSURE<sup>®</sup> PRISM MULTI

+ BLOOD GLUCOSE MONITORING SYSTEM



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

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# Table of Contents

	<b>Introduction</b> .....	i
<b>Section A</b>	<b>System Components</b>	
	Assure® Prism multi Blood Glucose Meter.....	1
	Meter Display Screen .....	2
	Assure® Prism multi Test Strips .....	3
	Assure® Prism Control Solution.....	5
	Meter Specifications .....	6
<b>Section B</b>	<b>Meter Operation and Set-up</b>	
	Meter Set-up .....	7
	Performing a Blood Glucose Test.....	9
	Performing a Control Solution Test .....	11
	Meter Memory .....	14
	Inserting or Replacing the Batteries .....	15
	Cleaning and Disinfecting the Meter .....	16
	Troubleshooting.....	18
<b>Section C</b>	<b>Regulatory Review and Guidelines for QA/QC Protocols</b>	
	Regulatory Review and Guidelines for QA/QC Protocols .....	20
	Accuracy and Precision Studies.....	21
	Alternative Site Testing Evaluation .....	22
<b>Section D</b>	<b>Addendums</b>	
	Product Ordering .....	23
	Warranty .....	23
<b>Section E</b>	<b>In-service Training</b>	
	In-service Training and Certification .....	24
	Competency Checklist.....	25
	Self-test .....	26
	Healthcare Professional In-service Training Record.....	29
	Instructor Training Record.....	30
<b>Section F</b>	<b>Quality Assurance/Quality Control Recording Forms</b>	
	Meter Tracking Record .....	31
	Quality Control Record .....	32
	Field Inspection Report .....	33

# 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, 24 hours a day, 7 days a week, U.S.A. and Canada.

## 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

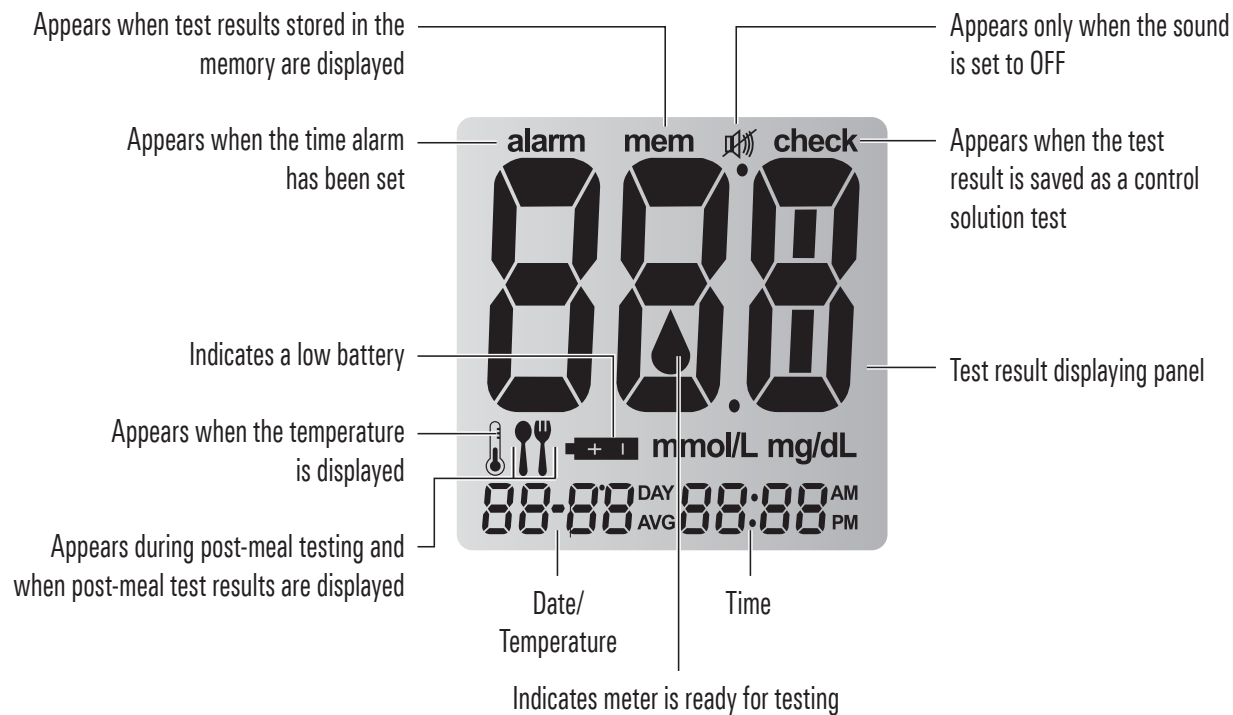
## ASSURE® PRISM MULTI BLOOD GLUCOSE METER



### ORDERING DETAILS

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

## METER DISPLAY SCREEN

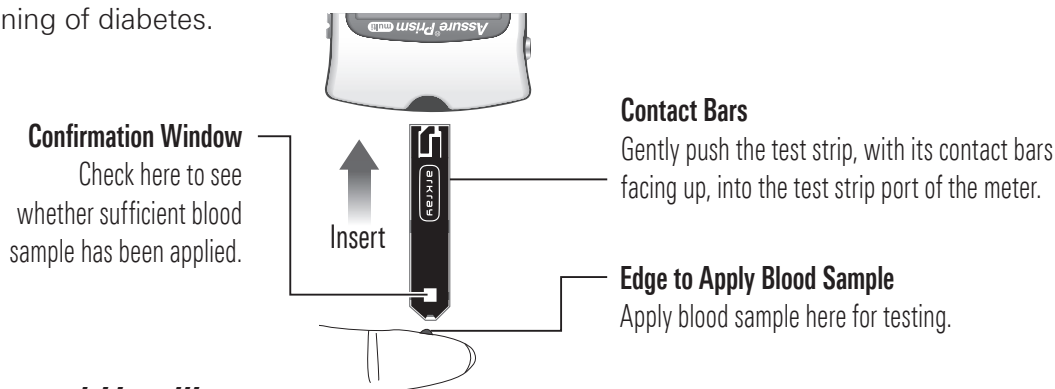


### NOTE

- 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 are not for the diagnosis or screening of diabetes.



### Storage and Handling

- Store unused test strips only in their original vial.
- 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 vial cap tightly immediately after taking out a test strip.
- Use the test strip immediately after taking it out of the vial.
- 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 vial 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 vials, test strips in vials that have been opened can be used until the expiration date printed on the test strip vial 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, 24 hours a day, 7 days a week, U.S.A. and Canada.

***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  $\mu$ L) of blood. Apply test strip tip to blood sample.

**CAUTION**

- 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. Use a fingertip sample if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.
- AST results should never be used to calibrate Continuous Glucose Monitoring Systems nor entered into an insulin dosing calculator or pump for dosing recommendations.
- For instructions on how to obtain samples from alternative sites, please refer to the AST section of the User Manual for your meter.

***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.
- For over-the-counter use.



## 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 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 vial was opened) on the bottle label.
- If the control solution test results are outside the range printed on the test strip vial, 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 vial 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 vial of 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:** Assure Prism Control Solution –Level 1 and 2

**ARKRAY Product #:** 530006 **NDC #:** 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.



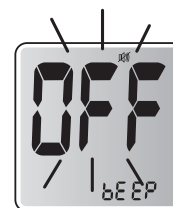
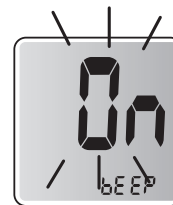
**Step 8: Setting the Sound On/OFF**

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. See the Cleaning and Disinfection section on page 16.

For more information, please refer to the following guidelines:

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

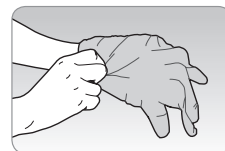
1. "Biosafety in Microbiological and Biomedical Laboratories (BMBL)", [www.cdc.gov/biosafety/publications/bmbl5/](http://www.cdc.gov/biosafety/publications/bmbl5/)
2. "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards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

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.

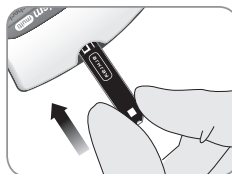



Wear appropriate protective gear such as disposable gloves.

### ***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.



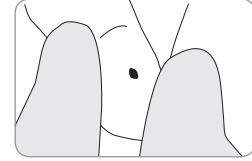
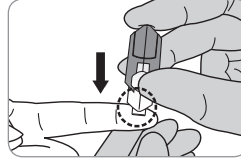
Push the test strip gently into the test strip port until the meter automatically turns on and the  symbol appears.



## 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.



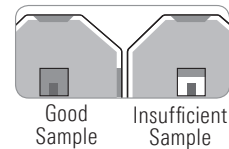
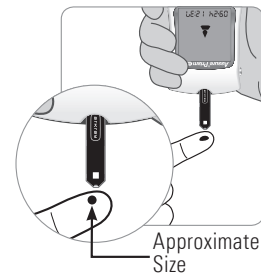
Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window.

### 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.

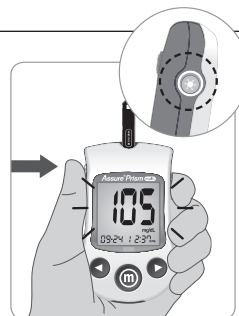
If the test strip is removed, the meter will automatically turn off after 3 seconds.



### 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 vials 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 vial. Before using a new meter or a new vial of test strips, you should conduct a control solution test following the procedure with two different levels of control solutions (Level 1 and 2).



### 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:

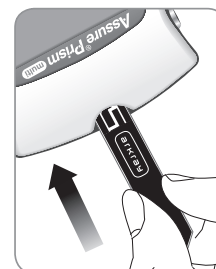
- To practice the test procedure using the control solution instead of blood.
- When using the meter for the first time.
- Whenever a new vial of test strips is opened.
- If the meter or test strips do not function properly.
- If the patient's symptoms are inconsistent with the blood glucose test result 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**

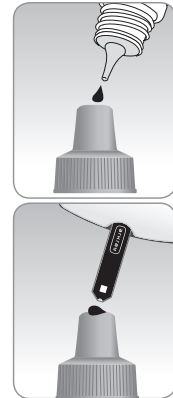
Shake the Assure® Prism Control Solution bottle well before each test.

**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 vial. 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 vial 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, 24 hours a day, 7 days a week, U.S.A. and Canada.



### ***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"><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 vial, the test strip and meter may not be working properly. Do not use your system and contact Technical Customer Service at **800.818.8877**, 24 hours a day, 7 days a week, U.S.A. and Canada.

## 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

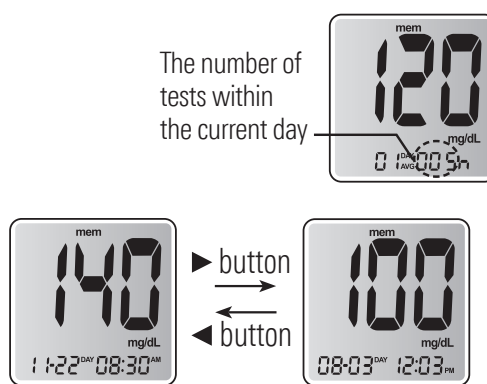
Press the ► or Ⓜ button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1-day average value and the number of the test results saved within the current day.

#### 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

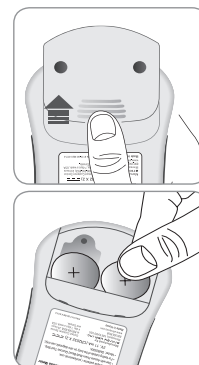
Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.

### 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.

### *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 **disinfection procedure** is needed to prevent the transmission of blood borne pathogens.

A variety of the most commonly used EPA-registered wipes have been tested and approved for cleaning and disinfecting of the Assure Prism multi Blood Glucose Monitoring System.

The disinfectant wipes listed below have been shown to be safe for use with this meter.

Please read the manufacturer's instructions before using their wipes on the meter.

Manufacturer	Disinfectant Brand Name	EPA #
Clorox® Professional Products Company	Clorox® Germicidal Wipes	67619-12
	Dispatch® Hospital Cleaner Disinfectant Towels and Bleach	56392-7
Professional Disposables International, Inc. (PDI)	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**, 24 hours a day, 7 days a week, U.S.A. and Canada.

### *Cleaning and Disinfecting Procedures*

#### **NOTE**

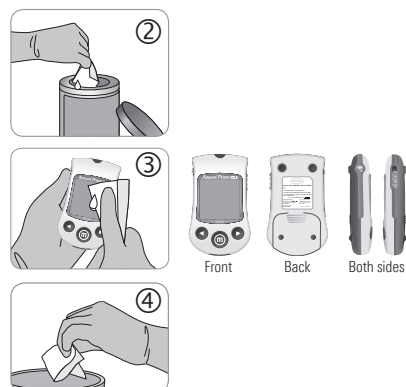
- Do not get fluids inside the meter through the test strip port, data port or battery compartment.
- Never immerse the meter or hold it under running water because it will damage the meter.
- Two disposable wipes will be needed for each cleaning and disinfecting procedure; one wipe for cleaning and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

#### **More information is available at:**

- [www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html](http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html)
- [www.cdc.gov/injectionsafety/blood-glucose-monitoring.html](http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html)
- [www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm)
- [www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html](http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.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.
- Step 4:** Dispose of the used towelette in a trash bin.

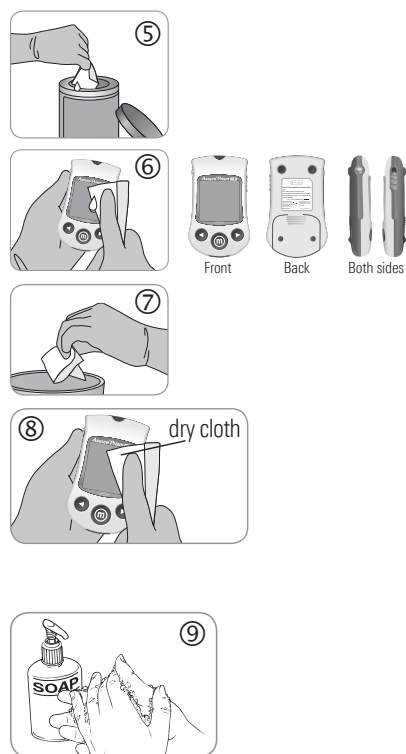


### NOTE

- 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.
- Step 7:** Dispose of the used towelette in a trash bin.
- Step 8:** Allow exteriors to remain wet for the appropriate contact time and then wipe the meter using a dry cloth.



Disinfectant Brand Name	Contact Time
Clorox Germicidal Wipes	1 minute
Dispatch Hospital Cleaner Disinfectant Towels and Bleach	1 minute
Super Sani-Cloth Germicidal Disposable Wipe	2 minutes
CaviWipes1	2 minutes

- 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, 24 hours a day, 7 days a week, U.S.A. and Canada.

- 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.

## TROUBLESHOOTING

### Display Screen Messages

**Please read this section first. If you still have questions, call Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week, U.S.A. and Canada only.**

If outside of the U.S.A. or Canada, contact your local ARKRAY distributor. 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.

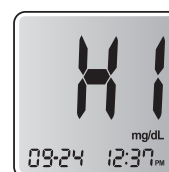
### HI and Lo Messages

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).

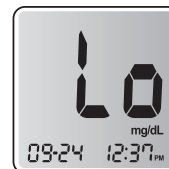
If “HI” is displayed again upon retesting, please contact the patient’s healthcare provider immediately.



#### 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**, 24 hours a day, 7 days a week, U.S.A. and Canada.

### 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.



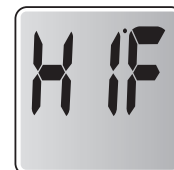
#### Er6: There is a problem with the meter.

Do not use the meter. Contact Technical Customer Service at **800.818.8877**, 24 hours a day, 7 days a week, U.S.A. and Canada.




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

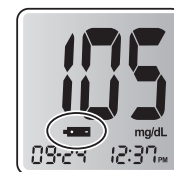
Move to an area where the temperature is within the operating range (50–104°F/10–40°C) and repeat the test after the meter and test strips have reached a temperature within the operating range.

**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**, 24 hours a day, 7 days a week, U.S.A. and Canada.

**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.	<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**, 24 hours a day, 7 days a week, U.S.A. and Canada.

# Regulatory Review and Guidelines for QA/QC Protocols

## SECTION

# C

## 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 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.



## 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 3.5%.

## 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 mg/dL	Within $\pm$ 10 mg/dL	Within $\pm$ 15 mg/dL	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 Control Solution – Level 1 and 2	530006	08317-5300-06

SECTION

D

## 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**, 24 hours a day, 7 days a week, U.S.A. and Canada only.

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"/> Toll-free 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

\_\_\_\_\_  
Next In-service (Month/Year)

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800.818.8877  
www.arkrayusa.com

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 trained to use the Assure® Prism multi Blood Glucose Monitoring System. If no, retrain and perform tasks again.

SECTION

E

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## 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 vial.

**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: \_\_\_\_\_

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## 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: \_\_\_\_\_

## HEALTHCARE PROFESSIONAL IN-SERVICE TRAINING RECORD

### Assure® Prism multi Blood Glucose Monitoring System

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

Trainer Name \_\_\_\_\_

Date	Healthcare Professional's Name	Unit/Station	Trainer Initials

SECTION

E

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

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

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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 \_\_\_\_\_

Date	Healthcare Professional's Name	Title	Training Date

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.

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

## METER TRACKING RECORD

Assure®Prism multi Blood Glucose Monitoring System

Date	Station/Cart	Active Meter Serial #	Replacement Meter Serial #

SECTION

F

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

# Quality Control Record

Assure® Prism multi Blood Glucose Monitoring System

	Assure® Prism multi Blood Glucose Meter	Serial # _____	Unit _____	Month/Year _____
--	-----------------------------------------	----------------	------------	------------------

[illegible]

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

## Field Inspection Report

Assure® Prism multi Blood Glucose Monitoring System

Facility: \_\_\_\_\_ Date: \_\_\_\_\_ Contact: \_\_\_\_\_

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

City, State & zip \_\_\_\_\_ ARKRAY Representative Signature: \_\_\_\_\_

Station	Meter Serial #	Level 1 – Control Solution		Level 2 – Control Solution		Time and Date Correct (Y/N)	Meter Replaced (Y/N)	Replacement Meter Serial #
		Range	Result	Range	Result			

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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