

ASSURE[®] PRISM MULTI

+ BLOOD GLUCOSE MONITORING SYSTEM

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 steadystate blood glucose conditions. The system is intended for use outside the body (in vitro) 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 the auto-disabling, single use lancing device. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

This comprehensive manual has been designed to provide you with a thorough reference source for the Assure® Prism multi System including:

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

All of these materials have been designed to assist you in meeting the necessary requirements for various 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 Customer Service Department at 800.818.8877.

System Components

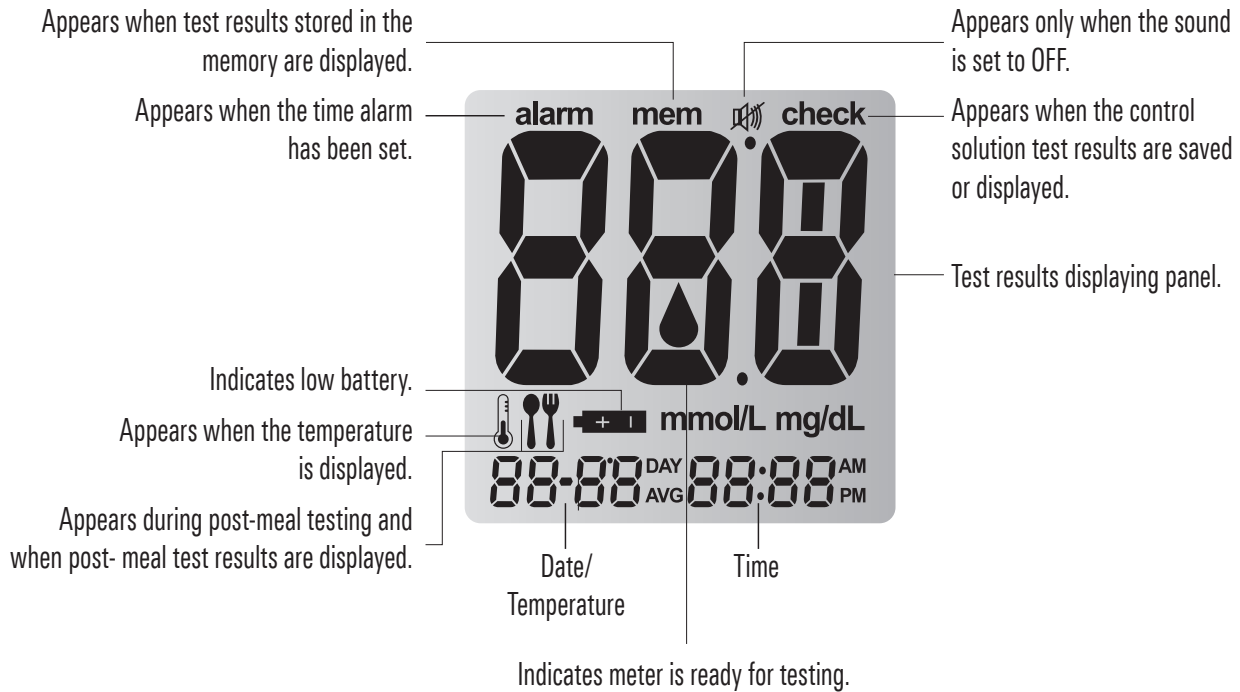
ASSURE® PRISM MULTI BLOOD GLUCOSE METER



ORDERING DETAILS

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

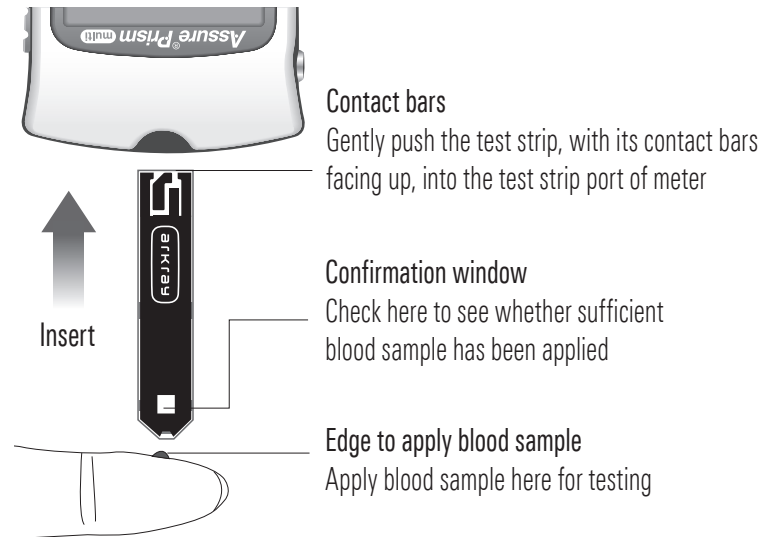
METER DISPLAY SCREEN

**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 Meter is preset and fixed in mg/dL.

ASSURE® PRISM MULTI TEST STRIPS

The Assure® Prism multi Blood Glucose Monitoring System measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the strip.



SAFETY INSTRUCTIONS FOR USING TEST STRIPS

- All components that come into contact with blood samples should be considered biohazards capable of transmitting viral diseases between patients and healthcare professionals.
- Assure Prism multi Test Strips should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use Assure Prism multi Test Strips beyond the expiration date. This may cause inaccurate results.
- Test strips in new, unopened vials and test strips in vials that have been opened can be used up until the expiration date printed on the test strip box and vial label if the test strips are used and stored according to its storage and handling methods.
- Store test strips in a cool and dry place at a temperature of 34-86°F (1-30°C).
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original vial.
- Close the vial tightly after taking out a test strip and use the test strip immediately.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.
- For detailed storage and usage information, refer to the Assure Prism multi Test Strip package insert.
- Keep the meter and testing supplies away from young children.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

ORDERING DETAILS

	ARKRAY Product Code#	NDC#
Assure® Prism multi Test Strips 50-count	530050	08317-5300-50
Assure® Prism multi Test Strips 100-count	530100	08317-5301-00

ASSURE PRISM CONTROL SOLUTION



Assure® Prism
Control Solution

ORDERING DETAILS

ARKRAY Product Code#	NDC#
Assure® Prism Control Solutions 1 & 2	530006
	08317-5300-06

METER SPECIFICATIONS

For additional information refer to the Assure® Prism multi User Manual.

Product Specifications	
Test strips	Assure® Prism multi 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	93 X 56 X 21 mm(3.66 x 2.20 x 0.83 in.)
Weight	59.6 g(2.10 oz)(with batteries)

Operating Ranges	
Temperature	50°F–104°F (10°C–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 the AM/PM 12-hour or the 24-hour clock format. Press **◀** or **▶** to select a format. The 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.



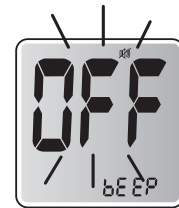
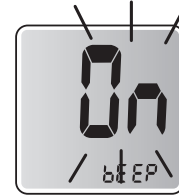
Step 8: Setting the Sound On/OFF

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

PERFORMING A BLOOD GLUCOSE TEST

Caution: To reduce the chance of infection

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

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

For more information, please refer to the following guidelines:

Preparing the Lancing Device

1. "Biosafety in Microbiological and Biomedical Laboratories(BMBL)", <http://www.cdc.gov/biosafety/publications/bmb15/>
2. "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.

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

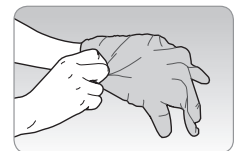
Please read the instructions provided by the lancing device manufacturer before using it.

Step 1

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



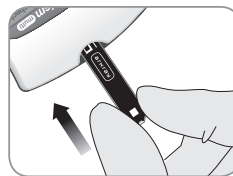
Wear appropriate protective gears such as disposable gloves.



Preparing the Meter and Test Strip

Step 2

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



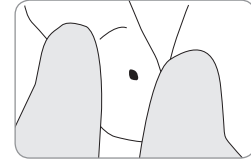
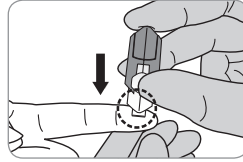
Push the strip gently into the strip port until the meter automatically turns on and the ▲ symbol appears.



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.



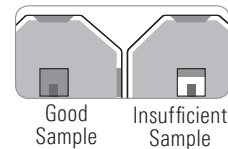
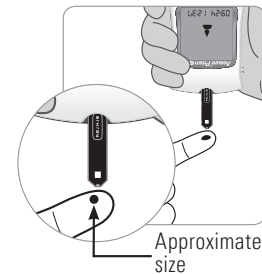
Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window.

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 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 discard used test strips safely in a disposable container.

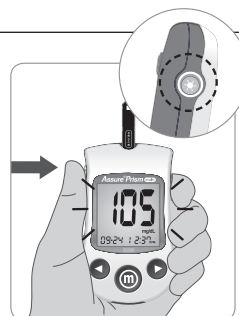
If the test strip is removed, the meter will automatically turn off after 3 seconds.



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 (Control 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 their 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 solutions (Control 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:

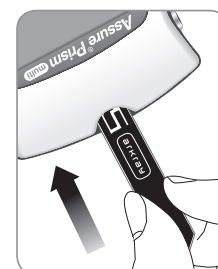
- When you want to practice the test procedure using the control solution instead of blood
- When using the meter for the first time
- Whenever you open a new vial of test strips
- If the meter or test strips do not function properly
- If your symptoms are inconsistent with the blood glucose test results and you feel that the meter or test strips are not working properly
- If you drop or damage the meter

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.

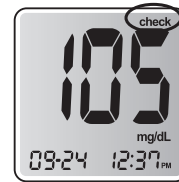


Note: The meter will switch off if the control solution sample is not applied within 2 minutes of the  symbol appearing on the screen. If the meter turns off, remove the strip, reinsert, and start from step 2.

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 your blood.

**Step 6**

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

Caution: The ranges printed on the test strip vial are for Assure® Prism Control Solutions only. They do not have any connection to your 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 Customer Service: 800.818.8877, 24 hours a day, 7 days a week, USA 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"> • When the control solution bottle was not shaken well • When the meter, test strip, or the control solution were exposed to high or low temperatures • When the first drop of the control solution was not discarded or the top of the cap was not wiped clean • When the meter is not functioning properly 	Repeat the control solution test
<ul style="list-style-type: none"> • When the control solution is past the expiration date printed on the bottle • When the control solution is past its discard date (the date the bottle was opened plus three (3) months) • When the control solution is contaminated 	Discard the used control solution and repeat the test using a new bottle of control solution

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

METER MEMORY

The Assure Prism multi 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.

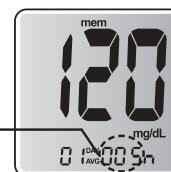
Note: We do not recommend using the memory feature including post meal alarms, pre-set blood glucose or averaging in a multi-patient setting. Results stored in the memory are not related to a specific patient.

Viewing Test Results

Step 1

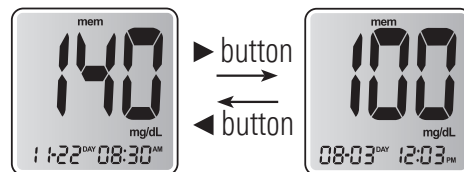
Press the ► or Ⓜ button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

The number of tests within the current day



Step 2

Use the ◀ button to scroll through the test results, starting from the most recent and ending with the oldest. 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 “check” symbol will be displayed with “check” symbol when you review the stored test results.

INSERTING OR REPLACING THE BATTERIES

The Assure® Prism multi 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

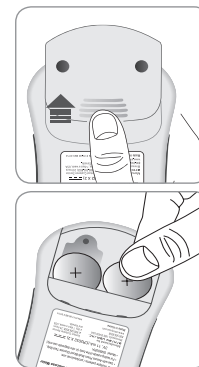
Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.

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. However, you may need to reset your meter settings.

CLEANING AND DISINFECTING THE METER

To minimize the risk of transmission of 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. This 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 as well as blood and other body fluids on the exterior of the meter before performing the disinfection procedure.

The **disinfection procedure** is needed to prevent transmission of blood-borne pathogens.

Clorox Germicidal Wipes with 0.55% sodium hypochlorite as the active ingredient have been tested and approved for cleaning and disinfecting the Assure Prism multi Meter. This disinfectant has been shown to be safe for use with this meter. Please read the instructions for use from the manufacturer of Clorox Germicidal Wipes before use.

Name	Clorox® Germicidal Wipes	
Manufacturer	Clorox Professional Products Company 1.800.537.1415 www.cloroxprofessional.com	
EPA Registration Number	67619-12	
Active Ingredients	0.55% Sodium Hypochlorite	

- Any disinfectant product with the EPA registration number of 67619-12 may be used on this device.
- A list of Environmental Protection Agency (EPA) registered disinfectants effective against HIV, Hepatitis B, and C virus can be found at the following website: http://www.epa.gov/oppad001/list_d_hepatitisbhiv.pdf

Go to <http://www.assureusa.com/cleandisinflect> for the most up-to-date information on approved cleaning and disinfecting procedures and materials for ARKRAY blood glucose meters. If you have any questions, please contact our Technical Customer Service department at **800.818.8877**.

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.

Cleaning

Step 1 Wear appropriate protective gear such as disposable gloves.

Step 2 Open the cap of the Clorox Germicidal Wipes 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 one towelette to clean blood and other body fluids.



Step 4 Dispose of the used towelette in a trash bin. The meter should be cleaned prior to disinfection.



Disinfecting

Step 5 Pull out 1 new towelette and wipe the entire surface of the meter 3 times horizontally and 3 times vertically using a new towelette to remove blood-borne pathogens.



Step 6 Dispose of the used towelette in a trash bin.



Step 7 Allow exteriors to remain wet for 1 minute, then wipe the meter using a dry cloth.



Step 8 After disinfection, the user's gloves should be removed to be thrown away and hands washed before proceeding to the next patient.

Prior to Re-Use

If any of the following deterioration signs appears after cleaning or disinfecting, please stop using the system and contact Customer Service: **800.818.8877**, 24 hours a day, 7 days a week, USA 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
- When control solution test results do not fall within the stated range on the test strip vial

More information is available at:

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html>

<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>

www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

TROUBLESHOOTING

Display Screen Messages

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

HI and Lo Messages

HI Message

The meter displays results between 20-600 mg/dL.

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

If “HI” is displayed again upon retesting, please contact 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 Customer Service: **800.818.8877**, 24 hours a day, 7 days a week, USA and Canada.

Error Messages

A used test strip was inserted.

Repeat the test with a new test strip.



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

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



The blood sample has abnormally high viscosity or insufficient volume.

Repeat the test with a new test strip.



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 test strip.



There is a problem with the meter.

Do not use the meter. Contact Customer Service: **800.818.8877**, 24 hours a day, 7 days a week, USA and Canada.



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.

**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.



Note: If the error messages persist, please contact Customer Service: **800.818.8877**, 24 hours a day, 7 days a week, USA and Canada.

General Troubleshooting

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

Note: If the problem is not resolved, please contact Customer Service: **800.818.8877**, 24 hours a day, 7 days a week, USA and Canada.

Assure® Prism multi Blood Glucose Test Strips

IMPORTANT

Please read this information and the User's Manual of your meter before using the Assure® Prism multi Test Strips.

INTENDED USE

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 such as the 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*) 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 lancening device. It is not intended for use on neonates and are not for the diagnosis or screening of diabetes.

TEST PRINCIPLE

The glucose in the blood sample mixes with special chemicals on the test strip to produce a small electrical current. The meter converts this electrical current to glucose concentration.

STORAGE AND HANDLING

- Store unused test strips only in their original vial.
- Store vial in a cool and dry place between 34-86°F (1-30°C).
- Keep the vial away from direct sunlight and heat.
- Do not freeze test strips or vial.
- Close vial cap tightly immediately after taking out a test strip.
- 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.
- Do not use the expired test strips and dispose the expired test strips immediately because using test strips past their expiration dates can produce incorrect test results.
- Test strips in new, unopened vials and test strips in vials that have been opened can be used until the expiration date printed on the test strip box and vial label if the test strips are used and stored according to its storage and handling methods.

WARNINGS AND PRECAUTIONS

- Keep test strips and the test strip vial away from children. The test strips and vial cap may be choking hazards. Drying agents in the vial cap may be harmful if inhaled or swallowed or may cause skin or eye irritation.
- Test strips are for single use only. Do not reuse.
- If the test strip does not absorb the blood sample properly, please contact Customer Service at 800.818.8877 (24 hours a day, 7 days a week, USA and Canada).

BLOOD SAMPLE COLLECTION PROCEDURE

Wash hands and sample site with soap and warm water. Rinse and dry thoroughly before collecting the blood sample with a lancening device. Wear appropriate protective gears such as disposable gloves.

Fingertip Site Blood Sampling

Place auto-disabling, single-use lancening device against the side of your fingertip. Press the release button. Massage the fingertip to obtain a round drop (at least 0.5 µL) of blood. Apply test strip tip to blood sample.

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 lancening 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.

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's manual for your meter.

CAUTION : To reduce the chance of infection

- All components that come into contact with blood samples should be considered to be biohazards capable of transmitting viral diseases between patients and healthcare professionals.
- Only auto-disabling, single use lancening device should be used for each patient.
- The meter should be disinfected after use on each patient. This BGMS may only be used for testing multiple patients when Standard Precautions and the pre-cleaning and disinfection procedures as recommended in the User's Manual that came with your system are followed.
- You can get more safety information at FDA Public Health Notification (<http://www.fda.gov/MedicalDevices/Safety/AiersandNotices/ucm224025.htm>) or at CDC Clinical Reminder (<http://www.cdc.gov/injection/safety/Fingerstick-DevicesBGMS.html>).

TEST PROCEDURE

- 1) Wash hands and sample site with soap and warm water. Rinse and dry thoroughly. Wear appropriate protective gears such as disposable gloves.
- 2) Insert the test strip into the meter's test strip port with the contact bars facing up. Push the strip in gently into the strip port until the power automatically turns on.
- 3) The ▲ symbol will appear.
- 4) Use a lancening device to get blood sample. The sample must be at least 0.5 µL to fill the test strip reaction cell. When the ▲ symbol appears on the display, apply the blood sample to the edge of the narrow end of the test strip until the meter beeps. If the confirmation window is not filled completely, an "Er4" message will appear.
- 5) Meter will count down from 5 to 1 on the display. The test result, time, and date will appear and automatically store in the meter memory. Remove the used test strip from the test strip port. The meter will turn off after 3 seconds.

TEST RESULTS

The Assure Prism multi Blood Glucose Meter will display results between 20 and 600 mg/dL.

Normal Blood Glucose Results

The range of a normal fasting * blood glucose level for non-diabetic adults is between 70 and 99 mg/dL. Two(2) hours after a meal, the range of a normal blood glucose level for non-diabetic adults is between 100 and 139 mg/dL.
*Fasting is defined as no caloric intake for at least eight(8) hours.

Extremely Low Blood Glucose Results

If the test result is below 20 mg/dL, Lo will appear on the display, showing extreme hypoglycemia (dangerously low blood glucose). Wash and dry your hands thoroughly, then repeat the test with a new test strip. If the result repeats, contact the patient's healthcare provider immediately for advice and treatment.

Extremely High Blood Glucose Results

If the test result is above 600 mg/dL, Hi will appear on the display, showing extreme hyperglycemia (much higher than normal blood glucose). Wash and dry your hands thoroughly, then repeat the test with a new test strip. If the result repeats, contact the patient's healthcare provider immediately for advice and treatment.

Unexpected Results

Low or high blood glucose readings can indicate a potentially serious medical condition. If your results are unusually high or low, or do not match the way you feel, repeat the test with a new test strip. If your reading is inconsistent with your symptoms or your result is less than 60 mg/dL or higher than 240 mg/dL, contact the patient's healthcare provider.

Please note that:

- 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-hypersmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Severe dehydration (excessive water loss) may cause falsely low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
- There is no effect from altitudes of up to 10,000 ft (3,000 m) above sea level.
- Interferences: Acetaminophene, 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.
- Discard used test strips properly in a container for sharp objects.

METER AND TEST STRIP PERFORMANCE CHECK

The Assure Prism Control Solutions (Control 1 and 2) contain fixed amounts of glucose and are used for checking whether the test strips and the meter are working together properly. Run a check when you:

- Want to practice the test procedure using the control solution instead of blood.
- Use the meter for the first time.
- Open a new vial of test strips.
- Have symptoms that are inconsistent with your blood glucose test results.
- Believe your test results are not accurate.
- Suspect your meter and test strips are not performing properly.
- Drop or damage the meter.

If your control solution test results do not fall within the range printed on the test strip vial, repeat the test. Out of range results may be due to one or more of the following factors:

- Error in performing the test.
- Expired or contaminated control solution.
- Expired or damaged test strip.
- Failure to shake the control solution bottle.
- Failure to discard the first drop of control solution and wipe the top of the bottle cap clean.
- Failure to continue to fall outside the range printed on the vial, the Assure Prism multi test strips and the meter may not be working properly. If so, do not use your system and contact Customer Service at 800.818.8877 (24 hours a day, 7 days a week, USA and Canada).

CHEMICAL COMPOSITION

Each Assure Prism multi Test Strip contains the following reagents:

- Glucose oxidase (*Aspergillus sp.*): 2.7 units
- Hexaammonium(III) chloride: 45.7 µg
- Other ingredients: 1.6 µg

PERFORMANCE CHARACTERISTICS

The performance of the Assure Prism multi Blood Glucose Test Strips has been evaluated in laboratory and clinical tests.

Measurement Range

The measurement range of the Assure Prism multi Blood Glucose Monitoring System is 20 to 600 mg/dL.

Accuracy

The Assure Prism multi BGM System is calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the system was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyser, a laboratory instrument. The results below were obtained by diabetic patients at clinic centers.

	Obtained by healthcare professionals	Obtained by lay users
Slope	1.017	1.022
y-intercept	-7.39 mg/dL	-8.31 mg/dL
Correlation coefficient (r)	0.992	0.992
Number of sample	122	118
Range tested	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%)

Accuracy 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%)

This study shows that the system compares well with a laboratory method.

Alternative Site Testing Evaluation

- Comparison of various AST with respect to the results of YSI measurements.
- Alternative site test results for glucose concentration < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip	2/2 (100%)	2/2 (100%)	2/2 (100%)
Forearm	2/2 (100%)	2/2 (100%)	2/2 (100%)
Palm	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
Thigh	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
Calf	1/2 (50.0%)	2/2 (100%)	2/2 (100%)

Alternative site test results for glucose concentration ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	34/56 (60.7%)	51/56 (91.1%)	55/56 (98.2%)	56/56 (100%)
Forearm	32/56 (57.1%)	52/56 (92.9%)	56/56 (100%)	56/56 (100%)
Palm	31/56 (55.4%)	52/56 (92.9%)	54/56 (96.4%)	56/56 (100%)
Thigh	27/56 (48.2%)	44/56 (78.6%)	54/56 (96.4%)	56/56 (100%)
Calf	24/56 (42.9%)	49/56 (87.6%)	53/56 (94.6%)	56/56 (100%)

Precision

Precision studies were performed in a laboratory.

<i>Within Run Precision</i>	
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%

<i>Total Precision</i>	
Control avg.	36.2 mg/dL SD = 1.3 mg/dL
Control avg.	117.0 mg/dL SD = 2.3%
Control avg.	321.8 mg/dL CV = 2.4%

This study shows that there could be variation of up to 3.5%.

Reference

1. American Diabetes Association. "Standards of Medical Care in Diabetes – 2012." Diabetes Care. January 2012; 35(1):S1-S63.

For questions / comments, contact Customer Service at 800.818.8877, 24 hours a day, 7 days a week, USA and Canada.

In case of emergency, consult the patient's healthcare provider or emergency medical response.

Manufactured for:

ARKRAY USA, INC.

Minneapolis, MN 55439 USA

www.arkrayusa.com

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PM 5111-02

FGCE0024 REV00 12/2014

Assure[®] Prism Control Solution

IMPORTANT

Please read the following information and the User's Manual for your meter before using the Assure[®] Prism Control Solution.

INTENDED USE

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

SUMMARY AND EXPLANATION

The Assure Prism Control Solutions (Control 1 and 2) each contain a specific amount of glucose that is used to test the meter and test strips in the Assure Prism multi brand. The Assure Prism Control Solution is for self-testing outside the body (*in vitro* diagnostic use). This control solution may be used to check the performance of your meter and test strip or your testing technique. The test results you obtain should fall within the control solution range printed on the vial of test strips that you are using.

CAUTION

The control solution ranges printed on the test strip vial are for the Assure Prism Control Solution only. These ranges are used to check the meter and test strip performance.

These are not recommended ranges for your blood glucose level.

Use Assure Prism Control Solution when:

- You want to practice the test procedure, without using blood.
- You use your Assure Prism multi brand meter for the first time.
- You begin using a new vial of test strips.
- You suspect that your meter or the test strips are not working properly.
- You think your test results are inaccurate or they do not reflect how you feel.
- You drop your meter.

STORAGE AND HANDLING

Store the Assure Prism Control Solution at temperatures between 46-86°F/8-30°C, tightly capped in the vial. 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.

WARNING AND PRECAUTIONS

- The Assure Prism Control Solution is for *in vitro* diagnostic use only.
- Use Assure Prism Control Solution only with your Assure Prism multi brand meter and its corresponding test strips.
- Do not swallow or inject the control solution.
- Check the expiration date shown on the vial label. Do not use if expired.
- Do not use beyond 3 months (90 days) after opening the vial. Record the discard date (3 months from the day the vial was opened) on the vial label.
- If the control test results are outside the range printed on the test strip vial, do not use your 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.
- This control solution contains a dye that may stain clothes.

TEST PROCEDURE

Step 1

Insert the test strip into the meter's port. The applied blood symbol will appear on the display after 3 seconds.

Step 2

Shake the control solution vial well before using.

Step 3

Discard one or two drops of control solution. Apply one drop of control solution to the top of the control solution cap.

Step 4

Touch the narrow edge of the test strip to the control solution until the meter beeps.

Step 5

Test results appear after the meter counts down to 1. Compare your control result with the appropriate control solution range printed on the test strip vial. If the result falls within the specified range, you are ready to use the meter and the test strips to test your blood.

Step 6

Remove the used test strip from the meter's test strip port. The meter will turn off automatically. Please read your User's Manual for further information before using the Assure Prism Control Solution.

INTERPRETATION OF OUT OF RANGE RESULTS

If your control solution test results do not fall within the expected range printed on the test strip vial, repeat the test. Out-of-range results may be due to one or more of the following factors:

- An error in the way you perform the test.
- Expired or contaminated control solution.
- Damaged or outdated test strips.
- A problem with the meter.
- Control solution is too warm or too cold.
- Failure to shake the control solution vial vigorously or to wipe the top of cap clean.

IMPORTANT

If your control solution test results continue to fall outside the range printed on the test strip vial, the system may not be working properly. Do not use the system. If you are unable to resolve the problem, contact Customer Service (800.818.8877).

CHEMICAL COMPOSITION

Each 4 mL vial of Assure Prism Control Solution contains:

- D-Glucose
- Preservative
- FD&C red dye

For questions / comments, contact Customer Service at 800.818.8877, 24 hours a day, 7 days a week, USA and Canada.

In case of emergency, consult the patient's healthcare provider or emergency medical response.

Manufactured for
ARKRAY USA, INC.
Minneapolis, MN 55439 USA
www.arkrayusa.com

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P/N 5122-02
PGK7E0006 REV 12/14

IN-SERVICE TRAINING

Name of facility: _____

IN-SERVICE GUIDE

ASSURE® PRISM MULTI BLOOD GLUCOSE MONITORING SYSTEM: IN-SERVICE TRAINING AND CERTIFICATION

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

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

Meter: <input type="checkbox"/> Features (strip release button, test strip port, etc.) <input type="checkbox"/> Serial Number <input type="checkbox"/> Storage <input type="checkbox"/> Cleaning and Disinfecting <input type="checkbox"/> Toll-free Customer Service Number	Test Strips: <input type="checkbox"/> Lot Number <input type="checkbox"/> Expiration Date <input type="checkbox"/> Storage <input type="checkbox"/> Control Solution Range <input type="checkbox"/> Proper Strip Insertion <input type="checkbox"/> Handling	Control Solutions: <input type="checkbox"/> Expiration Date <input type="checkbox"/> Acceptable Range <input type="checkbox"/> Test Procedure Safety Lancets: <input type="checkbox"/> Usage / Activation <input type="checkbox"/> Disposal
--	---	---

2. Describe/Demonstrate:

Initial Meter Set-Up Options:
<input type="checkbox"/> Audible Beep
<input type="checkbox"/> Time Format
<input type="checkbox"/> Date Format
<input type="checkbox"/> Backlight Setting

Instructor Name (Print)

Operator-Trainee Name (Print)

Date

Instructor Name (Signature)

Operator-Trainee Name (Signature)

Operator Certified Yes No

Next In-Service (Month/Year)

Date Due: _____

Name of facility: _____

COMPETENCY CHECKLIST

ASSURE PRISM® MULTI BLOOD GLUCOSE MONITORING SYSTEM

Certified Operator _____

Date _____

Certified Trainer _____

The Certified Trainer should observe the Operator performing the following tasks:

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

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, retrain and perform tasks again.

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 Meter. Answer the questions by circling the letter of the statement that is CORRECT. Check your answers against the correct answers, which are located at the end of the test. More than one answer may be acceptable on some questions.

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

- 1. The Assure® Prism multi Meter stores up to _____ tests in memory.**
 - a. 200
 - b. 50
 - c. 500
 - d. 10

- 2. The Assure® Prism multi Test Strips**
 - a. May be reused
 - b. Can be used with other meters besides the Assure® Prism multi
 - 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 not be used if strips have been exposed to extremes in temperature, light, or humidity

6. When applying blood to the Assure® Prism multi 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. If meter does not start after adding the first blood drop, you may apply a second drop.

7. The Assure® Prism multi can be used with

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

8. The Assure® Prism multi should be cleaned and disinfected between patient tests to avoid cross-contamination? True False**9. Nurses who use the Assure® Prism multi meter to test patients should**

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

10. The Assure® Prism multi 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 |

Name of facility: _____

NURSE 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.

Certified Trainer Name _____

Date	Healthcare Professional's Name	Unit/Station	Certified Trainer Initials

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

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

Name of facility: _____

Quality Assurance/Quality Control Recording Forms

METER TRACKING

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

Name of facility: _____

Quality Control Record Assure[®] Prism multi Blood Glucose Monitoring System

Assure[®] Prism multi Meter Serial # _____ Unit _____ Month/Year _____

Date	Station/ Shift	Operator Initials/ Shift	Meter Cleaned and Disinfected (Y / N)	Meter Strip Lot #	Test Exp. Date	Test Strip Normal Lot #	Expiration Date	Normal Control Range	Normal Control Result	Normal High Lot #	Exp. Date	High Control Range	High Control Result	High Corrective Action

ARKRAY USA, Inc.
 Minneapolis, MN 55439 USA
 TEL 800.818.8877
 FAX 952.646.3110
 www.arkrayusa.com

Name of facility: _____

Field Inspection Report Assure® Prism multi Blood Glucose Monitoring System

Facility: _____ Date: _____ Contact: _____

Address: _____ Time: _____ Phone: _____

_____ ARKRAY Representative Signature: _____

Station	Meter Serial #	Normal Control Solution		High Control Solution		Meter Cleaned and Disinfected (Y/N)	Batteries		Set to Correct Settings	Comments
		Range	Result	Range	Result		OK	Changed		

Comments: _____

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Regulatory Review and Guidelines for QA/QC Protocols

COMPETENCY CHECKLIST

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

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 BGM System is calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the Assure Prism multi 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
Slope	1.017	1.022
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Correlation coefficient(r)	0.992	0.992
Number of samples	122	118
Range tested	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 BGMS.

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 SITES TESTING EVALUATION

Comparison of results using various AST sites 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
Fingertip	2/2 (100%)	2/2 (100%)	2/2 (100%)
Forearm	2/2 (100%)	2/2 (100%)	2/2 (100%)
Palm	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
Thigh	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
Calf	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%
Fingertip	34/56 (60.7%)	51/56 (91.1%)	55/56 (98.2%)	56/56 (100%)
Forearm	32/56 (57.1%)	52/56 (92.9%)	56/56 (100%)	56/56 (100%)
Palm	31/56 (55.4%)	52/56 (92.9%)	54/56 (96.4%)	56/56 (100%)
Thigh	27/56 (48.2%)	44/56 (78.6%)	54/56 (96.4%)	56/56 (100%)
Calf	24/56 (42.9%)	43/56 (76.8%)	53/56 (94.6%)	56/56 (100%)

Addendums

PRODUCT ORDERING

PRODUCT	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 1 and 2	530006	08317-5300-06

WARRANTY

Manufacturer's Warranty

ARKRAY USA, Inc. warrants that the Assure® Prism multi Meter 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 part to ARKRAY without first calling to get approval to do so. Customer Service may be reached at **800.818.8877** (24 hours a day, 7 days a week, USA and Canada only).

Manufactured for
ARKRAY USA, INC.
Minneapolis, MN 55439 USA
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