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Introduction

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

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

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

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

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

We trust that this Quality Assurance/Quality Control manual will provide you with the needed support tools for your blood glucose monitoring program. If you have any questions after receiving the manual, please call ARKRAY’s Customer Service Department at 800.818.8877, 24 hours a day, 7 days a week, USA and Canada.
System Components

ASSURE PRISM MULTI BLOOD GLUCOSE METER

Test Strip Port
Insert test strip here

Backlight Button
Turns the backlight on/off (15-second duration)

Button
Selects or changes information, marks control solution test results and scrolls through memory results

Data Transmission Port
Used to transfer data from the meter to a computer with a cable

Test Strip Ejector

Display
Shows results, messages

Button
Selects or changes information, marks control solution test results and scrolls through memory results

Button
Selects or changes information

 ORDERRING DETAILS

ARKRAY Product Code # 530001  NDC # 08317-5300-01
METER DISPLAY SCREEN

- Appears when test results stored in the memory are displayed
- Appears when the time alarm has been set
- Indicates a low battery
- Appears when the temperature is displayed
- Appears during post-meal testing and when post-meal test results are displayed
- Appears only when the sound is set to OFF
- Appears when the test result is saved as a control solution test
- Test result displaying panel
- Indicates meter is ready for testing
- Appears when test results stored in the memory are displayed
- Appears when the time alarm has been set
- Indicates a low battery
- Appears when the temperature is displayed
- Appears during post-meal testing and when post-meal test results are displayed
- Appears only when the sound is set to OFF
- Appears when the test result is saved as a control solution test

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 BLOOD GLUCOSE 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 Blood Glucose Test Strips should be used only with fresh capillary whole blood samples.
• Do not reuse test strips.
• Do not use Assure Prism multi Blood Glucose Test Strips beyond the expiration date as this may cause inaccurate results.
• If the test strips are used and stored according to its storage and handling methods, test strips in new, unopened vials and open vials can be used up until the expiration date printed on the test strip box and vial label.

INDIVIDUALLY WRAPPED TEST STRIPS

When using the individually wrapped test strips:
• Check the expiration date on the rear side.
• Tear off the individual wrap on the notch, take the test strip out and use it immediately.

NOTE
• The control solution ranges for the individually wrapped test strips are printed on the test strip box.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>ARKRAY Product Code #</th>
<th>NDC #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assure Prism multi Blood Glucose Test Strips 50 count</td>
<td>530050</td>
<td>08317-5300-50</td>
</tr>
<tr>
<td>Assure Prism multi Blood Glucose Test Strips 100 count</td>
<td>530100</td>
<td>08317-5301-01</td>
</tr>
<tr>
<td>Assure Prism multi Blood Glucose Test Strips Foil-wrapped 50 count</td>
<td>532050</td>
<td>08317-5320-50</td>
</tr>
</tbody>
</table>
ASSURE PRISM CONTROL SOLUTION

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

### Ordering Details

<table>
<thead>
<tr>
<th>Product Description</th>
<th>ARKRAY Product Code #</th>
<th>NDC #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assure® Prism Control Solutions Control 1 and 2</td>
<td>530006</td>
<td>08317-5300-06</td>
</tr>
</tbody>
</table>

### Product Specifications

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

### Operating Ranges

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>50–104°F (10–40°C)</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>10–90%</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>20–60%</td>
</tr>
<tr>
<td>Altitude</td>
<td>10,000 ft (3,048 meters)</td>
</tr>
<tr>
<td>Unit of measurement</td>
<td>mg/dL</td>
</tr>
</tbody>
</table>
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

- 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 biohazards 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 14.

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/


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 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 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 (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 the labels.* Compare the result displayed on the meter to the Assure Prism Control Solution range printed on the test strip vial or on the individually wrapped test strip box. Before using a new meter or a new vial/box of test strips, you should conduct a control solution test following the procedure with two different levels of solutions (Control 1 and 2).

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

NOTE

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

You should do a control solution test:

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

Assure Prism Control Solution Testing

Step 1

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

Gently push the test strip into the test strip port until the meter beeps. Be careful not to bend the strip while pushing it in. The ▲ symbol will be displayed on the screen.
Step 2
Shake the Assure Prism Control Solution bottle well before each test.

Step 3
Remove the cap and squeeze the bottle to discard the first 1 or 2 drops. Apply one drop of control solution to the top of the control solution cap.

Step 4
After the ▲ symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.

NOTE
• The meter will switch off if the control solution sample is not applied within 2 minutes of the ▲ symbol appearing on the screen. If the meter turns off, remove the 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 or on the individually wrapped test strip box. 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 or on the individually wrapped test strip box 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 Customer Service at 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 or on the individually wrapped test strip box. 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:

<table>
<thead>
<tr>
<th>Situations</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• When the control solution bottle was not shaken well.</td>
<td>Repeat the control solution test.</td>
</tr>
<tr>
<td>• When the meter, test strip or the control solution were exposed to high or low temperatures.</td>
<td></td>
</tr>
<tr>
<td>• When the first drop of the control solution was not discarded or the top of the cap was not wiped clean.</td>
<td></td>
</tr>
<tr>
<td>• When the meter is not functioning properly.</td>
<td></td>
</tr>
<tr>
<td>• When the control solution is past the expiration date printed on the bottle.</td>
<td>Discard the used control solution and repeat the test using a new bottle of control solution.</td>
</tr>
<tr>
<td>• When the control solution is past its discard date (the date the bottle was opened plus three [3] months).</td>
<td></td>
</tr>
<tr>
<td>• When the control solution is contaminated.</td>
<td></td>
</tr>
</tbody>
</table>

If results continue to fall outside the range printed on the test strip vial or on the individually wrapped test strip box, the test strip and meter may not be working properly. Do not use your system and contact Customer Service at 800.818.8877, 24 hours a day, 7 days a week, USA 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/oppad001/list_d_hepatitisbhiv.pdf](http://www.epa.gov/oppad001/list_d_hepatitisbhiv.pdf)

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, USA 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.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.

<table>
<thead>
<tr>
<th>Disinfectant Brand Name</th>
<th>Contact Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clorox Germicidal Wipes</td>
<td>1 minute</td>
</tr>
<tr>
<td>Dispatch Hospital Cleaner</td>
<td>1 minute</td>
</tr>
<tr>
<td>Dispatch Hospital Cleaner Disinfectant</td>
<td>1 minute</td>
</tr>
<tr>
<td>Towels and Bleach</td>
<td></td>
</tr>
<tr>
<td>Super Sani-Cloth Germicidal Disposable</td>
<td>2 minutes</td>
</tr>
<tr>
<td>Wipe</td>
<td></td>
</tr>
<tr>
<td>CaviWipes1</td>
<td>2 minutes</td>
</tr>
</tbody>
</table>

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 Customer Service at 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.
TROUBLESHOOTING

Display Screen Messages

Please read this section first. 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 of the USA or 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

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 Customer Service at 800.818.8877, 24 hours a day, 7 days a week, USA 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 Customer Service at 800.818.8877, 24 hours a day, 7 days a week, USA 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 Customer Service at 800.818.8877, 24 hours a day, 7 days a week, USA and Canada.

General Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Troubleshooting</th>
</tr>
</thead>
</table>
| The display is blank even after inserting a test strip. | • 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. | • Check if the confirmation window is filled completely.  
• Repeat the test after inserting a new test strip. |
| The patient’s test result does not match their symptoms. | • 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 at 800.818.8877, 24 hours a day, 7 days a week, USA and Canada.
**Assure® Prism multi Blood Glucose Test Strips**

**INTENDED USE**
The Assure® Prism multi Blood Glucose Test Strips are for use with the Assure® Prism multi Blood Glucose Meter and are intended to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip and alternative sites (forearm, palm, thigh, calf). Alternative site testing should not be used for the monitoring of patients by healthcare professionals who are not trained in its use. Use of the device should only be performed by individuals that are trained in the use of the device.

**TEST PRINCIPLE**
The device uses a test Strip containing a reagent and an enzyme for the determination of glucose in whole blood samples. The reagent is coated with a polymeric material that binds glucose. The enzyme catalyzes the conversion of glucose to a color that is proportionate to the amount of glucose in the sample.

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

**NORMAL GLUCOSE RESULTS**
The range of normal testing blood glucose level for non-diabetic adults is between 70 and 100 mg/dL. Two-hour after meal. The range of a normal blood glucose level for non-diabetic adults is less than 140 mg/dL.

**LIMITATIONS**
- An abnormally high or low blood glucose levels, and less than 40 mg/dL or greater than 300 mg/dL is not within the normal range. It may indicate serious illness.

**ALTERNATIVE SITE TESTING**
- Wash hands and clean site with soap and water. Rinse and dry thoroughly before collecting the whole blood sample with a lancet. View appropriate precautions such as disposable gloves.
- Finger stick Blood Sampling
- Place a lancet on the side and repeat the step on the other. Press the release button to the bottom. Repeat the lancet on the other site.
- Advance site Blood Sampling (forearm, palm, thigh, calf)
- Select a clean, soft and sterile site free of visible veins and avoid from bones. Gently massage the site to increase blood circulation to minimize differences between fingerstick and alternative site testing results. Place a lancet on the side of your fingers. Press the release button to the bottom. Repeat the lancet on the other site. Perform the step on the site to obtain a round drop (0.5 m L) of blood. Apply Test strip to the device.

**CAUTION**
- Avoid the site and fingertip results may differ significantly due to rapid changes in the glucose levels after meals or exercise, hormonal dysfunction, or effects of drugs such as insulin or oral hypoglycemic agents. Avoid testing in conditions that affect blood glucose levels significantly. Avoid testing in conditions that affect blood glucose levels significantly.
- Avoid testing in conditions that affect blood glucose levels significantly.

**INDIVIDUALLY WRAPPED TEST STRIP**
- When using individually wrapped test strips, carefully remove the package and instruct the patient to:
  - Turn off the meter before affixing the test strip to the test strip port. The meter will be on after about 8 sec.

**PERFORMANCE CHARACTERISTICS**
- The performance of the Assure® Prism multi Blood Glucose Test Strips has been evaluated in laboratory and clinical tests.
- Accuracy of the Assure® Prism multi Blood Glucose Monitoring 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 101 Meter 2300 glucose analyzer, a laboratory instrument. The results were then obtained from diabetic patients at clinical centers.

**Manufactured for:**
ARKAY USA, Inc.
Minneapolis, MN 55439 USA
www.arkayusa.com
**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 meter 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 (Level 1 and 2) each contain a specific amount of glucose that is used to test the meter and test strips. The Assure® Prism Control Solutions are for self-testing outside the body (*In Vitro* diagnostic use). The control solution may be used to check the performance of the meter and test strip or your testing technique. The test results obtained should fall within the control solution range printed on the vial of test strips that you are using.

**INTERPRETATION OF OUT-OF-RANGE RESULTS**
If the 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

**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.

**Important**

Please read the following information and the User’s Manual for the meter before using the Assure® Prism Control Solutions.

**Use Assure® Prism Control Solution when:**
- You want to practice the test procedure, without using 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 your test results are inaccurate or they do not reflect how the patient feels
- You drop the meter

**STORAGE AND HANDLING**
Store the Assure® Prism Control Solution at temperatures between 46°F-86°F/8°C-30°C, tightly capped in the vial. It must be kept at room temperature (68°F-77°F/20°C-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 the Assure® Prism Control Solution 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 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 the system to test blood until you have resolved the problem.
- Control Solution, meter and test strips must be stored at room temperature (68°F-77°F/20°C-25°C) at least 30 minutes before testing.
- The 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 the control solution 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 test strips to test blood.

**Step 6**
Remove the used test strip from the meter’s test strip port. The meter will turn off automatically. Please read the User’s Manual for further information before using the Assure® Prism Control Solution.
### Regulatory Review and Guidelines for QA/QC Protocols

#### COMPETENCY CHECKLIST

<table>
<thead>
<tr>
<th>Category</th>
<th>Joint Commission on Accreditation of Healthcare Organizations (JCAHO)</th>
<th>Clinical and Laboratory Standards Institute (CLSI) (Formerly NCCLS)</th>
<th>Clinical Laboratory Improvement Amendments (CLIA)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personnel/Training</strong></td>
<td>• Staff members can describe or demonstrate their roles and responsibilities (HR.2.20).</td>
<td>• Formal training and written examination.</td>
<td>• Follow manufacturer’s instructions.</td>
</tr>
<tr>
<td></td>
<td>• Participate in ongoing in-services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Education is documented (HR.2.30).</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Competence to perform job responsibilities is assessed, demonstrated, and maintained (HR.3.10).</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quality Assurance</strong></td>
<td>• Current and complete policies are available to the person performing the test.</td>
<td>• Follow manufacturer’s instructions for calibration.</td>
<td>• Follow manufacturer’s instructions.</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
<td>• Written procedure manual.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Manual contains principles of operation, reagents/equipment, calibration, quality control, stepwise procedure, reporting results, procedure limitations, references, supplemental material, review and updates.</td>
<td>• Manual contains principles of operation, reagents/equipment, calibration, quality control, stepwise procedure, reporting results, procedure limitations, references, supplemental material, review and updates.</td>
<td></td>
</tr>
<tr>
<td><strong>Quality Control</strong></td>
<td>• Written quality control plan that specifies how procedures will be controlled.</td>
<td>• On each day of use, two control solutions (Level 1 and 2) should be performed per instrument.</td>
<td>• Follow manufacturer’s instructions.</td>
</tr>
<tr>
<td></td>
<td>• At the least, perform as frequently as recommended by manufacturer.</td>
<td>• Prior to the first test of the day, each operator is to perform a quality control test.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Should include two levels of control solution.</td>
<td>• Additional checks should be performed when:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• At the least, quality control procedures are performed once each day on each instrument used for resident testing (PC.16.50).</td>
<td>• A new bottle of strips is opened.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Each time a reagent lot is changed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• To ensure the strips and meter are functioning properly.</td>
<td></td>
</tr>
<tr>
<td><strong>Linearity/Calibration</strong></td>
<td>• Linearity not covered in the standards.</td>
<td>• Initially and as specified by manufacturer or as required by government or accrediting bodies.</td>
<td>• Follow manufacturer’s instructions.</td>
</tr>
<tr>
<td><strong>Proficiency Training</strong></td>
<td>• Not specified.</td>
<td>• Participate in program that meets accreditation, federal and state regulations.</td>
<td>• Not specified.</td>
</tr>
<tr>
<td><strong>Inspections</strong></td>
<td>• Currently triennial (APP-5).</td>
<td>• Not a certifying agency.</td>
<td>• Not subject to routine survey.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Conducted only when authorized by the RO.</td>
</tr>
</tbody>
</table>

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.

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

Accuracy
Results for glucose concentration < 75 mg/dL
<table>
<thead>
<tr>
<th>Within ± 5 mg/dL</th>
<th>Within ± 10 mg/dL</th>
<th>Within ± 15 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/11 (100%)</td>
<td>11/11 (100%)</td>
<td>11/11 (100%)</td>
</tr>
</tbody>
</table>

Results for glucose concentration ≥ 75 mg/dL
<table>
<thead>
<tr>
<th>Within ± 5%</th>
<th>Within ± 10%</th>
<th>Within ± 15%</th>
<th>Within ± 20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>47/111 (42%)</td>
<td>89/111 (80%)</td>
<td>109/111 (98%)</td>
<td>111/111 (100%)</td>
</tr>
</tbody>
</table>

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

Within Run Precision

<table>
<thead>
<tr>
<th>Blood avg.*</th>
<th>41.4 mg/dL</th>
<th>SD = 1.8 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood avg.*</td>
<td>79.6 mg/dL</td>
<td>SD = 2.8 mg/dL</td>
</tr>
<tr>
<td>Blood avg.*</td>
<td>129.8 mg/dL</td>
<td>CV = 2.6%</td>
</tr>
<tr>
<td>Blood avg.*</td>
<td>201.9 mg/dL</td>
<td>CV = 3.1%</td>
</tr>
<tr>
<td>Blood avg.*</td>
<td>349.6 mg/dL</td>
<td>CV = 2.7%</td>
</tr>
</tbody>
</table>

Total Precision

<table>
<thead>
<tr>
<th>Control avg.*</th>
<th>36.2 mg/dL</th>
<th>SD = 1.3 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control avg.*</td>
<td>117.0 mg/dL</td>
<td>CV = 2.3%</td>
</tr>
<tr>
<td>Control avg.*</td>
<td>321.8 mg/dL</td>
<td>CV = 2.4%</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th></th>
<th>Within ± 5 mg/dL</th>
<th>Within ± 10 mg/dL</th>
<th>Within ± 15 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fingertip</strong></td>
<td>2/2 (100%)</td>
<td>2/2 (100%)</td>
<td>2/2 (100%)</td>
</tr>
<tr>
<td><strong>Forearm</strong></td>
<td>2/2 (100%)</td>
<td>2/2 (100%)</td>
<td>2/2 (100%)</td>
</tr>
<tr>
<td><strong>Palm</strong></td>
<td>1/2 (50.0%)</td>
<td>2/2 (100%)</td>
<td>2/2 (100%)</td>
</tr>
<tr>
<td><strong>Thigh</strong></td>
<td>1/2 (50.0%)</td>
<td>2/2 (100%)</td>
<td>2/2 (100%)</td>
</tr>
<tr>
<td><strong>Calf</strong></td>
<td>1/2 (50.0%)</td>
<td>2/2 (100%)</td>
<td>2/2 (100%)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Within ± 5 mg/dL</th>
<th>Within ± 10 mg/dL</th>
<th>Within ± 15 mg/dL</th>
<th>Within ± 20%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fingertip</strong></td>
<td>34/56 (60.7%)</td>
<td>51/56 (91.1%)</td>
<td>55/56 (98.2%)</td>
<td>56/56 (100%)</td>
</tr>
<tr>
<td><strong>Forearm</strong></td>
<td>32/56 (57.1%)</td>
<td>52/56 (92.9%)</td>
<td>56/56 (100%)</td>
<td>56/56 (100%)</td>
</tr>
<tr>
<td><strong>Palm</strong></td>
<td>31/56 (55.4%)</td>
<td>52/56 (92.9%)</td>
<td>54/56 (96.4%)</td>
<td>56/56 (100%)</td>
</tr>
<tr>
<td><strong>Thigh</strong></td>
<td>27/56 (48.2%)</td>
<td>44/56 (78.6%)</td>
<td>54/56 (96.4%)</td>
<td>56/56 (100%)</td>
</tr>
<tr>
<td><strong>Calf</strong></td>
<td>24/56 (42.9%)</td>
<td>43/56 (76.8%)</td>
<td>53/56 (94.6%)</td>
<td>56/56 (100%)</td>
</tr>
</tbody>
</table>
Addendums

PRODUCT ORDERING

<table>
<thead>
<tr>
<th>Product Description</th>
<th>ARKRAY Product Code #</th>
<th>NDC #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assure Prism multi Meter Blood Glucose Meter</td>
<td>530001</td>
<td>08317-5300-01</td>
</tr>
<tr>
<td>Assure Prism multi Test Strips 50 count</td>
<td>530050</td>
<td>08317-5300-50</td>
</tr>
<tr>
<td>Assure Prism multi Test Strips 100 count</td>
<td>530100</td>
<td>08317-5301-01</td>
</tr>
<tr>
<td>Assure Prism multi Test Strips – Foil-wrapped 50 count</td>
<td>532050</td>
<td>08317-5320-50</td>
</tr>
<tr>
<td>Assure Prism Control Solution – Control 1 and 2</td>
<td>530006</td>
<td>08317-5300-06</td>
</tr>
</tbody>
</table>

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. Customer Service may be reached at 800.818.8877, 24 hours a day, 7 days a week, USA and Canada only.
IN-SERVICE TRAINING AND CERTIFICATION
ASSURE® PRISM MULTI BLOOD GLUCOSE MONITORING SYSTEM

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:

<table>
<thead>
<tr>
<th>Meter</th>
<th>Test Strips</th>
<th>Control Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Features (strip release button, test strip port, etc.)</td>
<td>□ Lot Number</td>
<td>□ Expiration Date</td>
</tr>
<tr>
<td>□ Serial Number</td>
<td>□ Expiration Date</td>
<td>□ Acceptable Range</td>
</tr>
<tr>
<td>□ Storage</td>
<td>□ Storage</td>
<td>□ Test Procedure</td>
</tr>
<tr>
<td>□ Cleaning and Disinfecting</td>
<td>□ Control Solution Range</td>
<td></td>
</tr>
<tr>
<td>□ Toll-free Customer Service Number</td>
<td>□ Proper Strip Insertion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Handling</td>
<td></td>
</tr>
</tbody>
</table>

*Actual blood sampling is not required.

2. Describe/Demonstrate:

<table>
<thead>
<tr>
<th>Initial Meter Set-Up Options</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Audible Beep</td>
<td></td>
</tr>
<tr>
<td>□ Time Format</td>
<td></td>
</tr>
<tr>
<td>□ Date Format</td>
<td></td>
</tr>
</tbody>
</table>

Name of facility: ________________________________________________

Instructor Name (Print) ________________________________ Operator/Trainee Name (Print) ________________________________ Date ____________

Instructor Name (Signature) ________________________________ Operator/Trainee Name (Signature) ________________________________ Date ____________

Operator Certified □ Yes □ No Next In-service (Month/Year) ____________

Minneapolis, MN 55439 USA
TEL 800.818.8877
FAX 952.646.3110
www.arkrayusa.com
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. Follow facility protocol for quality control testing. □ YES □ NO
2. Change battery. □ YES □ NO
3. Select and prepare the fingerstick site correctly. □ YES □ NO
4. Use lancet/lancing device correctly.* □ YES □ NO
5. Dispose of lancet correctly. □ YES □ NO
6. Insert test strip into meter correctly. □ YES □ NO
7. Apply blood to sample-application tip correctly. □ YES □ NO
8. Record result correctly. □ YES □ NO
9. Identify when to repeat test or check result with a laboratory test. □ YES □ NO
10. Perform control solution test correctly. □ YES □ NO
11. Saving control solution test correctly. □ YES □ NO
12. Clean/disinfect meter correctly. □ YES □ NO

* Actual blood sampling is not required.

Did the Operator perform each task correctly? □ YES □ NO
If yes, the Operator is now certified to use the Assure® 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 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 certified 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 not be used if strips have been exposed to extremes in temperature, light, or humidity.

6. **When applying blood to the Assure Prism multi Blood Glucose Test Strips**
   a. Smear the blood sample.
   b. Apply it to the narrow end of the test strip until the meter beeps.
   c. The test result will appear after the meter counts down from 5 to 1.
   d. You may apply a second blood drop if meter does not start after adding the first drop.

7. **The Assure Prism multi Blood Glucose Meter can be used with**
   a. Whole blood.
   b. Serum or plasma.
   c. Neonatal blood samples.
   d. Venous blood.

8. **The Assure Prism multi Blood Glucose Monitoring System should be cleaned and disinfected between patient tests to avoid cross-contamination?**
   - [ ] True  
   - [ ] False

9. **Nurses who use the Assure Prism multi Blood Glucose Monitoring System to test patients should**
   a. Wear gloves when cleaning the meter.
   b. Test the meter with two control solutions.
   c. Not rely on the memory or average features as they are not related to a specific patient.
   d. Use a safety lancet, such as the Assure® Lance, to obtain a patient’s blood sample.

10. **The Assure Prism multi Blood Glucose Meter uses four 3.0V lithium batteries**
    - [ ] True  
    - [ ] False

Name: ____________________________________________________________

Date: ____________________________________________________________

Score: ________________________________
**SELF-TEST**

ASSURE® PRISM MULTI BLOOD GLUCOSE MONITORING SYSTEM

### Answer Key

<p>| | |</p>
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<td>1.</td>
<td>c</td>
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<tr>
<td>2.</td>
<td>c, d</td>
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<td>b, c</td>
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<td>a, b, c, d</td>
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<td>10.</td>
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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 ________________________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Healthcare Professional’s Name</th>
<th>Unit/Station</th>
<th>Certified Trainer Initials</th>
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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: ____________________________________________

arkray USA, INC.
Minneapolis, MN 55439 USA
TEL 800.818.8877
FAX 952.646.3110
www.arkrayusa.com
CERTIFIED INSTRUCTOR TRAINING RECORD
ASSURE® PRISM MULTI BLOOD GLUCOSE MONITORING SYSTEM
The healthcare professionals listed below have been trained to serve as Certified Trainers for the Assure® Prism multi Blood Glucose Monitoring System. They are qualified to perform initial training of certified operations, conduct performance reviews, and maintain records concerning Certified Operators.

ARKRAY Representative Name ______________________________________________

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 Certified Trainer.

Table:

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<th>Date</th>
<th>Healthcare Professional’s Name</th>
<th>Title</th>
<th>Recertification Date</th>
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Quality Assurance/Quality Control Recording Forms

Name of facility: ______________________________________________________

**METER TRACKING RECORD**
**ASSURE® PRISM MULTI BLOOD GLUCOSE MONITORING SYSTEM**

<table>
<thead>
<tr>
<th>Date</th>
<th>Station/Cart</th>
<th>Active Meter Serial #</th>
<th>Replacement Meter Serial #</th>
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# Quality Control Record
**Assure® Prism multi Blood Glucose Monitoring System**

**Assure® Prism multi Blood Glucose Meter Serial #** _________________  **Unit** _________________  **Month/Year** ____________

<table>
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<tr>
<th>Date</th>
<th>Station/Shift</th>
<th>Operator Initials/Shift</th>
<th>Meter Cleaned and Disinfected (Y/N)</th>
<th>Test Strip Lot #</th>
<th>Test Strip Exp. Date</th>
<th>Control 1 Exp. Date</th>
<th>Control 1 Range</th>
<th>Control 1 Result</th>
<th>Control 2 Exp. Date</th>
<th>Control 2 Range</th>
<th>Control 2 Result</th>
<th>Ctl. Sol. Discard Date</th>
<th>Corrective Action (Y/N)</th>
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**Corrective Action Date and Explanation**  _________________

**arkray usa, inc.**  
Minneapolis, MN 55439 USA  
TEL 800.818.8877  
FAX 952.646.3110  
www.arkrayusa.com
### Field Inspection Report

Assure® Prism multi Blood Glucose Monitoring System

<table>
<thead>
<tr>
<th>Station</th>
<th>Meter Serial #</th>
<th>Control 1 – Control Solution</th>
<th>Control 2 – Control Solution</th>
<th>Time and Date Correct</th>
<th>Meter Replaced</th>
<th>Replacement Meter Serial #</th>
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Comments: ____________________________________________________________

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