



EVENCARE[®] ProView[™]

Blood Glucose Monitoring System



Healthcare Professional Operator's Manual
Operator's Manual & In-Service Guide



EVENCARE[®] **ProView**[™]

Blood Glucose Monitoring System





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OPERATOR'S MANUAL

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OPERATOR'S MANUAL

Thank you for choosing the EVENCARE ProView Professional Blood Glucose Monitoring System to help monitor your patients' blood glucose levels. The EVENCARE ProView Professional Blood Glucose Monitoring System is designed to be accurate and easy to use. The EVENCARE ProView Professional Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is indicated to be used for multiple patients in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus. This system should only be used with single-use, auto-disabling lancing devices.

If you need assistance, please call Medline's Technical Service Center at 1-866-274-2131 Monday through Friday between 8:00 am and 5:00 pm (Central Time).

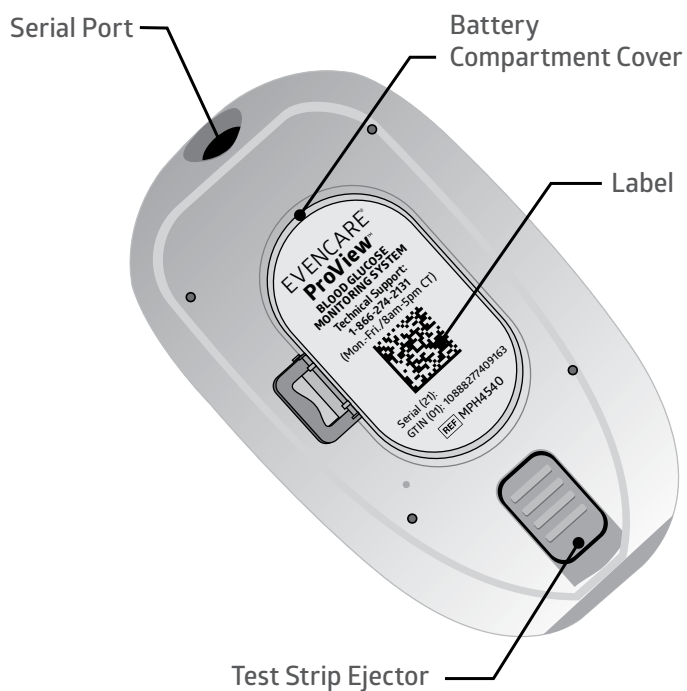


EVENCARE PROVIEW METER OVERVIEW

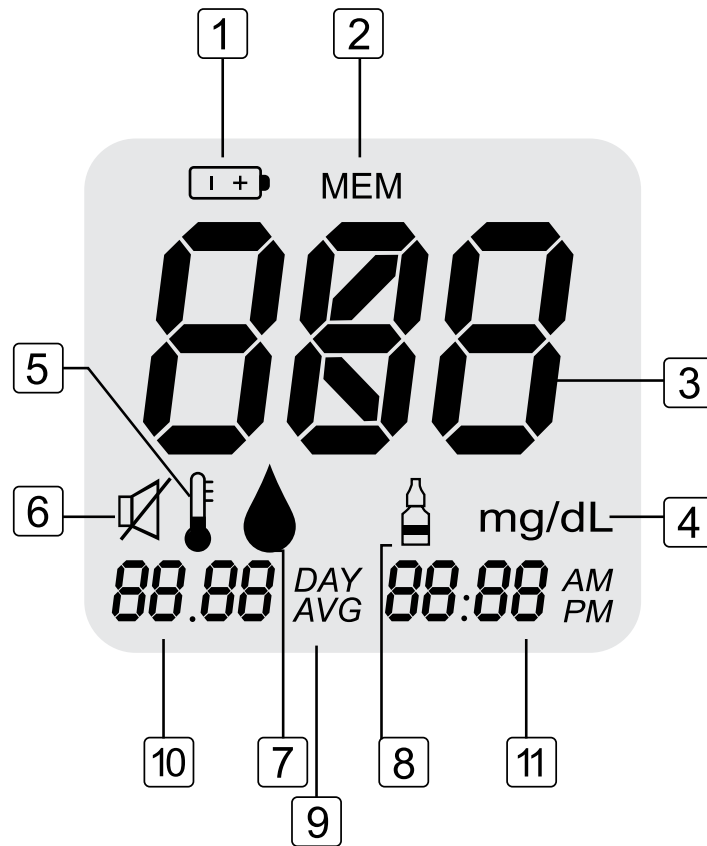
EVENCARE ProView Meter Front



EVENCARE ProView Meter Back



METER DISPLAY SCREEN



1		Low Battery Warning
2	MEM	Stored Test Results
3	000	Test Results
4	mg/dL	Unit of Measure
5		Temperature Error
6		Beeping Sound Muted
7		Ready to Test
8		Control Solution
9	AVG	Average Result
10	88.88	Month/Date
11	88:88	Time

SYSTEM SPECIFICATIONS

Test Strips:	EVENCARE ProView Blood Glucose Test Strips (not included)
Dimensions (L x W x H):	18 x 51 x 88 mm
Weight:	48 g (with batteries)
Test Range:	20–600 mg/dL
Calibration:	Plasma-equivalent
Test Time:	5 seconds
Sample Size:	Minimum 0.5µL
Hematocrit Range:	30%–55%
Display Type:	LCD screen
Memory:	300 test results
Result Averaging:	14 day averaging
Battery:	2 x 3V CR2032 Lithium coin cell battery
Automatic Power-Off:	After 2 minutes of non use
Operating Temperature:	50°F–104°F
Operating Humidity:	10%–90% RH.
Meter:	EVENCARE ProView Blood Glucose Test Meter
Test Sample:	Fresh capillary whole blood
Storage Temperature:	39.2°F–86°F

For additional information, refer to the EVENCARE ProView Blood Glucose Test Strip insert.

EVENCARE PROVIEW CONTROL SOLUTION TESTING

EVENCARE ProView Glucose Control Solution is the standard glucose concentration solution required to perform a control solution test. It is available at two levels, EVENCARE ProView Level 2 Glucose Control Solution and EVENCARE ProView Level 3 Glucose Control Solution. Run the control tests to make sure the meter and test strips are working properly together, to practice testing procedure, and when using a new package of EVENCARE ProView Blood Glucose Test Strips.

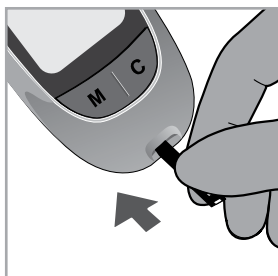
You should perform a control solution test when:

- » Using the meter for the first time.
- » Using a new package of EVENCARE ProView Blood Glucose Test Strips.
- » At least once per week to verify that the meter and test strips are working properly together.
- » For vial strips, if the test strip bottle is left open.
- » The meter is dropped.
- » You suspect the meter and test strips are not working properly together.
- » A patient's test results do not agree with how they feel.
- » A patient's readings appear to be abnormally high or low.
- » Test strips have been exposed to a condition outside the specified storage conditions.
- » Practicing your testing technique.

MATERIALS NEEDED:

- » EVENCARE ProView Meter
- » EVENCARE ProView Glucose Control Solutions (Level 2 or Level 3)
- » A new EVENCARE ProView Blood Glucose Test Strip






Insert test strip.



Results will appear in 5 seconds.

Step 1. Insert a test strip into the meter with the arrow facing up. Make sure to firmly and completely insert the test strip into the meter. The meter will turn on automatically.

Step 2. When the blood drop icon  appears on the screen, shake the bottle of control solution and then squeeze a drop of the control solution onto a clean, dry, non-absorbent surface such as a table top. Bring the test strip gently to the drop of control solution so the sampling end of the test strip touches the control. The drop of control solution will be drawn in automatically by the test strip.

Step 3. When the test strip confirmation window is full, the meter will beep. The meter will count down from five seconds and then show the control solution result.

Step 4. Press the **M button** to mark the control solution result. The control solution bottle symbol will appear on the display with the result.

Step 5. Compare the result on the screen to the control solution range printed on the test strip bottle.

NOTE:

- » Mark all control solution tests with the control solution symbol to distinguish them from blood glucose test results in the meter memory. Marked control solution results will not be included in 14 day average.
- » Each LOT of test strip vial may have a different acceptable range.

Step 6. Eject the test strip into a proper waste container.

IMPORTANT

- » Use only EVENCARE ProView Glucose Control Solutions with the EVENCARE ProView Blood Glucose Test Strips. Other brands of control solutions will produce inaccurate results.
- » Always check the expiration date of the control solution. DO NOT use expired control solution.
- » Record the date on the bottle when opening a new bottle of control solution. Discard any unused control solution three months after the opening date.
- » Control solutions are good three months after opening date or until the last day of the month of expiration, whichever comes first.
- » DO NOT FREEZE. Store the control solution at room temperature of 39.2°F–86°F.
- » Do not use test strips that are expired. Check the expiration date printed on the test strip package.
- » Use each test strip immediately after removing it from the bottle.
- » Close the cap of the bottle immediately after removing a test strip.
- » Do not use wet, bent, scratched, or visibly damaged test strips.
- » Keep the test strips away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- » Record the date on the bottle when you open a new bottle of test strips. Discard any unused test strips three months after opening.
- » Test strips are good three months after opening or until the last day of the month of expiration, whichever comes first.
- » Make sure you are performing the test in an environment that is between 50°F–104°F.
- » Replace the cap of the control solution immediately after use.
- » If there is an insufficient sample, the strip icon will flash and the message “Er 4” will be shown. Eject and discard the used test strip. Repeat the control solution test with a new test strip.
- » DO NOT reuse test strips.
- » Repeat with another level of control solution.

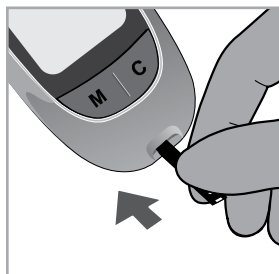
BLOOD GLUCOSE TESTING

MATERIALS NEEDED:

- » EVENCARE ProView Meter
- » A new EVENCARE ProView Blood Glucose Test Strip
- » Auto-disabling single-use lancing device

IMPORTANT

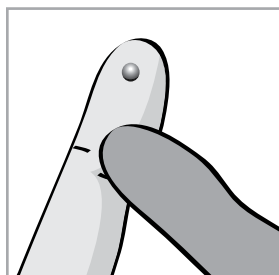
Users need to adhere to standard precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. A new pair of clean gloves should be worn by the user before testing each patient.



Insert test strip.

Step 1. Insert a test strip into the meter. The meter will turn on automatically. Make sure it is inserted completely without bending the test strip.

Step 2. For Fingertip Testing: Wash the patient's hand thoroughly and dry well. Hold the single-use lancing device against the side of the patient's fingertip and lance the finger. Follow the manufacturer's instructions for how the lancing device should be used.

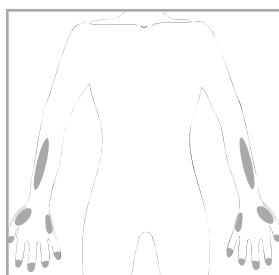


Lance the testing site.

IMPORTANT

- » Gently massage the hand and finger toward the puncture site to form a drop of blood. Do not "milk" or squeeze around the puncture site.
- » Prick the side of fingertip to avoid soreness. To avoid calluses, choose a different testing site each time.
- » If alcohol wipes are used to cleanse the fingertip, make sure the fingertip is completely dry before the blood sample is obtained.

For Testing on the Palm and Forearm (AST): Hold the lancing device against the test site (base of palm or forearm). Avoid a test site that has veins, moles, excessive hair, or bone. Press the lancing device firmly against the test site and lance the site. Do not lift up the lancing device.



Possible testing sites

For forearm test sites, apply and release pressure to the lancing device for a few seconds while keeping the lancing device in constant contact with the skin. When a drop of blood is formed, lift the lancing device straight up without smearing the blood.

IMPORTANT

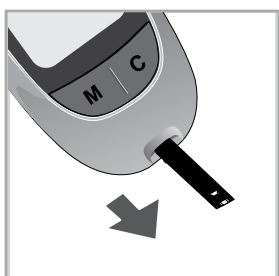
- » Dispose of lancets properly in biohazard waste.
- » You may need to wait a little longer to get a large enough drop of blood from the forearm or palm. Do not squeeze the site excessively.
- » If the sample drop of blood runs or spreads due to contact with hair or a crease in the palm, do not use that sample. Try puncturing again in a smoother area.



Touch test strip to drop of blood.



Test results will appear in 5 seconds.



Eject the test strip.

Step 3. When the blood drop icon appears on the screen, gently bring the test strip to the test site and touch the drop of blood. The drop of blood will be drawn in automatically by the test strip.

IMPORTANT

- » DO NOT touch the sampling end of the test strip.
- » DO NOT smear the blood drop onto the sampling end.
- » DO NOT add or apply a second drop of blood. This may cause a false result.
- » When there is an insufficient blood sample, the strip icon and the message "Er 4" will appear. Eject and discard the used test strip. Repeat the test with a new test strip.
- » Do not drop the blood directly on the end of the test strip.
- » The sample channel at the end of the test strip should show full. When you hear a beeping sound, you have enough blood in the test strip.
- » Do not hold or shake a meter while it is testing.

Step 4. When the test strip has enough blood the meter will beep and count down from five seconds. After five seconds the test result will appear. The test result will be stored in meter memory automatically.

Step 5. Eject the test strip into a proper waste container.

IMPORTANT

If you see "HI" or "LO" displayed, the patient's blood glucose level may be above 600 mg/dL or below 20 mg/dL. Repeat the blood glucose test. If you receive the same result, contact the patient's physician or healthcare provider.

UNDERSTANDING TEST RESULTS

Blood glucose test results will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are¹:

- » Less than 100 mg/dL before meals.
- » Less than 140 mg/dL 2 hours after meals.

If the meter displays a result that is "HI" or "LO" OR a patient gets a result that is more than 250 mg/dL or less than 50 mg/dL, AND the patient feels ill:

- » Contact the patient's healthcare provider or physician.

If the meter displays a result that is "HI" or "LO" OR a patient gets a result that is more than 250 mg/dL or less than 50 mg/dL and the patient DOES NOT feel ill:

- » Test again using a new test strip.
- » Call the Medline Technical Service Center at 1-866-274-2131.

IMPORTANT

- » Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- » Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- » Critically ill patients should not be tested with blood glucose meters.

USING THE METER MEMORY

The EVENCARE ProView Meter automatically stores up to 300 glucose test results together with the date and time. The meter also provides a 14 day average to help track a patient's blood glucose trend. The time and date must be set in order to use the memory and day averaging function.

MATERIALS NEEDED:

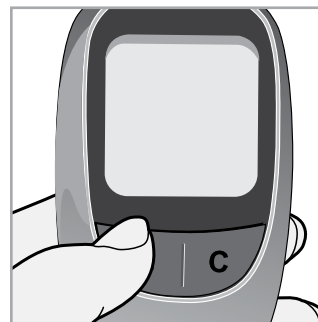
- » EVENCARE ProView Meter

Step 1. Press and release the **M button** to turn on the meter.

Step 2. The meter will display the most recent test result.

Step 3. Press the **C button** to see the next result, and the next, and so on. Press and hold the **C button** to flash through the results in the meter.

Step 4. After the oldest result in meter memory, continue to press the **C button** to view the day averages. The meter will display the 14 day average.



Press and release the M button.

The number of test results included in the 14 day average calculation is shown to the right of the 14 days icon. Control solution test results will not be included in the 14 day average calculation.

Step 5. Press the **M button** at any time to exit memory recall mode and turn off the meter.

NOTE:

- » If the meter memory is full, adding a new test result will cause the oldest one to be deleted.
- » Meter memory test results and day averages will not be erased when battery is removed.
- » The meter will automatically turn off after 2 minutes of non-use.

CLEANING AND DISINFECTING

IMPORTANT

- » DO NOT get water inside the EVENCARE ProView Meter. Never immerse the meter or hold it under running water or spray any cleaning solution directly onto the meter.
- » DO NOT use glass cleaners or household cleaners or corrosive liquid (e.g. Benzene, Acetone) on the meter.
- » DO NOT try to get moisture on the test strip, test strip slot or serial port.
- » DO NOT take the EVENCARE ProView Meter apart. Doing so will void the warranty. If there are technical problems or questions in the use of the meter, contact Medline Technical Service Center at 1-866-274-2131 between 8:00 am and 5:00 pm (Central Time), Monday through Friday.
- » Handle the meter with care – severe shock, such as dropping the meter, could damage the electronics.
- » Squeeze the excess liquid from the cloth before you wipe the meter.
- » The meter must be off when you clean or disinfect the meter.
- » Please use a soft cotton cloth to wipe the system.
- » Single-use medical protective gloves should always be worn during disinfection procedures and also by anyone performing blood glucose testing on another person.
- » Lancing devices used in a clinical setting should be the auto-disabling safety model marketed for single-use only.
- » Glucose meters used in a clinical setting for testing multiple persons must be cleaned and disinfected between patients.
- » Used gloves should be removed and hands washed before proceeding to the next patient.
- » Do not use other cleaners or disinfectants. They may damage the meter.
- » Healthcare professionals should change gloves between patients, even if patient-dedicated testing devices and single-use, self-disabling lancing devices are used.
- » DO NOT re-use the single-use lancing device.
- » Keep disinfecting wipes out of reach of children.
- » DO NOT flush disinfecting wipes down toilet.

The list of things you should look for as signs of deterioration after disinfection include:

- » Control solution out of range
- » Clouding of the LCD display
- » Corroding of the plastic housing
- » Corroding of the buttons
- » Malfunction of any meter buttons

If these signs of deterioration are noted, stop using the meter and call Medline Technical Service at 1-866-274-2131.

NOTE:

Only one disinfectant should be used on the device for the life of the device, as the effect of using more than one disinfectant interchangeably has not been evaluated.

The EVENCARE ProView Meter should be cleaned and disinfected between each patient.

MATERIALS NEEDED:

- » EVENCARE ProView Meter
- » Gloves
- » An EPA-registered disinfecting wipe, such as CaviWipes®. The CaviWipes disinfectant products have been shown to be safe in disinfecting the ProView system. Other EPA-registered wipes may be used for disinfecting the ProView system, however these wipes have not been validated and could affect the performance of your meter.

Cleaning Instructions: Cleaning is the removal of visible dirt and debris. Whenever your glucose meter is dirty, clean the outside of the meter with a new CaviWipes towelette or an EPA-registered disinfecting wipe. The cleaning process does not reduce the risk for transmission of infectious diseases.

Step 1. Wash hands with soap and water and put on single-use medical protective gloves.

Step 2. Prepare the CaviWipes towelette, or other EPA-registered disinfecting wipe. Take out a wipe from the container and follow the instructions on the package. If needed squeeze the wipe slightly to remove the excess liquid.

Step 3. Wipe the glucose meter thoroughly including the front, back and sides. Take care not to get any liquid in the test strip port and serial port. Do not wrap the meter in a wipe. Dispose of the wipe when finished.

Step 4. Remove gloves.

Disinfection Instruction: The meter must be disinfected between patient uses by wiping it with a CaviWipe towelette or EPA-registered disinfecting wipe in between tests and be cleaned prior to disinfecting. The disinfection process reduces the risk of transmitting infectious diseases if it is performed properly.

Step 1. Before disinfecting, clean the meter as described in Cleaning Instructions above.

Step 2. Wash hands with soap and water and put on single-use medical protective gloves.

Step 3. Prepare the CaviWipes towelette or other EPA-registered disinfecting wipe. Take out a wipe from the container and follow the instructions on the package. If needed, squeeze the wipe slightly to remove the excess liquid.

Step 4. Wipe the glucose meter thoroughly including the front, back and sides, and take care not to get any liquid in the test strip port and serial port. Do not wrap the meter in a wipe.

Step 5. If using the CaviWipes towelette, allow to remain wet for two minutes. For other EPA-registered disinfecting wipes, allow the surface of the meter to remain wet for the contact time listed on the disinfecting wipe's instructions for use. Dispose of wipe when finished.

Step 6. After disinfection, user should take off gloves and wash hands thoroughly with soap and water before proceeding to the next patient.

The EVENCARE ProView Blood Glucose Monitoring System was demonstrated that there was no change in performance or in the external materials of the meter after 11,000 cleaning with disinfection cycles with the CaviWipes towelette designed to simulate three years of device use.

Disposal of infectious material:

Blood, body fluids and cleaning materials should be disposed of according to federal, state and local regulations for infectious waste disposal.

CHANGING THE BATTERIES

MATERIALS NEEDED:

- » EVENCARE ProView Meter
- » Two 3V Lithium coin cell batteries (CR2032)

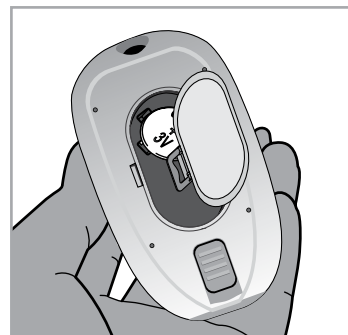
Step 1. Remove the battery compartment cover.

Step 2. If there are old batteries in the compartment, take them out. Insert new batteries with the plus (+) side facing up.

Step 3. Replace the battery cover.

NOTE:

Whenever replacing the battery, you need to reset the current date and time. However, test results stored will not be deleted.









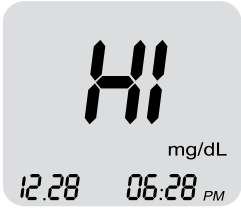

Remove battery compartment cover.

STORAGE AND PRECAUTIONS

- » The meter and the test strips are designed to be used within a temperature range of 50°F–104°F. Please place the meter and test strips under the same temperature environment (50°F–104°F) for about 20 minutes.
- » Avoid leaving the meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car.
- » Do not store or use the meter or test strips at high humidity levels, such as in the bathroom or kitchen.
- » Always close the cap of the test strip bottle immediately after removing a test strip. Make sure the cap is tightly closed.
- » Do not allow dirt or dust in the test strip slot in order to avoid affecting the system's performance.
- » Do not leave the meter near any electromagnetic field (e.g. TV, microwave oven, mobile phone).
- » Keep away from the direct sunlight.

TROUBLESHOOTING

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
	<p>The meter has detected a problem with the test strip. The test strip is either used or damaged.</p>	<p>Repeat the test with a new test strip.</p>
	<p>The blood sample was applied to the test strip before the blood symbol appeared on the screen.</p>	<p>Remove and discard the test strip and insert a new one. Apply blood to the test strip after the blood symbol appears on the screen.</p>
	<p>The temperature is above or below the proper range for testing.</p>	<p>The temperature should be 50°F–104°F. Move the meter and test strips to an area that is within the temperature range to perform the test. Wait about 20 minutes or until the meter has reached the proper range and retest. Do not raise or lower the meter temperature artificially.</p>
	<p>There is not enough blood in the strip to perform a test.</p>	<p>Repeat the test with a new test strip and make sure enough blood has been applied to the strip.</p>
	<p>The wrong strip has been put into the meter.</p>	<p>Make sure you are using a ProView test strip and repeat the test.</p>
	<p>There is an internal error with the meter.</p>	<p>Please contact Customer Service at 1-866-274-2131.</p>

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
	<p>Glucose test result is higher than 600 mg/dL.</p>	<p>Wash and dry your hands and repeat the test on the patient's fingertip with a new test strip. If the result is still "HI," contact the patient's physician or healthcare provider.</p>
	<p>Glucose test result is lower than 20 mg/dL.</p>	<p>Wash and dry your hands and repeat the test on the patient's fingertip with a new test strip. If the result is still "LO," contact the patient's physician or healthcare provider.</p>

WHAT IS HAPPENING	WHAT YOU SHOULD DO
<p>The meter does not work after the blood is applied.</p>	<ul style="list-style-type: none"> » Make sure that the test strip is inserted into the test strip port completely. » See if the test strip is covered in debris or lint. » Make sure the blood is applied to the test strip correctly. » Make sure the test strip is inserted correctly and repeat the test.
<p>The test result is abnormal.</p>	<ul style="list-style-type: none"> » See if the test strip is covered in debris or lint. Also make sure the test strip has not been out of its container for any extended period of time. » Make sure the test strip has not been used before. » Verify the expiration date on the test strip vial. » Make sure the test strip vial has not been opened for longer than three (3) months.
<p>The thermometer icon appears on the screen.</p>	<ul style="list-style-type: none"> » Place the meter and test strip in a temperature environment of 50°F–104°F. You should use it after about 20 minutes in the appropriate conditions. » If the thermometer icon is constantly showing, contact Customer Service at 1-866-274-2131
<p>The meter does not work after the test strip is inserted.</p>	<ul style="list-style-type: none"> » Make sure the test strip is completely inserted into the test strip port. » Make sure the batteries are inserted correctly, with the + sign up and facing the right direction.

WARRANTY

The EVENCARE ProView Blood Glucose Meter is warranted to be free of defects in workmanship and materials for a period of three (3) years from the date of purchase. Medline's liability for warranty claims is limited to repair or replacement, and in no event shall Medline be liable for indirect or consequential damages, or for any loss arising from misuse, improper use, abuse, neglect, unauthorized repair or modification.

This warranty is void and of no force and effect in the event of product misuse, improper use, abuse, neglect, unauthorized repair or modification. This warranty specifically excludes EVENCARE ProView Test Strips and EVENCARE ProView Control Solution.

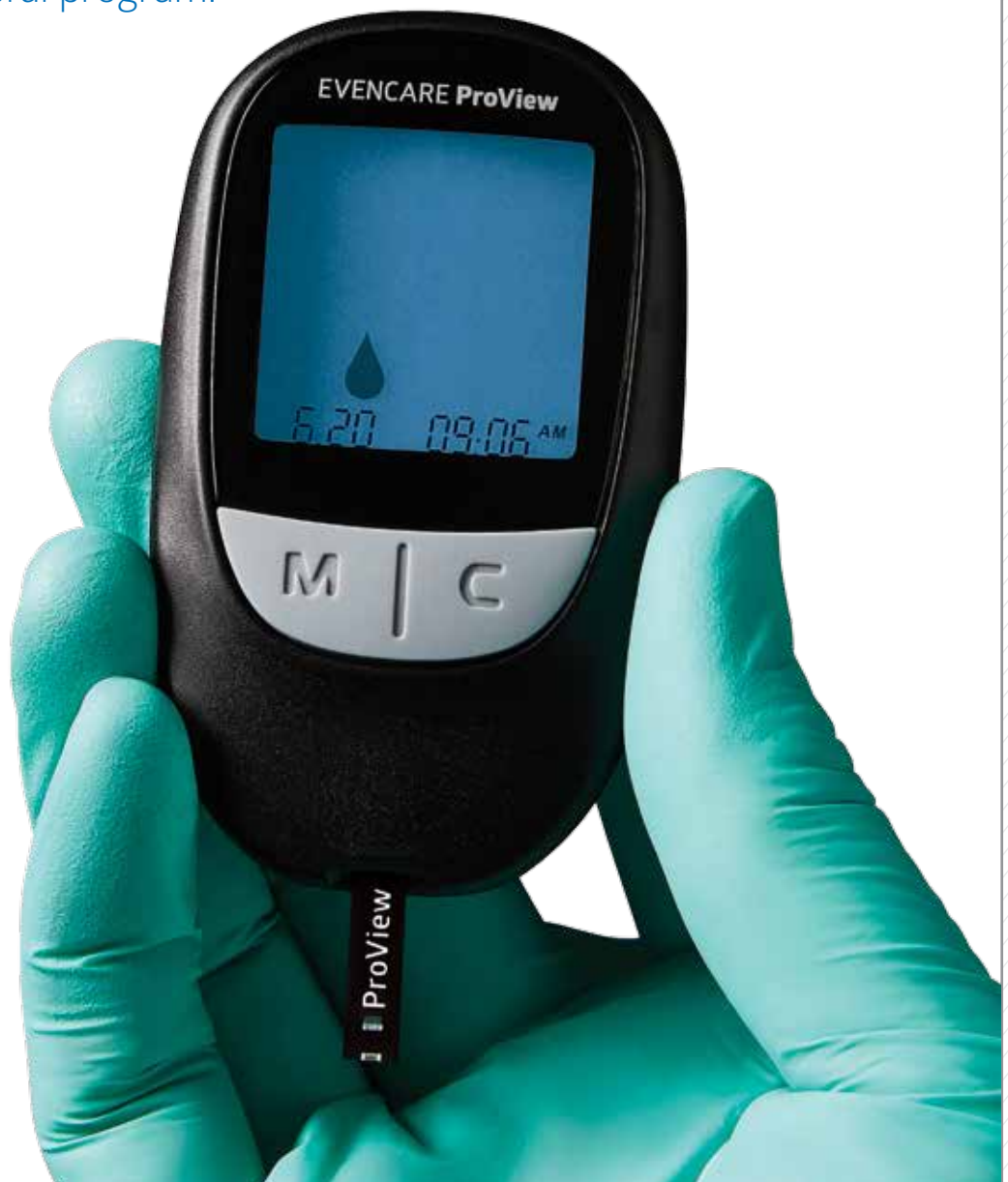
THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY TO THE EXCLUSION OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ALL OF WHICH ARE WAIVED AND DISCLAIMED.

All warranty claims must be directed to Medline's Technical Service Center at 1-866-274-2131. This warranty is extended only to the original purchaser of the meter.

IN-SERVICE GUIDE

The success of any bedside glucose-monitoring program depends on having consistent, well-documented methods, and procedures for testing and recording results.

This easy-to-follow guide will help you develop a strong, successful program.



IN-SERVICE TRAINING

At the conclusion of an EVENCARE ProView meter in-service training session, attendees should be able to do the following:

1. Identify and describe all components of the EVENCARE ProView Blood Glucose Monitoring System including:
 - » Test strip port
 - » Test strip ejector
 - » Battery compartment
 - » Serial number
 - » LCD screen
 - » EVENCARE ProView test strips
 - » EVENCARE ProView control solution
 - » EVENCARE ProView User's Guide
 - » Toll-free customer service number
2. Be familiar with the EVENCARE ProView test strip packaging and location of the lot number, expiration date, and control solution ranges.
3. Be familiar with the proper handling, insertion, and storage of the EVENCARE ProView test strips.
4. Check performance of the meter using control solutions.
5. Record quality control results.
6. Perform a blood glucose test.
7. Understand test results.
8. Clean and disinfect the meter.
9. Change the batteries.
10. Use memory function of the meter.
11. Understand the meanings of the error messages.
12. Understand the training certification process.

OPERATOR CERTIFICATION CHECKLIST

CERTIFIED INSTRUCTOR: Complete one checklist for each operator-trainee. Before signing this checklist, the trainee must meet objectives as listed below.

A. Familiarization with Components of the EVENCARE ProView Blood Glucose Monitoring System

1. EVENCARE ProView Meter

- Features (test strip port, test strip ejector, battery compartment and screen)
- Serial Number
- Toll-Free Customer Service Number
- Cleaning and Disinfecting
- Storage

2. EVENCARE ProView Blood Glucose Test Strips

- Expiration Date
- Lot Number
- Control Solution Ranges
- Handling of Strip
- Proper Insertion of Strip
- Storage

3. EVENCARE ProView Control Solution

- Expiration Date
- Lot Number
- Acceptable Range
- Test Procedure

B. Describe/Demonstrate

- Obtain a Blood Sample – Preparation, Obtaining Sample
- Perform a Blood Glucose Test
- Quality Control – Dropping Solution on Flat Surface, Marking Control Test in Meter, Perform Quality Control Test, Log Quality Control Result

C. Explain

- Batteries – Replacement Procedure
- Memory Function – Describe Process

Instructor Name

Date

Operator-Trainee Name

Operator Certified

Yes No

SELF TEST

1. True or False:
EVENCARE ProView needs to be calibrated/coded.
2. What is the purpose of testing with control solutions?
3. When performing a control solution test, you should:
 - a. Apply the control solution direct from the bottle to the test strip
 - b. Squeeze a drop of control solution to a flat surface, and touch the test strip to the control solution
 - c. Apply control solution to the test strip before inserting it into the meter
4. True or False:
You need to mark a control test as a control test, so that it shows as a control test in the memory of the meter.
5. True or False:
For vial test strips, the vial cap should be closed immediately after removing a test strip from the vial to avoid any degrading or contamination of the test strips.
6. How long is the test time on the EVENCARE ProView meter?
7. Where can you find information to troubleshoot error messages?
 - a. User's Guide
 - b. EVENCARE Technical Support Line
 - c. All of the above
8. What type of batteries are used in the EVENCARE ProView meter?
9. What is the procedure for disinfecting the EVENCARE ProView meter?

Name

Date

SELF TEST—ANSWER KEY

1. True or **False**:
EVENCARE ProView needs to be calibrated/coded.
2. What is the purpose of testing with control solutions?
To validate that the EVENCARE ProView meter is working properly with the test strips.
3. When performing a control solution test, you should:
 - a. Apply the control solution direct from the bottle to the test strip
 - b. Squeeze a drop of control solution to a flat surface, and touch the test strip to the control solution**
 - c. Apply control solution to the test strip before inserting it into the meter
4. **True** or False:
You need to mark a control test as a control test, so that it shows as a control test in the memory of the meter.
5. **True** or False:
For vial test strips, the vial cap should be closed immediately after removing a test strip from the vial to avoid any degrading or contamination of the test strips.
6. How long is the test time on the EVENCARE ProView meter?
5 seconds
7. Where can you find information to troubleshoot error messages?
 - a. User's Guide
 - b. EVENCARE Technical Support Line
 - c. All of the above**
8. What type of batteries are used in the EVENCARE ProView meter?
Two 3V CR2032
9. What is the procedure for disinfecting the EVENCARE ProView meter?
Wipe the meter with a disinfecting wipe. Wipe all external areas of the meter including both front and back surfaces until visibly wet. Allow the surface of the meter to remain wet at room temperature for the contact time/kill time listed on the canister. Then, wipe meter dry or allow to air dry.

EVENCARE PROVIEW BLOOD GLUCOSE MONITORING SYSTEM

Certified Instructor Record

The following individuals have undergone the appropriate training on the EVENCARE ProView Blood Glucose Monitoring System and are certified to serve as instructors in blood glucose monitoring using the EVENCARE ProView Blood Glucose Monitoring System. They are qualified to perform initial training of certified operations, conduct performance reviews, and maintain records concerning Certified Operators.

DATE	NAME	TITLE	RE-CERTIFICATION DATE

Medline Representative Signature

Medline Representative Printed Signature

Date

EVENCARE PROVIEW BLOOD GLUCOSE MONITORING SYSTEM

Certified Instructor Record — Competency Checklist

Certified Operator

Unit/Nurses Station

Date

Certified Trainer

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

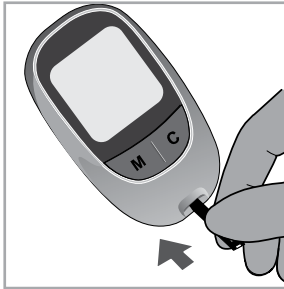
- | | | |
|--|------------------------------|-----------------------------|
| 1. Select and prepare the finger-stick site correctly. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Use lancet/lancing device correctly. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Insert EVENCARE ProView test strip into EVENCARE ProView meter correctly. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Apply blood to test strip 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 patient result correctly. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 8. Follow correct infection control procedures. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 9. Follow facility protocol for quality control testing. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 10. Clean/disinfect EVENCARE ProView meter correctly. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 11. Change batteries. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |



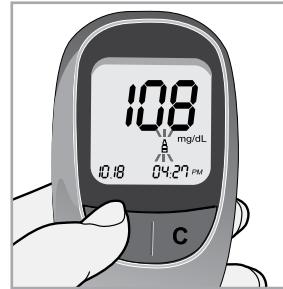
EVENCARE[®] ProView[™]

Blood Glucose Monitoring System

Performing a Control Solution Test




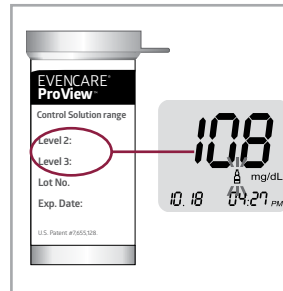
Step 1. Insert a test strip into the meter with the arrow facing up. Make sure to firmly and completely insert the test strip into the meter. The meter will turn on automatically.



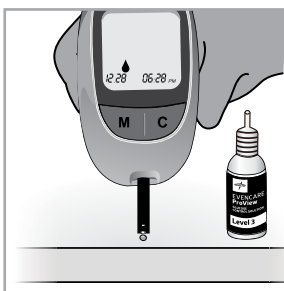
Step 4. Press the **M button** to mark the control solution result. The control solution bottle symbol will appear on the display with the result.



Step 2. When the blood drop icon  appears on the screen, shake the bottle of control solution and then squeeze a drop of the control solution onto a clean, dry, non-absorbent surface such as a table top.



Step 5. Compare the result on the screen to the control solution range printed on the test strip bottle. Each LOT of test strip vials may have a different acceptable range.



Step 3. Bring the test strip gently to the drop of control solution so the sampling end of the test strip touches the control. The drop of control solution will be drawn in automatically by the test strip.



Step 6. Eject the test strip into a proper waste container.

When the test strip confirmation window is full, the meter will beep. The meter will count down from five seconds and then show the control solution result.

NOTE: Mark all control solution tests with the control solution symbol to distinguish them from blood glucose test results in the meter memory. Marked control solution results will not be included in 14 day average.

CAUTION: Failure to follow instructions may cause out of range results. For more information on performing a control solution test, see the EVENCARE ProView User Guide or call Customer Support at 1-866-274-2131.



EVENCARE[®] ProView[™] BLOOD GLUCOSE TEST STRIPS

For In Vitro Diagnostic Use.

IMPORTANT: Please read this information and the EVENCARE ProView User's Guide before using the EVENCARE ProView test strips. Failure to follow instructions will cause incorrect results.

Intended Use

The EVENCARE ProView Blood Glucose Test Strips are to be used with the EVENCARE ProView Blood Glucose Meter, for the quantitative measurement of the concentration of glucose in fresh capillary whole blood drawn from the fingertip, palm, or forearm of diabetic patients by healthcare professionals as aid in the management of diabetes. The system is intended for testing multiple patients in professional healthcare settings. It is intended for use outside the body (In Vitro Diagnostic Use) and not for diagnosis of or screening for diabetes. It is not for use on neonates. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood.

Testing Principles

The test strip shows glucose concentration in a blood sample. Glucose in the blood sample reacts with glucose oxidase on the test strip and a harmless electrical current is produced. The strength of these currents change with the amount of glucose in the blood sample and the EVENCARE ProView Blood Glucose Meter automatically interprets this reaction. The EVENCARE ProView Blood Glucose Monitoring System is plasma-equivalent to compare results with laboratory methods. Blood glucose results from plasma-equivalent test strips are approximately 11% higher than whole-blood equivalent test strips.

Reagent Composition

Each EVENCARE ProView Test Strip contains:

- Glucose oxidase (A.Niger).....2.5 unit
- Redox mediator.....32.3µg
- Buffer & Non-reactant.....50.5µg

Storage and Handling

1. Always close the vial cap tightly after removing a test strip.
2. Store the test strips at indoor area between 39.2°F and 86°F. Do not freeze.
3. Store out of direct sunlight.
4. When properly stored, unopened test strips are stable until the expiration date printed on the Vial.
5. Use within 3 months of first opening or the expiration date on the label, whichever comes first.
6. Do not handle the test strips with wet or dirty hands.

Warnings and Precautions

- The EVENCARE ProView Blood Glucose Test Strips are for use outside the body (In Vitro Diagnostic Use).
- DO NOT use the test strips after their expiration date.
- DO NOT use test strips that are wet or damaged.
- DO NOT re-use the test strips.
- If a patient has symptoms that are not consistent with their blood glucose test results and you have eliminated common procedural errors described in the User's Guide, Call Medline Technical Support at 1-866-274-2131.
- Never make major changes in a patient's diabetes treatment program without consulting their physician.

Sample Collection and Preparation

The EVENCARE ProView Blood Glucose Test Strips are designed specifically for use with fresh capillary whole blood, taken from a fingertip, palm, or forearm. Testing must be performed immediately after the sample is obtained.

Test Procedure

See "Testing Blood Glucose" in the EVENCARE ProView Blood Glucose Monitoring System User's Guide.

Quality Control

Follow instructions in the EVENCARE ProView Blood Glucose Monitoring System User's Guide. Do control tests when:

- Using the meter for the first time.
- Using a new bottle of EVENCARE ProView Blood Glucose Test Strips.
- At least once per week to verify that the meter and test strips are working properly together.
- The test strip vial is left open.
- The meter is dropped.
- You suspect the meter and test strips are not working properly together.
- A patient's test results do not agree with how they feel.
- A patient's readings appear to be abnormally high or low.
- Test strips have been exposed to a condition outside the specified storage conditions.
- Practicing your testing technique.

Use only EVENCARE ProView Glucose Control Solutions. Control solution test results should fall within the control ranges printed on the test strip bottle. Repeat control solution testing if results fall out of range. Results may fall out of range due to:

- Errors in control solution testing procedure.
- Expired or contaminated control solution.
- Test strip is damaged or meter malfunctions.
- Control solution too warm or too cold. Control solution tested outside the 68°-77°F.
- Applying too much or too little control solution.

If the results still fall outside of control ranges, please call Medline Technical Support at 1-866-274-2131.

Expected Values

The ideal blood glucose ranges for non diabetics are:

- Before eating: < 100mg/dL
- 2 hours after meal: < 140mg/dL

The blood glucose values shown above are for reference only. Patients should always follow the recommendations of their healthcare professional.

*Reference: American Diabetes Association, *Clinical Practice Recommendations (2015) Diabetes Care, Vol. 38, Supplement 1, p S1 - S93*

Specifications

- Test Range : 20 - 600 mg/dL
- Sample Size : 0.5µl
- Operating Humidity : 10 - 90 % RH
- Permissible Hematocrit Range : 30 - 55 %
- Operating Temperature : 50°F - 104°F

Limitations

- Hematocrit is the percentage of red blood cells in the blood. Hematocrit levels of 30-55% were shown not to affect glucose measurements with this device.
- This test strip is not designed for use with arterial, venous, neonatal, serum or plasma samples.
- Testing out of the specification range may cause inaccurate results.
- This test strip may be used at altitudes up to 10,000 feet.
- Fresh capillary blood may be collected into test tubes containing only heparin if the blood is used within 10 minutes. Do not use any other anticoagulants or preservatives.
- Acetaminophen, salicylates, uric acid, ascorbic acid (Vitamin C) and other interfering substances with therapeutic concentration in normal blood, do not significantly affect results however, abnormally high concentrations in blood may cause inaccurate results.
- Patients undergoing oxygen therapy may register a false low result.
- Test results may register a false low if the patient is severely dehydrated, in shock or in a hyperosmolar state (with or without ketosis). Critically ill patients should not be tested using blood glucose meters.
- Lipemic samples (triglycerides) in excess of 1,500 mg/dL may produce elevated results.

Performance Evaluation Data

1. Accuracy:

Comparisons with the EVENCARE ProView System and YSI2300 Biochemical Analyzer for capillary whole blood samples from 108 subjects at the same time.

1-1. Acceptance Criteria

- ISO 15197 Minimum Acceptable Accuracy Requirement:
- 95% of individual glucose results must fall within ± 15mg/dL at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within ± 20% at glucose concentrations ≥ 75mg/dL

1-2. Result

- No. of samples: 108
- Regression Equation: $y = 1.005x + 0.6506$ (mg/dL) $r(\text{corr.coef}) = 0.9777$

System Accuracy Results for Glucose Concentration < 75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
9/20 (45%)	17/20 (85%)	20/20 (100%)	
System Accuracy Results for Glucose Concentration ≥ 75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
44/88 (50%)	68/88 (77.3%)	83/88 (94.3%)	87/88 (98.9%)

2. User Performance Test:

Compare results from the user and Healthcare Professional using the same samples, EVENCARE ProView System and YSI2300 Analyzer as the reference method.

2-1. Acceptance Criteria

ISO 15197 Minimum Acceptable Accuracy Requirement:

- 95% of individual glucose results must fall within ± 15mg/dL at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within ± 20% at glucose concentrations ≥ 75mg/dL

2-2. Result (Professional result vs. YSI reference result)

- No. of samples: 156
- Regression Equation $y = 0.9694x + 5.1823$ (mg/dL) $r(\text{corr.coef}) = 0.9762$

System Accuracy Results for Glucose Concentration < 75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
5/16 (31.3%)	12/16 (75%)	16/16 (100%)	
System Accuracy Results for Glucose Concentration ≥ 75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63/140 (45%)	109/140 (77.9%)	134/140 (95.7%)	140/140 (100%)

2-3. Result (User result vs. YSI reference result)

- No. of samples: 156
- Regression Equation $y = 0.966x + 4.8475$ (mg/dL) $r(\text{corr.coef}) = 0.9749$

System Accuracy Results for Glucose Concentration < 75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
3/16 (18.8%)	9/16 (56.3%)	16/16 (100%)	
System Accuracy Results for Glucose Concentration ≥ 75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63/140 (45%)	118/140 (84.3%)	136/140 (97.1%)	137/140 (97.9%)

3. Alternate Site Testing (AST):

Compare with EVENCARE ProView System and YSI2300 Biochemical Analyzer.

3-1. Acceptance Criteria

ISO 15197 Minimum Acceptable Accuracy Requirement:

- 95% of individual glucose results must fall within ± 15mg/dL at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within ± 20% at glucose concentrations ≥ 75mg/dL

3-2. Result - No. of samples: 104

Palm results vs. YSI results for Glucose Concentration < 75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
7/12 (58.3%)	12/12 (100%)	12/12 (100%)	
Palm results vs. YSI results for Glucose Concentration ≥ 75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
48/92 (52.2%)	81/92 (88%)	91/92 (98.9%)	92/92 (100%)
Forearm results vs. YSI results for Glucose Concentration < 75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
8/12 (66.7%)	12/12 (100%)	12/12 (100%)	
Forearm results vs. YSI results for Glucose Concentration ≥ 75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
51/92 (55.4%)	83/92 (90.2%)	92/92 (100%)	92/92 (100%)

Information for AST

- Contact the patient's Healthcare Professional before you begin using alternative sites to test blood glucose.
- Alternative site results may be different from fingertip results when glucose levels are changing rapidly (e. g. after a meal, after taking insulin, or during or after exercise).
- Use Alternative Site Testing (AST) only two hours or more after taking insulin, two hours or more after a meal, two hours or more after exercise.
- Do not use AST if you are aware that the glucose level is not as stable as usual, or if you think the patient may have hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose), or at times when you think the patient's blood glucose may be rising or falling rapidly.
- Do not use AST if the AST results do not match the way the patient feels.
- AST measurements should never be used to calibrate continuous glucose monitors (CGM).
- AST measurements should never be used in insulin dosing calculations.
- Do not rely on test results at an alternative sampling site if any of the following applies:
 - you think the patient's blood glucose is low.
 - the patient has hypoglycemic unawareness.
 - the site results do not agree with the way the patient feels.
 - after a meal.
 - during illness.
 - after exercise.
 - during times of stress.

WARNING:

- This product is only for In-Vitro Diagnostics Use Only.
- Before using please check the expiration date on the package.
- This product should be used with the EVENCARE ProView Blood Glucose Meter only.
- Do not touch test strips with wet or dirty hands.
- Do not touch the test strip sampling end.
- Do not force the test strip when inserting it into the meter.
- The results of this product should not be used for diabetic treatment or medications without consulting the patient's doctor.
- You are handling biologically hazardous material, please handle with care, incorrect test methods may cause serious health problems.
- Use the test strip immediately after retrieving it from the vial and keep the test strip vial closed tightly at all times.
- Do not change the patient's treatment without consulting their Physician or Healthcare Professional.
- Never ignore symptoms of high or low blood glucose.
- If the patient's blood glucose does not match how they feel, perform a fingertip test to confirm the result. If the fingertip test result still does not match how the patient feels, call their Physician or Healthcare Professional.
- Keep the test strip away from all children and pets; test strips may be a choking hazard.

Cleaning and Disinfection

User need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007. <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html> Refer to user manual of EVENCARE ProView Blood Glucose Monitoring System for cleaning and disinfection of blood glucose meter.

References

1. National Committee for Clinical Laboratory Standards, Point-Care Blood Glucose Testing in Acute and Chronic Care Facilities, Approved Guideline, 2nd Edition. NCCLS Document C30-A2(ISBN1-56238-471-6)
2. National Committee for Clinical Laboratory Standards, Statistical Quality Control for Quantitative Measurements: Principle and Definitions; Approved Guideline, 2nd Edition. NCCLS Document C24-A2(ISBN1-56238-371-X)1999
3. National Committee for Clinical Laboratory Standards, User Demonstration of performance for Precision and Accuracy; Approved Guideline. NCCLS Document EP15-A(156238-451-1)
4. National Committee for Clinical Laboratory Standards, Interference Testing in Clinical Chemistry; Approved Guideline. NCCLS Document EP7-A (Vol.22, No.27)

Medline Technical Support:

1-866-274-2131 (8:00am - 5:00pm CT/Monday - Friday)

If you have questions or need assistance outside the operational days and times, please contact your health care provider.

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1-866-274-2131
RF16EMQ



EVENCARE[®] ProView[™]

GLUCOSE CONTROL SOLUTIONS

IMPORTANT

Please read this insert before using your EVENCARE ProView Glucose Control Solution with the EVENCARE ProView System.

INTENDED USE

EVENCARE ProView Glucose Control Solutions are for use with EVENCARE ProView Blood Glucose Meters and Blood Glucose Test Strips to check that the meter and test strips are working together properly. It is intended for use by healthcare professionals in healthcare settings. EVENCARE ProView Glucose Control Solutions are for in vitro diagnostic use.

SUMMARY

The EVENCARE ProView Glucose Control Solutions contain a measured amount of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the meter and test strip are functioning properly.

CONTROL SOLUTIONS SHOULD BE USED WHEN:

- Using the meter for the first time.
- Using a new bottle or box of EVENCARE ProView Blood Glucose Test Strips.
- At least once per week to verify that the meter and test strips are working properly together.
- The test strip bottle is left open
- The meter is dropped, damaged or gets wet.
- You suspect the meter and test strips are not working properly together.
- A patient's test results do not agree with how they feel.
- A patient's readings appear to be abnormally high or low.
- Test strips have been exposed to a condition outside the specified storage conditions.
- Practicing your testing technique.

CHEMICAL COMPOSITION

The EVENCARE ProView Glucose Control Solution is an aqueous solution. It contains D-glucose in concentrations of:

- Level 2 0.11 % w/v glucose 99.89 % w/v nonreactive ingredients
- Level 3 0.23 % w/v glucose 99.77 % w/v nonreactive ingredients

The non-reactive ingredients included in the solution are buffers, stabilizer and preservative.

WARNINGS AND PRECAUTIONS

Control solutions are for In Vitro Diagnostic Use Only and are not intended for human consumption or injection.

- DO NOT apply a second drop of control solution to the sampling end of the test strip.
- DO NOT smear the solution with the tip of the bottle.
- Replace the cap of the control solution immediately after use.
- Use only EVENCARE ProView Glucose Control Solutions.
- Always check the expiration date. DO NOT use expired control solutions.
- Keep away from eyes.

STORAGE AND HANDLING

- Shake the EVENCARE ProView Glucose Control Solutions well before using.
- Control solutions should be stored at indoor area between 39.2°F - 86°F. DO NOT FREEZE.
- DO NOT use past the expiration date.
- Discard any unused control solution 90 days after first opening or after expiration date, whichever comes first.
- Daily control testing is recommended. Daily control test helps to ensure that system is operating properly.

CONTROL SOLUTION TEST PROCEDURE

Materials needed to perform control solution tests include:

- EVENCARE ProView Glucose Control Solutions (Level 2 and Level 3).
- EVENCARE ProView Meter and User's Guide.
- EVENCARE ProView Blood Glucose Test Strips.

Conduct test as follows:

1. Newly opened bottles of control solutions must be marked with the date opened on the space provided on the control solution labels. Check the expiration date of the control solutions to make sure they have not expired. Discard any unused control solutions 90 days after opening or after expiration date, whichever comes first.
2. Refer to the User's Guide for instructions on how to run a control solution test.

EXPECTED VALUES

The EVENCARE ProView Glucose Control Solution testing should provide results within the expected range indicated on the test strip bottle. If results are not within the acceptable range, carefully review each step before performing another test. Any error in technique or meter use could cause results to be outside the acceptable range. If the control solution test results continue to be outside the acceptable range and the testing technique is correct, use a new test strip from a previously unopened bottle of test strips and repeat the test. If readings are still not within the acceptable range, please call Medline Technical Support at 1-866-274-2131.

Results that fall outside the expected range may indicate:

- An error in the way you are doing the test.
- Expired or contaminated control solution.
- A problem with the meter.
- A problem with the test strip. (e.g. expired, damaged, etc.)
- Control solution is too warm or too cold.
- Control solution tested outside the 68°F-77°F.
- Applying too much or too little control solution.

LIMITATIONS

- The amount of glucose in this Control Solution, when tested by methods other than EVENCARE ProView Blood Glucose meters, may differ because the amount of glucose added makes up for differences between testing glucose in water and in whole blood sample.
- The glucose control ranges printed on the test strip vial label are for EVENCARE ProView Glucose Control Solutions only.
- Applying too much or too little control solution to the test strip may cause out of range results.
- If control solution results continue to be out of range after all instructions have been followed, the system is not working properly. DO NOT use the system to test blood glucose until you get a control solution reading that is within the acceptable range.

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RF16EMQ

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PLEASE CALL MEDLINE'S TECHNICAL
SERVICE CENTER
AT 1-866-274-2131
MONDAY THROUGH FRIDAY
BETWEEN 8:00 AM AND 5:00 PM (CST).**







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REFERENCES: 1. American Diabetes Association, Clinical Practice Recommendations (2015) Diabetes Care, Vol. 38, Supplement 1, p S1 - S93

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