



# EVENCARE<sup>®</sup> G3

## BLOOD GLUCOSE MONITORING SYSTEM



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



# EVENCARE<sup>®</sup> G3

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## BLOOD GLUCOSE MONITORING SYSTEM HEALTHCARE PROFESSIONAL OPERATOR'S MANUAL & IN-SERVICE GUIDE

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# OPERATOR'S MANUAL

**Thank you** for choosing the EVENCARE G3 Professional Blood Glucose Monitoring System to help monitor your patients' blood glucose levels. The EVENCARE G3 Professional Blood Glucose Monitoring System is designed to be accurate and easy to use. The EVENCARE G3 Professional Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples

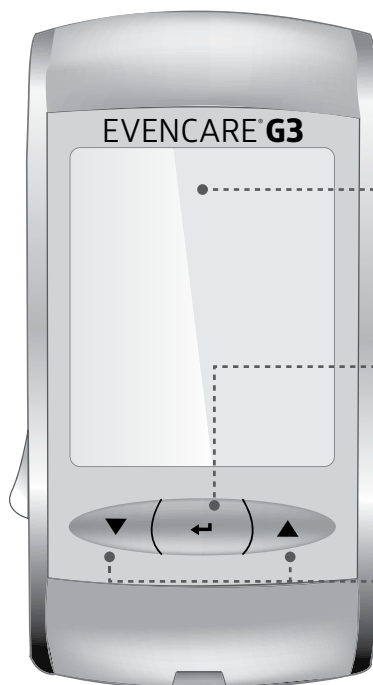
drawn from the fingertips, forearm, or palm. It is indicated to be used for multiple patients in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus. This system should only be used with single-use, auto-disabling lancing devices.

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).



# G3 METER OVERVIEW

## EVENCARE G3 METER FRONT



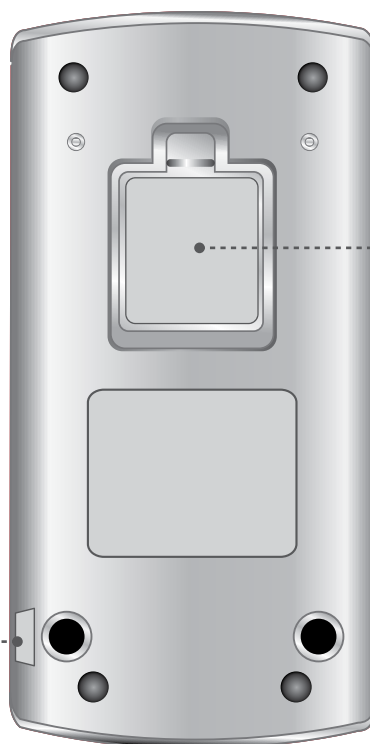
**Display Screen**  
Shows glucose blood test results, memory values, averages, and other messages

**Enter Button**  
Press and hold to turn the meter on or off

**Scroll (▲▼) Buttons**  
Press to enter control mode when test strip is inserted, during meter setup, or to view stored test results and averages.

**Test Strip Port**  
Insert the test strip to turn on the meter.

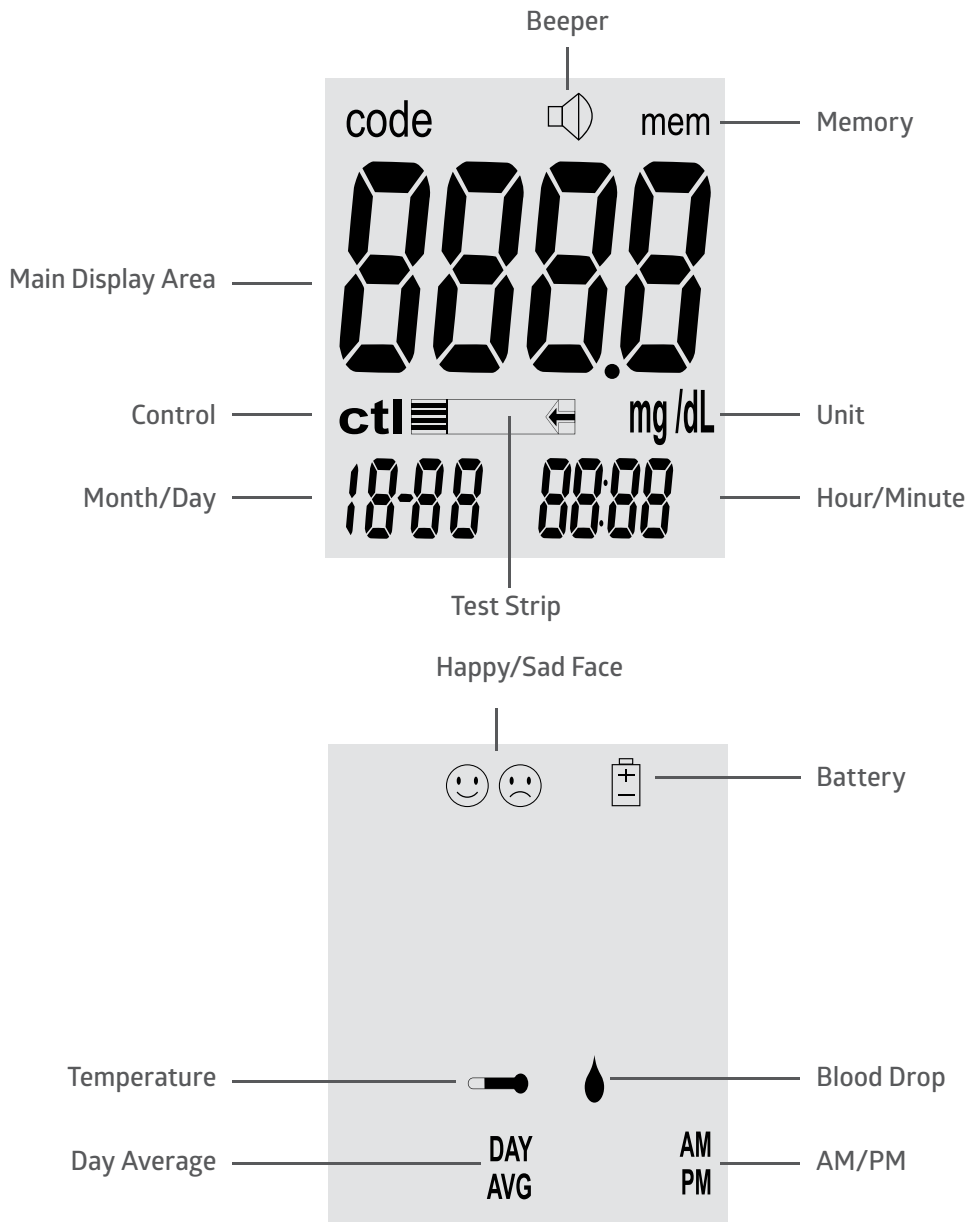
## EVENCARE G3 METER BACK



**Battery Compartment**  
Holds one 3V Lithium coin cell battery (CR2032).

**Test Strip Ejector**  
Slide to eject used test strip.

**Data Port**  
Function is not yet available.



## METER DISPLAY SCREEN

Main Display Area:	Displays test results, stored test results, result averages, and messages.
Beeper:	Indicates the beeper function is set.
Battery:	Appears when the battery is low and needs to be replaced.
Memory:	Indicates the number in the display area is a stored test result.
Unit:	Indicates the unit of measurement (mg/dL).
Control:	Indicates a control solution test.
Test Strip:	Indicates the meter is waiting for the test strip to be inserted.
Blood Drop:	Appears when a test strip is inserted into the meter and the meter is ready for testing.
Day Average:	Appears when viewing the day-averages.
Happy/Sad Face:	Indicates whether or not the meter's electronics are functioning properly.
Temperature:	Appears when it's either too hot or too cold to test.

## SYSTEM SPECIFICATIONS

Test Strips:	EVENCARE G3 Blood Glucose Test Strips
Test Range:	20–600 mg/dL
Calibration:	Plasma
Test Time:	6 seconds
Sample Size:	Minimum 0.8µL
Hematocrit Range:	30%–55%
Display Type:	Large LCD screen
Memory:	300 test results
Result Averaging:	7, 14, and 30 day averaging
Battery:	1 x 3V CR2032 Lithium coin cell battery
Automatic Power-Off:	After 3 minutes of non-use
Operating Temperature:	50°F–104°F
Operating Humidity:	22%–90%
Dimensions (L x W x H):	105 x 53 x 15 mm
Weight (including battery):	67.3 g

## EVENCARE G3 CONTROL SOLUTION TESTING

EVENCARE G3 Glucose Control Solution is the standard glucose concentration solution required to perform a control solution test. It is available at two levels. EVENCARE G3 Level 1 Glucose Control Solution (white cap) helps to validate the performance of the system at a low range blood glucose reading, while Level 3 Glucose Control Solution (blue cap) helps to validate system performance at a high range blood glucose reading. Run the control test to make sure the meter and test strips are working properly together, to practice testing procedure, and when using a new package of EVENCARE G3 Blood Glucose Test Strips.

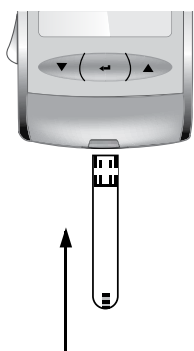
### You should perform a control solution test when:

- » Using the meter for the first time.
- » Using a new package of EVENCARE G3 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 G3 Meter
- » EVENCARE G3 Glucose Control Solutions (Level 1 or Level 3)
- » A new EVENCARE G3 Blood Glucose Test Strip

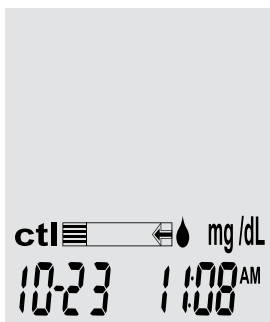




**Step 1.** Insert a test strip into the meter with the contact points facing up. Make sure to firmly and completely insert the test strip into the meter. The meter will turn on automatically.

**Step 2.** The meter will run a series of self-tests. The happy face icon will appear on the screen when all tests are complete. If the sad face icon or other error messages (Err 2, Err 3, etc.) appear, see Troubleshooting.

**NOTE:** The message “QC” flashes when the QC mode is turned on and control tests have not been performed within the past 24 hours. Control tests must be completed before the meter will perform a blood glucose test.



**Step 3.** Wait until the flashing blood drop and arrow icons appear next to the test strip icon on the meter display screen, press the down button ▼ or up button ▲ to enter control solution testing mode. The “ctl” icon will appear next to the test strip icon on the meter display screen, indicating that the meter is in control solution testing mode. Press the down button ▼ or the up button ▲ to exit control solution test mode.

**Step 4.** When the blood drop appears on the screen, squeeze a drop of the control solution onto a clean, dry, non-absorbent surface such as table top. Bring the test strip gently to the drop of control solution so the sampling end of the test strip touches the control solution. The drop of control solution will be drawn in automatically by the test strip.



**Step 5.** The screen will display count down bars ----. After 6 seconds, the control solution test result will appear on the screen.

**Step 6.** For vial test strips, compare the reading on the screen to the control solution range printed on the test strip bottle. For foil-wrapped test strips, compare the reading on the screen to the control solution range printed on the box.

**Step 7.** Eject the test strip into a proper waste container.

## IMPORTANT

- » Use only EVENCARE G3 Glucose Control Solutions with the EVENCARE G3 Blood Glucose Test Strips. Other brands of control solutions will produce inaccurate results.
- » Always check the expiration date of the control solution and the test strips. DO NOT use expired control solution or test strips.
- » 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 expiration date on the bottle, whichever comes first.
- » DO NOT FREEZE. Store the control solutions at room temperature of 59°F–86°F.
- » For foil-wrapped test strips, use each test strip immediately after removing it from the foil.
- » For vial test strips, 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.
- » For vial test strips, record the date on the bottle when you open a new bottle of test strips. Discard any unused test strips six months after opening.
- » Vial test strips are good six months after opening or until the expiration date on the vial, whichever comes first.
- » Foil-wrapped test strips are good until the expiration date on the packaging.



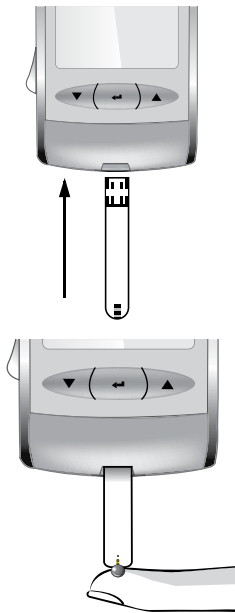
# BLOOD GLUCOSE TESTING

## MATERIALS NEEDED:

- » EVENCARE G3 Meter
- » A new EVENCARE G3 Blood Glucose Test Strip
- » Auto-disabling single use lancing device—use an auto-disabling single use lancing device to take the blood sample. Follow the manufacturer’s instructions for how the lancing device should be used.

## 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.



**Step 1.** Insert a test strip into the meter.

**Step 2.** The meter will run a series of self-tests. The happy face icon will appear on the screen when all tests are complete. If the sad face icon or other error messages (Err 2, Err 3, etc.) appear, see Troubleshooting.

**Step 3.** 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.

**Step 4.** 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.

**Step 5.** The screen will display count down bars ----. After 6 seconds, test result will appear on the screen. The test result will be stored in meter memory automatically. Record the result in the patient’s chart.

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

# 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 are<sup>1</sup>:

- » less than 100 mg/dL before meals.
- » less than 140 mg/dL 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 physician or healthcare provider.

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.

## USING THE METER MEMORY

The EVENCARE G3 Meter automatically stores up to 300 glucose test results together with the date and time. The meter also provides 7, 14, and 30 day averages 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. The meter memory will not store test results if the date and time are not set.

### MATERIALS NEEDED:

- » EVENCARE G3 Meter



**Step 1.** Press and hold the main button to turn on the meter.

**Step 2.** The meter will run a series of self-tests. The happy face icon will appear on the screen when all tests are complete. If the sad face icon or other error messages (Err 2, Err 3, etc.) appear, see Troubleshooting.

**Step 3.** Press the down button ▼ once to enter the meter memory mode. The screen will show the icon “mem.”

**Step 4.** Press the main button to enter memory mode.

**Step 5.** The most recent glucose test result is shown on the screen. Press the down button ▼ to see the next result, and the next, and so on. Press and hold the up button will allow you to flash through the results in the meter. “nil” will appear on the display after the last record, if less than 300 results are stored. Press the up button ▲ to go back, viewing from the oldest to the most recent results.

**Step 6.** Press the main button to exit memory recall mode and return to the testing mode.

## CLEANING AND DISINFECTING

### IMPORTANT

- » DO NOT get water inside the EVENCARE G3 Meter.
- » Never immerse the meter or hold it under running water.
- » DO NOT use glass cleaners or household cleaners on the meter.
- » DO NOT try to clean the test strip holder.
- » DO NOT take the EVENCARE G3 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.

### MATERIALS NEEDED:

- » EVENCARE G3 Meter
- » Gloves
- » A validated disinfecting wipe

The EVENCARE G3 Meter should be cleaned and disinfected between each patient. The meter is validated to withstand a cleaning and disinfection cycle of ten times per day for an average period of three years. The following products have been approved for cleaning and disinfecting the EVENCARE G3 Meter:

- » Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration Number: 56392-8)
- » Medline Micro-Kill+™ Disinfecting, Deodorizing, Cleaning Wipes with Alcohol (EPA Registration Number: 59894-10)
- » Clorox Healthcare® Bleach Germicidal and Disinfectant Wipes (EPA Registration Number: 67619-12)
- » Medline Micro-Kill™ Bleach Germicidal Bleach Wipes (EPA Registration Number: 69687-1)

Other EPA registered wipes may be used for disinfecting the EVENCARE G3 system, however, these wipes have not been validated and could affect the performance of your meter. If you use an EPA registered wipe and notice any of the below signs, stop using the device and call Medline technical service at 1-866-274-2131.

- » Control solution out of range
- » Clouding of meter LCD display
- » Corrosion or erosion of plastic housing or buttons
- » Cracking of plastic housing
- » Malfunction of any meter button

**Step 1.** Wash hands with soap and water.

**Step 2.** Put on single-use medical protective gloves.

**Step 3.** Inspect for blood, debris, dust, or lint anywhere on the meter. Blood and bodily fluids must be thoroughly cleaned from the surface of the meter.

**Step 4.** To clean the meter, use a moist (not wet) lint-free cloth dampened with a mild detergent. Wipe all external areas of the meter including both the front and back surfaces until visibly clean. Avoid wetting the meter test strip port.

**Step 5.** To disinfect your meter, clean the meter surface with one of the approved disinfecting wipes. Other EPA registered wipes may be used for disinfecting the EVENCARE G3 system, however, these wipes have not been validated and could affect the performance of the meter. Wipe all external areas of the meter including both front and back surfaces until visibly wet. Avoid wetting the meter test strip port.

Wipe meter dry, or allow to air dry.



**Step 6.** Remove gloves. 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.

**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:**

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 safety models 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. 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.

## CHANGING THE BATTERY

**Step 1.** Remove the battery compartment cover.

**Step 2.** If there is an old battery in the compartment, take it out. Insert a new battery, with the plus (+) side facing up.

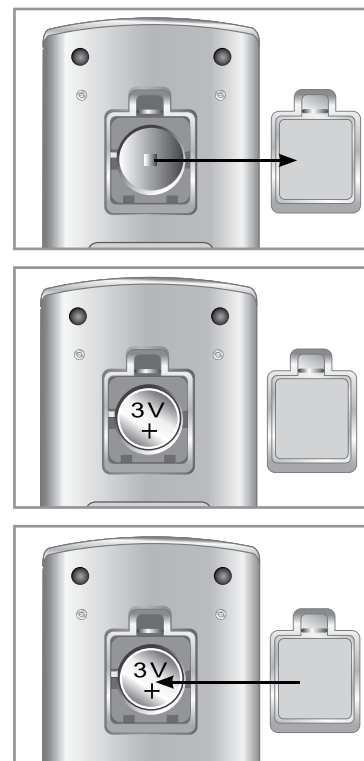
**Step 3.** Replace the battery cover.

**IMPORTANT**

Dispose of used batteries according to local regulations.

**NOTE:**

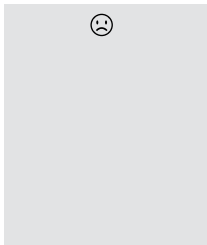
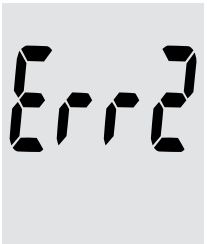

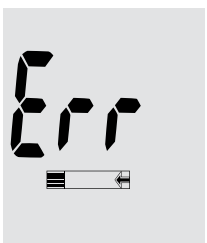
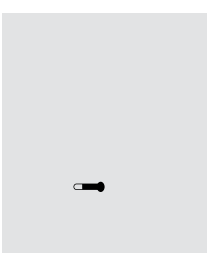
Stored test results will not be erased when the battery is changed.

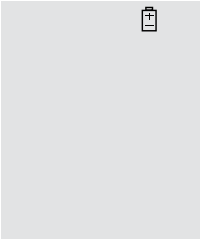

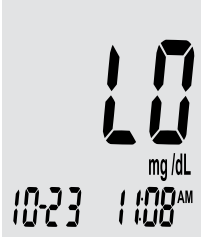
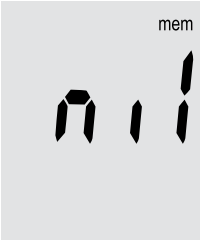


## STORAGE AND PRECAUTIONS

- » The meter and the test strips are designed to be used within a temperature range of 50°F to 104°F.
- » 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.
- » For vial test strips, always close the cap of the test strip bottle immediately after removing a test strip. Make sure the cap is tightly closed.

# TROUBLESHOOTING

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
	<p>Problem with the meter's electronics.</p>	<p>Replace the battery and turn on the meter again.</p>
	<p>Used test strip.</p>	<p>Repeat the test with a new test strip.</p>
	<p>The strip was removed from the meter while testing was in progress.</p>	<p>Repeat the test with a new test strip.</p>
	<p>The size of the blood sample was too small.</p>	<p>Repeat the test with a new test strip.</p>
	<p>The temperature is out of range.</p>	<p>Move the meter into an area that is between 50°F–104°F, and allow 15 minutes for it to reach the new temperature.</p>

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
	<p>Battery is low.</p>	<p>Change the battery according to the User's Guide.</p>
	<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>
	<p>There are no results stored in the meter.</p>	<p>Check if the date and time are set up correctly.</p>

**WARRANTY**

The EVENCARE G3 Blood Glucose Meter is warranted to be free of defects in workmanship and materials for a period of two (2) 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 G3 Test Strips and EVENCARE G3 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.



\*This in-service guide is optional and is provided to your facility only as an additional resource should you choose to use it.

# IN-SERVICE TRAINING

At the conclusion of an EVENCARE G3 meter in-service training session, attendees should be able to do the following:

1. Identify and describe all components of the EVENCARE G3 Blood Glucose Monitoring System including:
  - » Test strip port
  - » Test strip ejector
  - » Battery compartment
  - » Serial number
  - » LCD screen
  - » EVENCARE G3 test strips
  - » EVENCARE G3 control solution
  - » EVENCARE G3 User's Guide
  - » Toll-free customer service number
2. Be familiar with the EVENCARE G3 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 G3 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 battery.
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 G3 Blood Glucose Monitoring System

### 1. EVENCARE G3 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 G3 Blood Glucose Test Strips

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

### 3. EVENCARE G3 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

- Battery – Replacement Procedure
- Memory Function – Describe Process

\_\_\_\_\_  
Instructor Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Operator-Trainee Name

Operator Certified       Yes     No

# SELF TEST

1. True or False:  
EVENCARE G3 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 G3 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 battery is used in the EVENCARE G3 meter?
9. What is the procedure for disinfecting the EVENCARE G3 meter?

\_\_\_\_\_

Name

\_\_\_\_\_

Date

# SELF TEST—ANSWER KEY

1. True or **False**:  
EVENCARE G3 needs to be calibrated/coded.
2. What is the purpose of testing with control solutions?  
**To validate that the EVENCARE G3 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 G3 meter?  
**6 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 battery is used in the EVENCARE G3 meter?  
**One 3V CR2032**
9. What is the procedure for disinfecting the EVENCARE G3 meter?  
**Clean 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 G3 BLOOD GLUCOSE MONITORING SYSTEM: NURSE IN-SERVICE TRAINING RECORD

The healthcare professionals listed below have been trained to use the EVENCARE G3 Blood Glucose Monitoring System:

\_\_\_\_\_  
 Certified Trainer's Name

DATE	HEALTHCARE PROFESSIONAL'S NAME	UNIT/STATION	CERTIFIED TRAINER'S INITIALS

# EVENCARE G3 BLOOD GLUCOSE MONITORING SYSTEM: CERTIFIED INSTRUCTOR RECORD

The following individuals have undergone the appropriate training on the EVENCARE G3 Blood Glucose Monitoring System and are certified to serve as instructors in blood glucose monitoring using the EVENCARE G3 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 G3 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.  Yes  No
2. Use lancet/lancing device correctly.  Yes  No
3. Insert EVENCARE G3 test strip into EVENCARE G3 meter correctly.  Yes  No
4. Apply blood to test strip correctly.  Yes  No
5. Dispose of lancet correctly.  Yes  No
6. Identify when to repeat test or check result with a laboratory test  Yes  No
7. Record patient result correctly.  Yes  No
8. Follow correct infection control procedures.  Yes  No
9. Follow facility protocol for quality control testing.  Yes  No
10. Clean/disinfect EVENCARE G3 meter correctly.  Yes  No
11. Change battery.  Yes  No

# EVENCARE G3 BLOOD GLUCOSE MONITORING SYSTEM: REVIEW OF NURSE'S TECHNIQUE

DATE	CERTIFIED TRAINER	CERTIFIED TRAINER'S SIGNATURE	NURSE REVIEWED	NURSE'S SIGNATURE

IN-SERVICE GUIDE





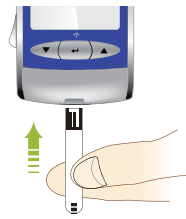


## EvenCare® G3 Blood Glucose System

### Performing a Control Solution Test

step  
**1**

Insert test strip to turn on meter.



step  
**4**

Bring meter and strip to the droplet. The meter will beep and display count down bars after enough control solution is drawn into the test strip.



step  
**2**

Press ▼ or ▲ once to enter control solution mode for low or high. The “ctl” icon will display in the lower left corner of the LCD, indicating the meter is in control mode.



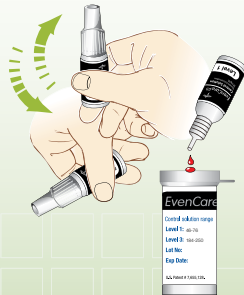
step  
**5**

Compare result to the low or high range printed on test strip vial.



step  
**3**

Invert and gently shake the control solution bottle three times. Apply drop to top of test strip vial.



step  
**6**

Eject and discard the used test strip. The meter will automatically turn off. Wipe clean the top of the strip vial.



**CAUTION:** Failure to follow instruction may cause out of range results.

**NOTE:**

- Write down the date when the control solution is first opened. Discard three months after the date of the first opening.
- For more information on performing a control solution test, see the EvenCare G3 User's Guide or call Customer Support at **1-866-274-2131**.

We reserve the right to correct any errors.

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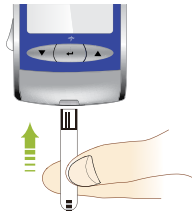


# EvenCare®G3 Blood Glucose System

## Performing a Control Solution Test

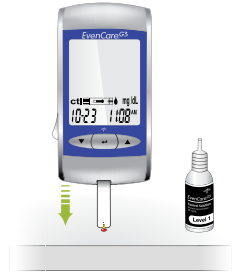
step  
**1**

Insert test strip to turn on meter.



step  
**4**

Bring meter and strip to the droplet. The meter will beep and display count down bars after enough control solution is drawn into the test strip.



step  
**2**

Press ▼ or ▲ once to enter control solution mode for low or high. The “ctl” icon will display in the lower left corner of the LCD, indicating the meter is in control mode.



step  
**5**

Compare result to the low or high range printed on test strip box.



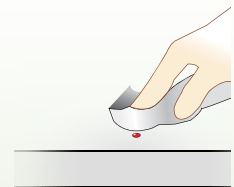
step  
**3**

Invert and gently shake the control solution bottle three times. Apply a drop onto a clean, dry, non-absorbent surface such as a table top.



step  
**6**

Eject and discard the used test strip. The meter will automatically turn off. Wipe the droplet clean.



**CAUTION:** Failure to follow instruction may cause out of range results.

**NOTE:**

- Write down the date when the control solution is first opened. Discard three months after the date of the first opening.
- For more information on performing a control solution test, see the EvenCare G3 User's Guide or call Customer Support at **1-866-274-2131**.

We reserve the right to correct any errors.

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### IMPORTANT

PLEASE READ THIS INFORMATION AND THE EVENCARE G3 USER'S GUIDE BEFORE USING EVENCARE G3 TEST STRIPS.

### INTENDED USE

The EVENCARE G3 Blood Glucose Test Strips are to be used with the EVENCARE G3 Blood Glucose Meter; to quantitatively measure glucose in capillary whole blood taken from a fingertip, palm, or forearm. 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. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

- 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. For more information, refer to "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings", <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.
- The meter should be disinfected after use on each patient. This blood glucose monitoring system may only be used for testing multiple patients when standard precautions and the manufacturer's disinfection procedures are followed.
- Only auto-disabling, single-use lancing devices may be used with this device.

The link of public health notification and standard practice guideline are:

- "FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
- "CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) <http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

### INTRODUCTION

The biosensor-based EVENCARE G3 Blood Glucose Test Strip uses an enzyme to measure blood glucose. The enzyme is specific for blood glucose measurements from 20 to 600 mg/dL. When blood touches the tip of the test strip, it flows into the sampling end. The enzyme reacts with glucose in the blood and produces an electrical current. The meter measures the current. The result appears on the screen within six seconds.

### REAGENT COMPOSITION

Each cm<sup>2</sup> of test strip contains:

- Glucose Oxidase (*A. niger*) 2.3%
- Electron Shuttle 25%
- Non- Reactive Ingredients 72.7%

### WARNINGS AND PRECAUTIONS

The EVENCARE G3 Blood Glucose Test Strips are for use outside the body (in vitro diagnostic use).

- DO NOT use 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.

- Abnormal red blood cell counts (hematocrits below 30% or above 55%) can cause incorrect results.
- Never make major changes in patient's diabetes treatment program without consulting their physician.
- Operating temperature for the meter and the test strips is between 50°F - 104°F.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyposmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Inaccurate result may occur in individuals who are dehydrated.

### STORAGE AND HANDLING

- Always close the vial cap tightly after removing a test strip.
- Store the test strips between 39°F and 86°F. Do not freeze.
- Store out of direct sunlight.
- When stored properly, unopened test strips are stable until the expiration date printed on the bottle.
- Use within 6 months of first opening or the expiration date on the label, whichever comes first.
- Do not handle the test strips with wet or dirty hands.

### SAMPLE COLLECTION AND PREPARATION

The EVENCARE G3 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. Neonatal, plasma, or serum samples are not validated and should not be used with the EVENCARE G3 Blood Glucose Test Strips.

### TEST PROCEDURE

See "Testing Blood Glucose" in the EVENCARE G3 Blood Glucose Monitoring System User's Guide.

### CLEANING PROCEDURE

See "Cleaning and Disinfecting Procedures" in the EVENCARE G3 Blood Glucose Monitoring System User's Guide.

### ALTERNATIVE SITE TESTING

You can also test from the palm and forearm. This is called alternative site testing (AST). AST results may differ from finger tip readings <sup>(1)</sup>.

DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- 2 hours or more after taking insulin.
- 2 hours or more after exercise.

Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs). Alternative site measurements should never be used for insulin dosing calculations.

Alternative Site Testing SHOULD NOT be used when:

- Patients have hypoglycemic unawareness.
- Within 2 hours of a meal, exercise, or medication.
- Operating machinery or driving a car.
- During times of stress.
- Patient is ill.
- Patient's blood glucose is low.
- Testing for hyperglycemia.
- Patient's routine glucose results are often fluctuating.

NOTE: If results from alternative site testing do not agree with how the patient feels, use fingertip testing instead.

### EXPECTED VALUES

Blood glucose values obtained from EVENCARE G3 Blood Glucose Test Strips are calibrated to plasma equivalents. Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are <sup>(2)</sup>:

- less than 100 mg/dL before meals.
- less than 140 mg/dL after meals.

### QUALITY CONTROL

Follow instructions in the EVENCARE G3 Blood Glucose Monitoring System User's Guide. Do control tests when:

- Using the meter for the first time.
- Using a new bottle of EVENCARE G3 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.
- 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 G3 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.
- Meter malfunction.

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

### TROUBLESHOOTING

- Confirm the test strips are not expired.
- Make sure the blood fills the sampling end of the test strip. If there is too little blood, DO NOT add a second drop of blood. Discard the test strip and retest with a new test strip.
- Check the system with control solution.
- Refer to "Troubleshooting" in the EVENCARE G3 Blood Glucose Monitoring System User's Guide.

If the issue continues, call Medline Technical Support at 1-866-274-2131.

### LIMITATIONS

- DO NOT use neonatal, plasma, or serum samples.
- Altitudes up to 10,000 feet will not affect test results.
- Hematocrit range: 30% - 55%.
- Triglyceride levels up to 500 mg/dL have no significant effect on test results. Levels above 2000 mg/dL may give falsely low test results (normal range: 36 - 165 mg/dL).
- Ldopa levels above 1.5 mg/dL may cause falsely high test results. People taking this drug should consult their medical professional if they are taking high doses of Ldopa.
- Ibuprofen levels above 40 mg/dL may give falsely high test results (therapeutic range: 1 - 7 mg/dL).
- Tolazamide levels above 60 mg/dL may give falsely low test results (therapeutic level: 23 mg/dL).
- Ascorbic acid levels above 5 mg/dL may give falsely high test results (therapeutic range: 0.4 - 2 mg/dL).

- Fructose levels above 15 mg/dL may give falsely high test results (endogenous range: 1 - 6 mg/dL).
- Uric acid levels above 15 mg/dL may give falsely high test results (normal range: 2.4 - 8 mg/dL).
- Cholesterol levels above 400 mg/dL may give falsely high test results (reference range: 114 - 201 mg/dL).
- Unconjugated bilirubin levels above 15 mg/dL, and conjugated bilirubin levels above 25 mg/dL, may give falsely high test results (normal ranges: unconjugated bilirubin: 0.3 - 1.2 mg/dL; conjugated bilirubin: 0 - 0.3 mg/dL).
- Icodextrin and its metabolites (maltose, maltotriose and maltotetraose) do not significantly affect test results.
- Methyldopa will not affect test results in therapeutic range (1 - 7.5 mg/dL).

### PERFORMANCE EVALUATION DATA

#### Accuracy:

Total of 120 fingertip blood samples were collected. Twenty-two (22) samples were from glucose levels below 75 mg/dL. Ninety-eight (98) samples were above or equal to 75 mg/dL. A total of 111 fresh blood samples were collected from the palm and forearm. Fourteen (14) samples were below 75 mg/dL, and ninety-seven (97) samples were above or equal to 75 mg/dL. Fingertip and alternate site samples were tested by healthcare professionals. Blood was tested on the YSI 2300 Blood Glucose Analyzer as a reference test.

Sample Source	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip by professional vs YSI	16/22 (73%)	21/22 (96%)	22/22 (100%)
Palm by professional vs YSI	10/14 (71%)	14/14 (100%)	14/14 (100%)
Forearm by professional vs YSI	5/14 (36%)	14/14 (100%)	14/14 (100%)

Sample Source	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip by professional vs YSI	65/98 (66%)	95/98 (97%)	98/98 (100%)	98/98 (100%)
Palm by professional vs YSI	60/97 (62%)	89/97 (92%)	96/97 (99%)	97/97 (100%)
Forearm by professional vs YSI	55/97 (57%)	87/97 (90%)	97/97 (100%)	97/97 (100%)

#### Precision:

Three lots of EVENCARE G3 Blood Glucose Test Strips were used for the precision study. Venous blood in heparin-tubes was spiked to 5 concentrations. Blood glucose readings were recorded for 20 days with 200 data points at each level.

Number of Readings:	200	200	200	200	200
Average (mg/dL):	42	80	129	202	320
Mean SD (mg/dL):	3.1	3.0	3.7	5.7	6.5
Mean CV %:	--	3.7	2.9	2.8	2.0

Number of Readings:	200	200	200	200	200
Average (mg/dL):	42	80	129	201	320
Mean SD (mg/dL):	3.1	3.1	3.9	5.7	6.6
Mean CV %:	--	3.9	3.0	2.8	2.1

Number of Readings:	200	200	200	200	200
Average (mg/dL):	42	81	129	201	302
Mean SD (mg/dL):	3.0	3.0	3.8	5.6	6.6
Mean CV %:	--	3.7	3.0	2.8	2.1

#### REFERENCES:

- Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differs Among Blood Glucose Monitoring Sites. *Diabetes Care* 28(3):708-709, 2005
- American Diabetes Association Position Statement: Standards of Medical Care in Diabetes—2010. *Diabetes Care* 2010; 33 (Suppl. 1):S1-S61.

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Technical Support: 1-866-274-2131  
(8:00 am - 5:00 pm CT / Monday - Friday)  
To Reorder: 1-800-MEDLINE  
RH16APB U.S. Patent # 7,655,128.



### IMPORTANT

PLEASE READ THIS INFORMATION AND THE EVENCARE G3 USER'S GUIDE BEFORE USING EVENCARE G3 TEST STRIPS.

### INTENDED USE

The EVENCARE G3 Blood Glucose Test Strips are to be used with the EVENCARE G3 Blood Glucose Meter; to quantitatively measure glucose in capillary whole blood taken from a fingertip, palm, or forearm. 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. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

- 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. For more information, refer to "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings", <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.
- The meter should be disinfected after use on each patient. This blood glucose monitoring system may only be used for testing multiple patients when standard precautions and the manufacturer's disinfection procedures are followed.
- Only auto-disabling, single-use lancing devices may be used with this device.

The link of public health notification and standard practice guideline are:

- "FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
- "CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

### INTRODUCTION

The biosensor-based EVENCARE G3 Blood Glucose Test Strip uses an enzyme to measure blood glucose. The enzyme is specific for blood glucose measurements from 20 to 600 mg/dL. When blood touches the tip of the test strip, it flows into the sampling end. The enzyme reacts with glucose in the blood and produces an electrical current. The meter measures the current. The result appears on the screen within six seconds.

### REAGENT COMPOSITION

Each cm2 of test strip contains:

- Glucose Oxidase (A. niger) 2.3%
- Electron Shuttle 25%
- Non-Reactive Ingredients 72.7%

### WARNINGS AND PRECAUTIONS

The EVENCARE G3 Blood Glucose Test Strips are for use outside the body (in vitro diagnostic use).

- DO NOT use 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, contact the patient's physician.

- If a patient's test results are below 50 mg/dL or above 250 mg/dL, perform a control solution test to make sure the system is working properly. Then repeat the test using fingertip blood. If the result is the same, contact the patient's physician.
- Abnormal red blood cell counts (hematocrits below 30% or above 55%) can cause incorrect results.
- Never make major changes in patient's diabetes treatment program without consulting their physician.
- Operating temperature for the meter and the test strips is between 50°F – 104°F.
- 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.
- Inaccurate result may occur in individuals who are dehydrated.

### STORAGE AND HANDLING

- Store the test strips between 39°F and 86°F. Do not freeze.
- Store out of direct sunlight.
- When stored properly, unopened test strips are stable until the expiration date printed on the foil wrapping.
- Use test strip immediately after opening the foil wrapping.
- Do not handle the test strips with wet or dirty hands.

### SAMPLE COLLECTION AND PREPARATION

The EVENCARE G3 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. Neonatal, plasma, or serum samples are not validated and should not be used with the EVENCARE G3 Blood Glucose Test Strips.

### TEST PROCEDURE

See "Testing Blood Glucose" in the EVENCARE G3 Blood Glucose Monitoring System User's Guide.

### CLEANING PROCEDURE

See "Cleaning and Disinfecting Procedures" in the EVENCARE G3 Blood Glucose Monitoring System User's Guide.

### ALTERNATIVE SITE TESTING

You can also test from the palm and forearm. This is called alternative site testing (AST). AST results may differ from finger tip readings<sup>(1)</sup>.

DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- 2 hours or more after taking insulin.
- 2 hours or more after exercise.

Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs). Alternative site measurements should never be used for insulin dosing calculations.

Alternative Site Testing SHOULD NOT be used when:

- Patients have hypoglycemic unawareness.
- Within 2 hours of a meal, exercise, or medication.
- Operating machinery or driving a car.
- During times of stress.
- Patient is ill.
- Patient's blood glucose is low.
- Testing for hyperglycemia.
- Patient's routine glucose results are often fluctuating.

NOTE: If results from alternative site testing do not agree with how the patient feels, use fingertip testing instead.

### EXPECTED VALUES

Blood glucose values obtained from EVENCARE G3 Blood Glucose Test Strips are calibrated to plasma equivalents. Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are<sup>(2)</sup>:

- less than 100 mg/dL before meals.
- less than 140 mg/dL after meals.

### QUALITY CONTROL

Follow instructions in the EVENCARE G3 Blood Glucose Monitoring System User's Guide. Do control tests when:

- Using the meter for the first time.
- Using a new package of EVENCARE G3 Blood Glucose Test Strips.
- At least once per week to verify that the meter and test strips are working properly together.
- 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 G3 Glucose Control Solutions. Control solution test results should fall within the control ranges printed on the test strip box. 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.
- Meter malfunction.

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

### TROUBLESHOOTING

- Confirm the test strips are not expired.
- Make sure the blood fills the sampling end of the test strip. If there is too little blood, DO NOT add a second drop of blood. Discard the test strip and retest with a new test strip.
- Check the system with control solution.
- Refer to "Troubleshooting" in the EVENCARE G3 Blood Glucose Monitoring System User's Guide.

If the issue continues, call Medline Technical Support at 1-866-274-2131.

### LIMITATIONS

- DO NOT use neonatal, plasma, or serum samples.
- Altitudes up to 10,000 feet will not affect test results.
- Hematocrit range: 30% – 55%.
- Triglyceride levels up to 500 mg/dL have no significant effect on test results. Levels above 2000 mg/dL may give falsely low test results (normal range: 36 – 165 mg/dL).
- Ldopa levels above 1.5 mg/dL may cause falsely high test results. People taking this drug should consult their medical professional if they are taking high doses of Ldopa.
- Ibuprofen levels above 40 mg/dL may give falsely high test results (therapeutic range: 1 – 7 mg/dL).
- Tolazamide levels above 60 mg/dL may give falsely low test results (therapeutic level: 23 mg/dL).
- Ascorbic acid levels above 5 mg/dL may give falsely high test results (therapeutic range: 0.4 – 2 mg/dL).
- Fructose levels above 15 mg/dL may give falsely high test results (endogenous range: 1 – 6 mg/dL).
- Uric acid levels above 15 mg/dL may give

falsely high test results (normal range: 2.4 – 8 mg/dL).

- Cholesterol levels above 400 mg/dL may give falsely high test results (reference range: 114 – 201 mg/dL).
- Unconjugated bilirubin levels above 15 mg/dL, and conjugated bilirubin levels above 25 mg/dL, may give falsely high test results (normal ranges: unconjugated bilirubin: 0 – 1.2 mg/dL; conjugated bilirubin: 0 – 0.3 mg/dL).
- Icodextrin and its metabolites (maltose, maltotriose and maltotetraose) do not significantly affect test results.
- Methyldopa will not affect test results in therapeutic range (1 – 7.5 mg/dL).

### PERFORMANCE EVALUATION DATA

#### Accuracy:

Total of 120 fingertip blood samples were collected. Twenty-two (22) samples were from glucose levels below 75 mg/dL. Ninety-eight (98) samples were above or equal to 75 mg/dL. A total of 111 fresh blood samples were collected from the palm and forearm. Fourteen (14) samples were below 75 mg/dL, and ninety-seven (97) samples were above or equal to 75 mg/dL. Fingertip and alternate site samples were tested by healthcare professionals. Blood was tested on the YSI 2300 Blood Glucose Analyzer as a reference test.

Table 1. Accuracy for blood glucose concentration < 75 mg/dL.

Sample Source	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip by professional vs YSI	16/22 (73%)	21/22 (96%)	22/22 (100%)
Palm by professional vs YSI	10/14 (71%)	14/14 (100%)	14/14 (100%)
Forearm by professional vs YSI	5/14 (36%)	14/14 (100%)	14/14 (100%)

Table 2. Accuracy for blood glucose concentration ≥ 75 mg/dL.

Sample Source	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip by professional vs YSI	65/98 (66%)	95/98 (97%)	98/98 (100%)	98/98 (100%)
Palm by professional vs YSI	60/97 (62%)	89/97 (92%)	96/97 (99%)	97/97 (100%)
Forearm by professional vs YSI	55/97 (57%)	87/97 (90%)	97/97 (100%)	97/97 (100%)

#### Precision:

Three lots of EVENCARE G3 Blood Glucose Test Strips were used for the precision study. Venous blood in heparin-tubes was spiked to 5 concentrations. Blood glucose readings were recorded for 20 days with 200 data points at each level.

#### Reagent Lot TLS0010A

Number of Readings:	200	200	200	200	200
Average (mg/dL):	42	80	129	202	320
Mean SD (mg/dL):	3.1	3.0	3.7	5.7	6.5
Mean CV %:	--	3.7	2.9	2.8	2.0

#### Reagent Lot TLS0010B

Number of Readings:	200	200	200	200	200
Average (mg/dL):	42	80	129	201	320
Mean SD (mg/dL):	3.1	3.1	3.9	5.7	6.6
Mean CV %:	--	3.9	3.0	2.8	2.1

#### Reagent Lot TLS0010C

Number of Readings:	200	200	200	200	200
Average (mg/dL):	42	81	129	201	302
Mean SD (mg/dL):	3.0	3.0	3.8	5.6	6.6
Mean CV %:	--	3.7	3.0	2.8	2.1

### REFERENCES:

- Shi M, Osamu F, Kazuhiro H, Yoshitomo A: Hypoglycemia Detection Rate Differs Among Blood Glucose Monitoring Sites. Diabetes Care 28(3):708-709, 2005
- American Diabetes Association Position Statement: Standards of Medical Care in Diabetes—2010. Diabetes Care 2010; 33(Suppl.1):S1-S61.

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Technical Support: 1-866-274-2131 (8:00 am – 5:00 pm CT / Monday – Friday)  
To Reorder: 1-800-MEDLINE  
RH16APB U.S. Patent # 7,655,128.

REF MPH3550FL



# EVENCARE® G3

## GLUCOSE CONTROL SOLUTIONS

### INTENDED USE

The purpose of the control solution test is to validate the performance of the EVENCARE G3 Blood Glucose Monitoring System using a testing solution with a known range 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.

### SUMMARY

The EVENCARE G3 Glucose Control Solutions contain a measured amount of glucose. These solutions are used with the EVENCARE G3 Blood Glucose Test Strips to confirm the meter and test strips are working correctly.

### CONTROL SOLUTIONS SHOULD BE USED WHEN:

- Using the meter for the first time.
- Using a new bottle or box of EVENCARE G3 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 (for vial test strips).
- 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.

### CHEMICAL COMPOSITION

The EVENCARE G3 Glucose Control Solution is an aqueous solution. It contains D-glucose in concentrations of:

- Level 1 Control 38 mg/dL
- Level 3 Control 130 mg/dL

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.

- Shake the EVENCARE G3 Glucose Control Solutions well before using.
- DO NOT apply a second drop of control solution to the yellow 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 G3 Glucose Control Solutions.
- Always check the expiration date.
- DO NOT use expired control solutions.

### STORAGE AND HANDLING

- Control solutions should be stored between 59°F – 86°F. DO NOT FREEZE OR REFRIGERATE.
- DO NOT use past the expiration date.
- Discard any unused control solution 90 days after first opening or after expiration date, whichever comes first.

### CONTROL SOLUTION TEST PROCEDURE

#### Materials needed to perform control solution tests include:

- EVENCARE G3 Glucose Control Solutions (Level 1 and Level 3).
- EVENCARE G3 Meter and User's Guide.
- EVENCARE G3 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 G3 Glucose Control Solution testing should provide results within the expected range indicated on the test strip bottle (for vial test strips) or the box (for foil-wrapped test strips). If results are not within the acceptable ranges, 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 (for vial test strips) or the box (for foil-wrapped test strips) 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.

### CAUTION

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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RH16APB U.S. Patent # 7,655,128.

[REF] MPH3560

**IF YOU NEED ASSISTANCE,  
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REFERENCES: 1. American Diabetes Association Position Statement: Standards of Medical Care in Diabetes—2010. Diabetes Care 2010; 33 (Suppl.1):S11–S61.

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