



# EvenCare<sup>G2</sup><sup>®</sup>

## BLOOD GLUCOSE MONITORING SYSTEM



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



# EvenCare<sup>G2</sup><sup>®</sup>

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

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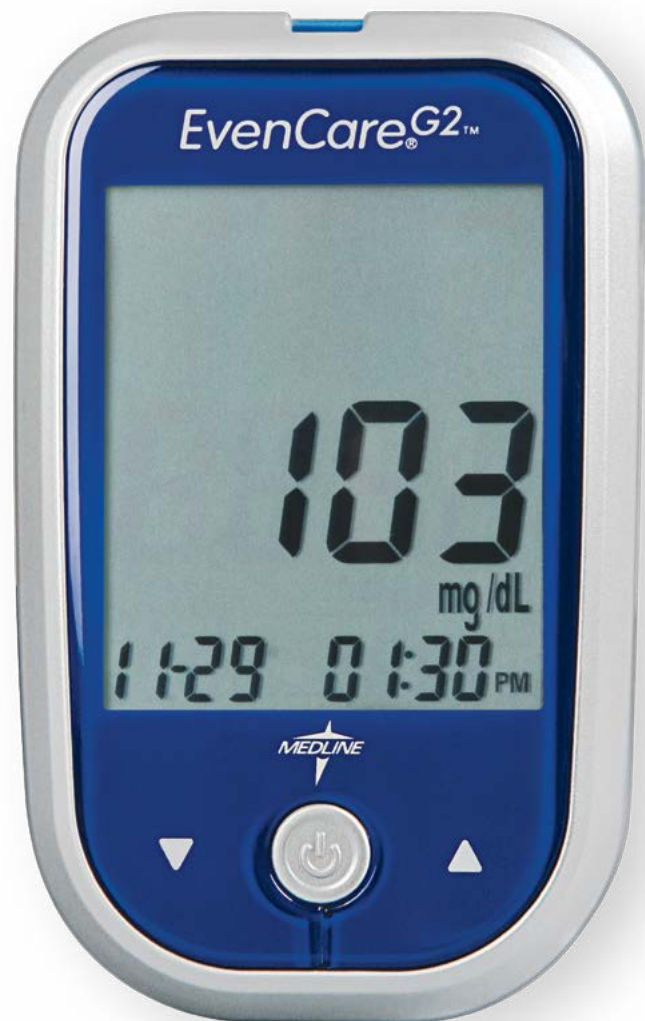
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# OPERATOR'S MANUAL

**Thank you** for choosing the EvenCare G2 Blood Glucose Monitoring System to help monitor your patient's blood glucose levels. The EvenCare G2 Blood Glucose Monitoring System is designed to be accurate and easy to use. The EvenCare G2 Blood Glucose Monitoring System is intended for both lay use by people with diabetes and in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus.

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).





# G2 METER OVERVIEW

## EVENCARE G2 METER FRONT



### TEST STRIP PORT

Insert test strip to turn on the meter.

### METER DISPLAY

Shows your blood glucose test results, memory values, averages, and other messages.

### ENTER (⏻) and ▲▼BUTTONS

Press and hold Enter (⏻) for 2 seconds to turn on or off the meter. Press Enter (⏻) to go into setup mode when not testing

Press ▲ or ▼ to enter control mode with test strip inserted, during meter setting, or to navigate the stored test values and averages

## EVENCARE G2 METER BACK

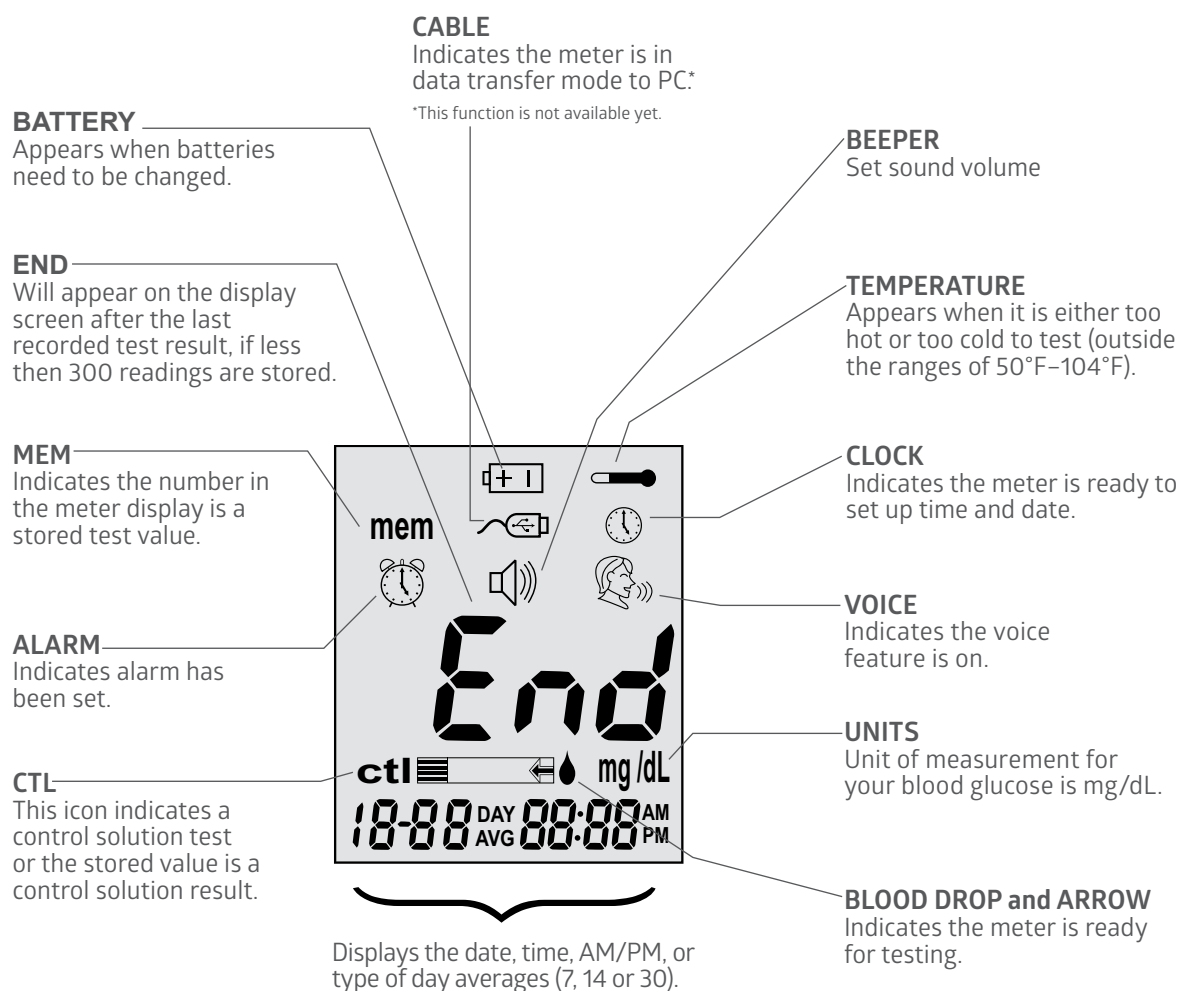


### BATTERY COMPARTMENT

Holds two AAA batteries.

### DATA PORT

This function is not yet available.



## SYSTEM SPECIFICATIONS

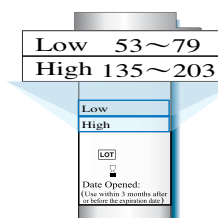
Test Strips:	EvenCare G2 Blood Glucose Test Strips
Test Range:	20–600 mg/dL
Calibration:	Plasma
Test Time:	6 Seconds
Sample Size:	Larger than 1uL
Hematocrit Range:	30–55%
Display Type:	Large LCD screen
Memory:	300 blood test results with date and time
Result Averaging:	7, 14 and 30 days averaging
Dimensions:	93L x 58W x 20.5H (mm)
Weight:	79g
Battery:	2 Alkaline AAA Battery
Battery Life:	1,000 tests of continuous use or 1 year
Automatic Power-off:	After 2 minutes of non-use
Operating Temperature:	50°F–104°F
Relative Humidity:	Less than 85%
Storage Condition:	Meter at 39°F–122°F, Test Strips at 39°F–86°F



DO NOT touch the sampling end of the test strip with the bottle of control solution. See illustration of sampling end below.



**Step 5.** Gently touch the tip of the test strip to the drop of control solution. The meter will beep indicating it has received the control solution. The screen will start to count down. After 6 seconds, the control solution test result will appear on the meter display screen.



**Step 6.** Compare the reading on the screen to the Low range printed on the test strip bottle. If the reading falls outside the Low range printed on the test strip bottle, see Control Solution Troubleshooting section in User's Guide.

#### NOTE:

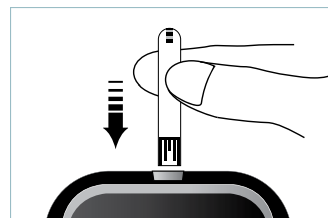
- » Control solution test results will be stored in meter memory and indicated by **ctl** icon.
- » Control solution test results will not be used for calculating averages.

**Step 7.** Remove the used test strip. The meter will automatically turn off. Discard the used test strip. Follow steps 8 through 14 to perform the High control solution testing.

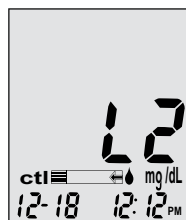
#### IMPORTANT

Do not reuse test strips.

**Step 8.** Take out an EvenCare G2 Test Strip from the test strip bottle and close the bottle immediately. Insert the test strip to turn on the meter.



**Step 9.** Wait until the flashing blood drop and arrow icons appear on the meter display screen. The meter will also announce, "Please apply blood onto the test strip" if you have the voice feature turned on. Press ▼ two times to enter L2 (HIGH) control solution testing.

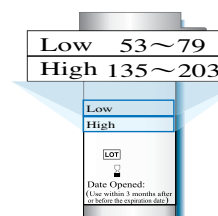


**Step 10.** **ctl** icon will appear next to the test strip icon and L2 will appear on the meter display screen. The meter will also announce "L2 control solution test, please apply control solution onto the test strip." If you decide not to do a control solution test, press ▼ one time and **ctl** will disappear from the meter display.

**Step 11.** Squeeze a drop of High control solution onto a clean, dry, non-absorbent surface. Do not apply control solution to the test strip directly from the control solution bottle.

Replace the bottle cap on the control solution bottle immediately.

**Step 12.** Gently touch the tip of the test strip to the drop of control solution. The meter will beep indicating it has received the control solution. The screen will start to count down. After 6 seconds, the control solution test result will appear on the meter display screen.



**Step 13.** Compare the reading on the screen to the High range printed on the test strip bottle. If the reading falls outside the High range printed on the test strip bottle, see Control Solution Troubleshooting in the User's Guide.

**Step 14.** Remove the used test strip. The meter will automatically turn off. Discard the used strip.

# BLOOD GLUCOSE TESTING

## MATERIALS NEEDED:

- » EvenCare G2 Meter
- » A new EvenCare G2 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.

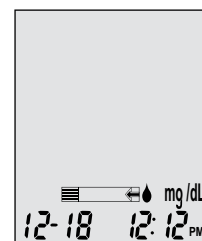
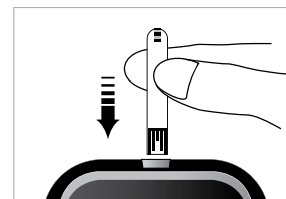
## IMPORTANT

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.** Take out an EvenCare G2 Test Strip from the test strip bottle and close the bottle immediately. Insert the test strip to turn on the meter.

## IMPORTANT

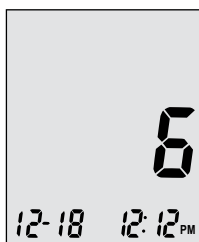
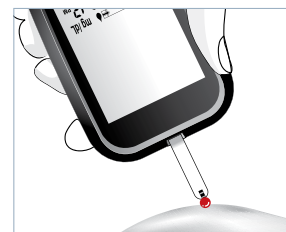
- » Check the expiration date printed on the test strip bottle and its package. Do not use expired test strips.
- » Use each test strip immediately after removing it from the bottle.
- » Do not use wet or damaged test strips.
- » Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- » Record the "date opened" on the bottle label. Discard the bottle and any remaining test strip after 6 months from date of opening.
- » The flashing blood drop icon will appear once the test strip has been fully inserted.



**Step 2.** Wait for a flashing blood drop and an arrow icon to appear on the meter display screen. The meter will also announce, "Please apply blood onto the test strip" if you have the voice feature turned on.

**Step 3.** Obtain blood sample.

**Step 4.** Gently bring the test strip and touch the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in. Keep the test strip in the blood drop until the meter beeps to indicate the test strip has enough blood to test.



**Step 5.** The screen will start to count down. After 6 seconds, the blood glucose result will appear on the meter display screen and will be announced verbally if you have the voice feature turned on. The test result will be automatically stored into the meter memory.

## CAUTION:

- » If you see "HI" or "LO" displayed, the patient's blood glucose level may be above 600 mg/dL or below 20 mg/dL. Test again using fingertip testing. DO NOT test on the forearm. If you still receive the same result, call the patient's physician or healthcare professional immediately.

**Step 6.** Properly discard the used test strip. The meter will automatically shut off.

## IMPORTANT

- » Used lancets and strips are biohazardous materials and can transmit blood-borne diseases. Dispose of them according to local government regulation to avoid injury or contamination.

# UNDERSTANDING TEST RESULTS

Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal range for adults with and without diabetes should be<sup>1</sup>:

- » 70 to 100 mg/dL before meals.
- » 70 to 140 mg/dL after meals.

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

- » Treat their diabetes according to the instruction from their doctor and/or consult their healthcare provider.

If the meter displays results that are "HI" or "LO," or the patient gets a result that is more than 250 mg/dL or below 50 mg/dL AND the patient DOES NOT feel ill:

- » Test the meter with a control solution, Control Solution Testing.
- » Test the meter again with control solution.

If the patient still gets a high or low reading, contact their healthcare professional.

## NOTE:

- » Inaccurate results may occur in severely hypotensive individuals or if the patient is 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.

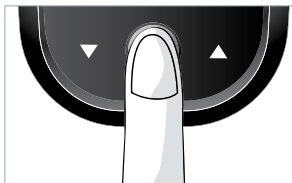
Reference: 1. American Diabetes Association. Standards of Medical Care in Diabetes—2008. Diabetes Care. 2008;31:S12–S54.

# USING THE METER MEMORY

The EvenCare G2 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.

## YOU WILL NEED:

- » EvenCare G2 Meter



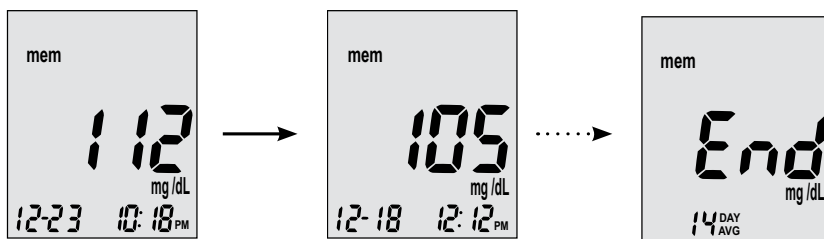
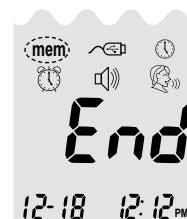
**Step 1.** Press and hold Enter (  $\phi$  ) to turn on the meter.

**Step 2.** Press Enter (  $\phi$  ) to enter setup screen.

**Step 3.** Press  $\blacktriangle$  or  $\blacktriangledown$  until **MEM** starts to flash. If the voice function is on, the meter will say "memory recall." Press Enter (  $\phi$  ) to enter.

**MEM** will appear at the upper left corner of the display screen together with your most recent testing result. Press  $\blacktriangle$  to see the next result, and the next, and so on. Holding  $\blacktriangle$  will flash through the results.

**END** will appear on the display screen after the last recorded test result if less than 300 readings are stored. You can press  $\blacktriangledown$  to go back viewing from the oldest to the most recent readings.



**Step 4.** When you reach the most recent result, continue to press  $\blacktriangledown$  to start viewing day averages. The meter will display the 7 day average, press  $\blacktriangledown$  again to see 14 day average, and press  $\blacktriangledown$  again to see 30 day average.

## NOTE:

- » Control test results are flagged by **ctl** on the bottom left corner of the display screen in addition to **MEM**.
- » When the meter memory is blank, the display screen will show nil.
- » When there are no day average results available, the display screen will show 4 dashes.
- » If the meter memory is full, adding a new test result will cause the oldest result to be deleted.
- » Meter memory test results and day averages will not be erased when changing batteries.
- » You can begin testing anytime by inserting a test strip.



# CLEANING AND DISINFECTING YOUR EVENCARE G2 METER

## IMPORTANT

- » DO NOT get water inside the EvenCare G2 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 G2 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 G2 Meter
- » Gloves
- » A validated disinfecting wipe

Cleaning and disinfecting the meter and lancing device is very important in the prevention of infectious disease. Cleaning is the removal of dust and dirt from the meter and lancing device surface so no dust or dirt gets inside. Cleaning also allows for subsequent disinfection to ensure germs and disease causing agents are destroyed on the meter and lancing device surface.

The EvenCare G2 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 are validated for disinfecting the EvenCare G2 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: 59894-10-37549)
- » Clorox Healthcare® Bleach Germicidal and Disinfectant Wipes (EPA Registration Number: 67619-12)
- » Medline Micro-Kill™ Bleach Germicidal Bleach Wipes (EPA Registration Number: 69687-1)

These disinfecting wipes are available through major retailers online or call 1-866-274-2131 to purchase.

Other EPA Registered wipes may be used for disinfecting the EvenCare G2 system, however, these wipes have not been validated and could affect the performance of the meter. If you use an EPA Registered wipe not listed above and you notice any of the below signs after cleaning and disinfecting the meter, stop using the device and call Medline Technical Service at 1-866-274-2131.

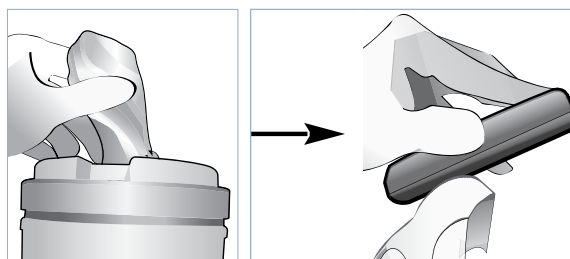
- » Control solution out of range.
- » Clouding meter LCD display.
- » Corrosion or erosion of plastic housing or buttons.
- » Cracking of plastic housing.
- » Malfunction of any meter button.

1. Wash hands with soap and water and dry thoroughly.
2. Inspect for blood, debris, dust, or lint anywhere on the meter.
3. 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 front and back surfaces until visibly clean. Avoid wetting the meter test strip port.

**NOTE:**

- » Do not get water inside the meter or immerse the meter in water or any other liquids.
- » Do not use glass or household cleaners on the meter.
- » Avoid using ammonia to clean the meter.
- » Avoid wetting the test strip port of the meter.

4. To disinfect the meter, clean the meter with one of the validated disinfecting wipes listed below. Other EPA registered wipes may be used for disinfecting the EvenCare G2 system, however these other wipes have not been validated and could affect the performance of the 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: 59894-10-37549).
- » Clorox Healthcare® Bleach Germicidal and Disinfectant Wipes (EPA Registration Number: 67619-12).
- » Medline Micro-Kill™ Bleach Germicidal Bleach Wipes (EPA Registration Number: 69687-1).

Wipe all external areas of the meter including both front and back surfaces until visibly clean. Avoid wetting the meter test strip port. Allow the surface of the meter to remain wet at room temperature for the contact time listed on the wipe's directions for use.

5. Wipe meter dry or allow to air dry.
6. Wash hands with soap and water and dry thoroughly.

**NOTE:**

- » Keep disinfecting wipes out of reach of children and stored according to their instructions.
- » Do not flush disinfecting wipes down toilet.

**IMPORTANT**

If you notice any of the below signs after cleaning and disinfecting the meter stop using the device and call Medline Technical Service immediately at 1-866-274-2131.

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


# CHANGING THE BATTERIES

Batteries need to be changed when the  icon appears on the meter display.

## MATERIALS YOU WILL NEED:

- » Two Alkaline AAA Batteries
- » EvenCare G2 Meter

**Step 1.** Press firmly on the battery cover and slide in the direction of the arrow.

**Step 2.** Insert new batteries . Slide the battery cover back into the meter firmly.

## NOTE:

- » The test results, alarm settings, volume setting, and language choice stay in memory when the batteries are changed.



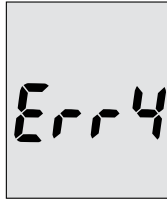
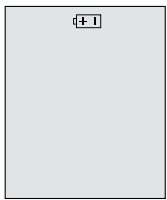
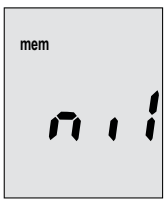


# STORAGE AND PRECAUTIONS


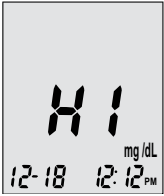
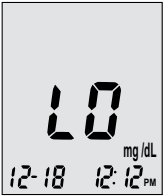
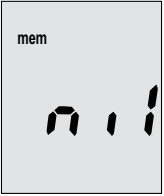
- » Handle the meter with care — severe shock, such as dropping the meter, could damage the electronics.
- » The meter and test strips are designed to be used within the temperature ranges between 50°F to 104°F.
- » Avoid leaving the meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car.
- » Do not store or use the meter or test strips in high humidity levels, such as bathroom or kitchen.
- » Always close bottle cap immediately after removing a test strip and make sure it's closed tightly.
- » Do not take the meter apart as doing so will void the warranty.

# TROUBLESHOOTING

This section details the significant display screen messages and error codes you will encounter when using your EvenCare G2 Meter and EvenCare G2 test strips.

WHAT YOU SEE	WHAT THE METER SAYS	WHAT IT MEANS	WHAT YOU SHOULD DO
	"Error 1 Meter Failure"	The meter's electronics or test strip is damaged.	<ul style="list-style-type: none"> <li>» Remove the battery and turn on the meter again.</li> <li>» Remove the test strip and insert a new test strip again.</li> <li>» If the problem persists, please call 1-866-274-2131 Monday through Friday, 8:00 a.m.–5:00 p.m. (CST).</li> </ul>
	"Error 3 used test strip"	Used or damaged test strip.	<ul style="list-style-type: none"> <li>» Repeat the test with a new test strip. Remember to add sample only when you see the prompt on the display screen or the meter verbally prompts you to add sample.</li> </ul>
	Not Applicable	There are no results in the memory.	<ul style="list-style-type: none"> <li>» Check to see if the date and time on the meter are set up.</li> <li>» Start testing glucose.</li> </ul>
	"Low Battery"	Batteries are low	<ul style="list-style-type: none"> <li>» Change the batteries.</li> </ul>
	Not Applicable	There are no results in the memory.	<ul style="list-style-type: none"> <li>» Check to see if the date and time on the meter are set up.</li> <li>» Start testing glucose.</li> </ul>

# TROUBLESHOOTING

WHAT YOU SEE	WHAT THE METER SAYS	WHAT IT MEANS	WHAT YOU SHOULD DO
	"Temperature is out of range"	Used test strip.	Move the meter into an area that is between 50°F–104°F, and allow 10 to 15 minutes for it to reach the new temperature.
	"Your blood glucose reading is above 600 mg/dL."	Test result is higher than 600 mg/dL.	Wash and dry your hands and repeat the test on a different fingertip with a new test strip. If the result is still "HI," contact the patient's physician or healthcare professional immediately.
	"Your blood glucose reading is below 20 mg/dL."	Test result is lower than 20 mg/dL.	Wash and dry your hands and repeat the test on your fingertip with a new test strip. If the result is still "LO," contact the patient's physician or healthcare professional immediately.
	Not Applicable.	There are no results in the memory.	Check to see if the date and time on the meter are set up. Start testing glucose.

## WARRANTY

The EvenCare G2 Blood Glucose Meter is warranted to be free of defects in workmanship and materials for a period of five (5) 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 G2 Test Strips and EvenCare G2 Control Solution.

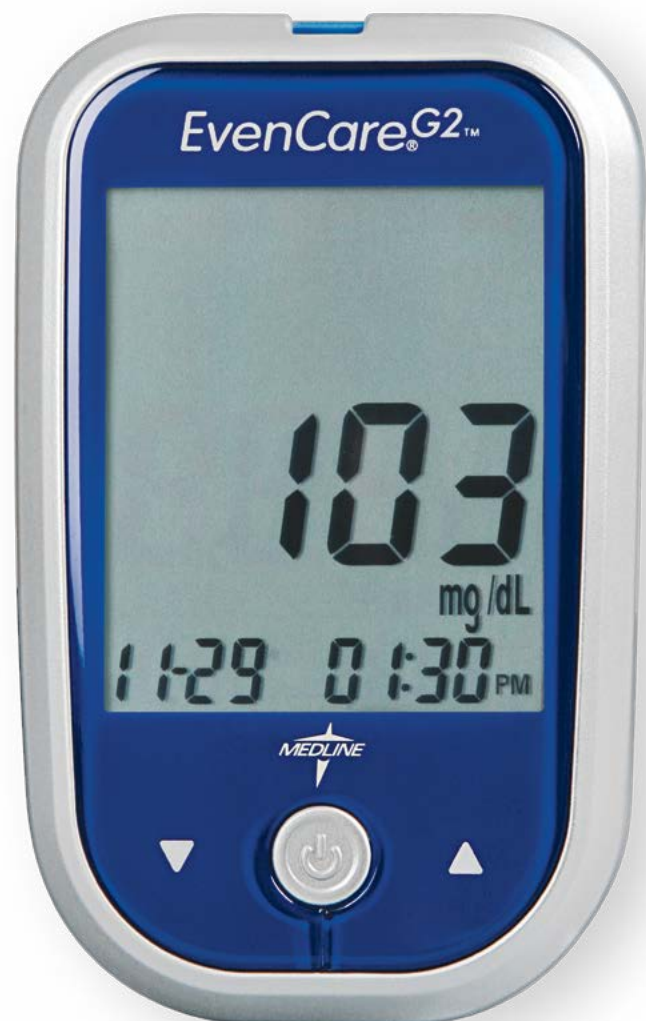
THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY TO THE EXCLUSION OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ALL OF WHICH ARE WAIVED AND DISCLAIMED.

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 G2 Meter in-service training session, attendees should be able to do the following:

1. Identify and describe all components of the EvenCare G2 Blood Glucose Monitoring System including:
  - » Test strip port
  - » Battery compartment
  - » Serial number
  - » LCD screen
  - » EvenCare G2 test strips
  - » EvenCare G2 control solution
  - » EvenCare G2 User's Guide
  - » Toll-free customer service number
2. Be familiar with the EvenCare G2 test strip bottle 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 G2 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 G2 Blood Glucose Monitoring System

### 1. EvenCare G2 Meter

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

### 2. EvenCare G2 Blood Glucose Test Strips

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

### 3. EvenCare G2 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 G2 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:  
The test strip vial should be closed immediately after taking a test strip out of the vial to avoid any degrading or contamination of the strips.
6. How long is the test time on the EvenCare G2 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 G2 meter?
9. What is the procedure for disinfecting the EvenCare G2 meter?

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

# SELF TEST—ANSWER KEY

1. True or **False**:  
EvenCare G2 needs to be calibrated/coded.
2. What is the purpose of testing with Control Solutions?  
**To validate that the EvenCare G2 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:  
The test strip vial should be closed immediately after taking a test strip out of the vial to avoid any degrading or contamination of the strips.
6. How long is the test time on the EvenCare G2 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 batteries are used in the EvenCare G2 meter?  
**Two AAA**
9. What is the procedure for disinfecting the EvenCare G2 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.**

## IN-SERVICE GUIDE

## IN-SERVICE GUIDE

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## IN-SERVICE GUIDE

## IN-SERVICE GUIDE

# EVENCARE G2 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 G2 Test Strip into EvenCare G2 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 G2 Meter correctly.                        | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 11. Change batteries.   | <input type="checkbox"/> Yes <input type="checkbox"/> No |

## IN-SERVICE GUIDE

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# EVENCARE G2 QUALITY CONTROL LOG

[illegible]



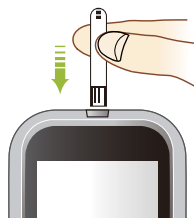
## EvenCare®G2® Blood Glucose System

### Performing a Control Solution Test

step

1

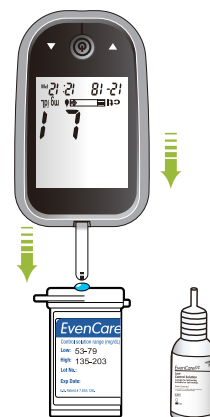
Insert test strip to turn on meter.



step

4

Bring meter and strip onto the droplet. The meter will beep and start counting down after enough control solution is drawn into the test strip.



step

2

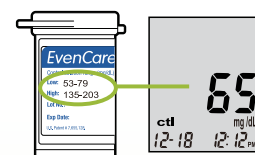
Press ▼ or ▲ once to enter control solution mode for low or high. "Ctl" icon will display on lower left corner of the LCD, indicating the meter is in control mode.



step

5

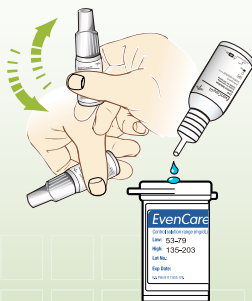
Compare result to the low or high range printed on test strip vial.



step

3

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



step

6

Remove 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 EvenCare G2 User's Guide or call Customer Support at 1-866-274-2131.

We reserve the right to correct any errors.

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## Blood Glucose Test Strips/Tiras Reactivas De Glucemia

### IMPORTANT

PLEASE READ THIS INFORMATION, AND YOUR EVENCARE G2 USER'S GUIDE, BEFORE USING EVENCARE G2 TEST STRIPS.

Please call 1-866-274-2131, 8 am - 5 pm (Central Time), Monday - Friday, if you have any questions. At other times, please contact your healthcare provider.

### IMPORTANTE

POR FAVOR LEA ESTA INFORMACIÓN, Y SU GUÍA DEL USUARIO EVENCARE G2, ANTES DE USAR TIRAS REACTIVAS EVENCARE G2.

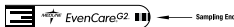
Por favor llame al 1-866-274-2131, de 8 am - 5 pm (hora del Centro), de lunes - viernes, si usted tiene alguna pregunta. En otras ocasiones, por favor contacte con su proveedor de atención médica.

**INTENDED USE** - The EvenCare G2 Blood Glucose Test Strips are to be used with the EvenCare G2 Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The EvenCare G2 Blood Glucose Monitoring System is plasma-calibrated for easy comparison to lab results. It is intended for self-testing by persons with diabetes and by health care professionals. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

**USO PREVISTO** - Las tiras de prueba de glucemia EvenCare G2 se utilizan con el Medidor de glucemia EvenCare G2 para medir cuantitativamente glucosa en sangre capilar tomada de la punta de los dedos, la palma o el antebrazo. El Sistema de Monitoreo de glucemia EvenCare G2 es calibrado por plasma para facilitar la comparación con los resultados de laboratorio. Está diseñado para el auto diagnóstico de las personas con diabetes y para profesionales del cuidado de la salud. No está indicado para el diagnóstico o detección de la diabetes o para uso neonatal.

**INTRODUCTION** - The EvenCare G2 Blood Glucose Test Strips use an enzyme to measure blood glucose. When blood touches the tip of the test strip, it flows into the Sampling End. See illustration of Sampling End below.

**INTRODUCCIÓN** - Las tiras de prueba de glucemia EvenCare G2 usan una enzima para medir la glucosa en la sangre. Cuando la sangre toca la punta de la tira de prueba, ésta fluye al Extremo de Muestra. Vea la Ilustración del Extremo de Muestra a continuación.



The enzyme reacts with glucose in blood and produces electrical current. The meter measures the current. The meter shows the test result in 6 seconds.

La enzima reacciona con la glucosa en la sangre y produce corriente eléctrica. El medidor mide la corriente. El medidor muestra el resultado de la prueba en 6 segundos.

**REAGENT COMPOSITION/COMPOSICIÓN DE REACTIVO** - Each cm<sup>2</sup> of test strip contains: Cada cm<sup>2</sup> de la tira de prueba contiene:

- Glucose Oxidase (A, Nigen) 7.6%
- Electron Shuttle (Transporte de Electrones) 53.3%
- Non-Reactive Inert Ingredients/Ingredientes no Reactivos 38.1%

**WARNINGS AND PRECAUTIONS** - The EvenCare G2 Blood Glucose Test Strips are for use outside the body (IN VITRO diagnostic use).

- Do not use test strips after their expiration date. Please check the expiration date on the test strip bottle.
- Do not use strips that are wet or damaged.
- Do not re-use the strips.
- If your test result is below 50 mg/dL, or above 250 mg/dL, do Control Solution testing to make sure your system is working properly. Then repeat testing using fingertip blood. If the result is still very high or very low, contact your healthcare professional immediately.
- If you have symptoms that are inconsistent with your test results and you have eliminated common errors as described in the User's Guide, contact your healthcare professional immediately.
- Never make major changes in your diabetes treatment program or ignore symptoms without consulting your physician.
- Operation temperature for meter and test strip is 50° F - 104° F.
- Incorrect results may occur in severely hypotensive individuals or patients in shock, inaccurate low results may occur for individuals experiencing a hyperglycemic-hypotensive state, with or without ketosis.
- Do not test critically ill patients with blood glucose meters.
- Incorrect result may occur in individuals who are dehydrated.
- Abnormal red blood cell counts (hematocrits below 30% or above 55%) can cause incorrect results.

**ADVERTENCIAS Y PRECAUCIONES** - Las tiras de prueba de glucemia EvenCare G2 son para uso fuera del cuerpo (uso diagnóstico in vitro).

- No utilice las tiras reactivas después de su fecha de caducidad. Por favor, compruebe la fecha de caducidad en el envase de tiras reactivas.
- No utilice las tiras que están húmedas o dañadas.
- No vuelva a usar las tiras.
- Si el resultado de su prueba es inferior a 50 mg/dL, o superior a 250 mg/dL, hacer pruebas de solución de control para asegurarse que su sistema está funcionando correctamente. Luego repita la prueba utilizando sangre del dedo. Si el resultado sigue siendo muy alto o muy bajo, contacte con su médico inmediatamente.
- Si usted tiene síntomas que son incompatibles con los resultados de la prueba y ha eliminado errores comunes que se describen en la Guía del usuario, comuníquese con su profesional de la salud inmediatamente.
- Nunca haga cambios importantes en su programa de tratamiento de la diabetes ni ignore los síntomas sin consultar a su médico.
- Temperatura de operación para medidor y tira de prueba es de 50° F - 104° F.
- Resultados incorrectos pueden ocurrir en individuos severamente hipotensos o pacientes en shock. Resultados inexactos bajos pueden producirse para individuos que experimentan un estado hiperglicémico hipotensor, con o sin cetosis.
- No pruebe pacientes críticamente enfermos con medidores de glucemia.
- Resultados incorrectos pueden ocurrir en individuos que están deshidratados.
- Recuentos anormales de glóbulos rojos (hematocritos por debajo del 30% o superiores al 55%) pueden producir resultados incorrectos.

### STORAGE AND HANDLING

- Always close the lid cap tightly after removing a test strip. This avoids moisture and direct sunlight.
- 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.
- The month printed on the label refers to the END of that month.
- Use within 6 months after first opening.
- Do not handle the test strips with wet or dirty hands.

### ALMACENAMIENTO Y MANEJO

- Cierre siempre el tapón del vial después de retirar una tira reactiva. Esto evita la humedad y la luz solar directa.
- Almacene las tiras de prueba entre 39°F y 86°F. No congelar.
- Almacene fuera de la luz directa del sol.
- Quando se almacenan adecuadamente, las tiras reactivas sin abrir son estables hasta la fecha de caducidad impresa en la botella.
- El mes que aparece en la etiqueta se refiere al FIN de ese mes.
- Usar dentro de 6 meses después de la primera apertura.
- No manipule las tiras reactivas con las manos mojadas o sucias.

**SAMPLE COLLECTION AND PREPARATION** - Fresh finger stick capillary whole blood may be collected into heparin or sodium EDTA test tubes. Test within 15 minutes. Do not test on plasma or serum samples. Do not use fluoride-based preservatives.

**TOMA Y PREPARACIÓN DE MUESTRAS** - Sangre entera captada de dedo fresco puede ser recogida en tubos de prueba con heparina o EDTA de sodio. Pruebe antes de 15 minutos. No pruebe en muestras de plasma o suero. No utilice preservativos basados en fluor.

**TEST PROCEDURE** - See "Testing Your Blood Glucose" in the EvenCare G2 Blood Glucose Meter User's Guide.

**PROCEDIMIENTO DE PRUEBA** - Consulte la sección "Prueba de glucemia" en la Guía del usuario del Medidor de Glucemia EvenCare G2.

**ALTERNATE SITE TESTING** - You can also test from palm and forearm. This is called alternate site testing (AST). AST can be used only during steady-state blood conditions. AST results may differ from fingertip readings.

**PRUEBA DE SITIO ALTERNATIVO** - También puede probar desde palma y el antebrazo. Esto se llama prueba de sitio alternativo (AST). AST se puede utilizar solamente durante condiciones de la sangre de estado estable. Los resultados de AST pueden diferir de las lecturas de dedo.

**ALTERNATE SITE TESTING SHOULD BE USED:**

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

**LA PRUEBA DE SITIO ALTERNATIVO DEBE SER USADA:**

- Antes de una comida o en ayunas (más de 2 horas desde la última comida)
- 2 horas o más después de tomar insulina.
- 2 horas o más después del ejercicio.

**ALTERNATE SITE TESTING SHOULD NOT BE USED WHEN:**

- You have Hypoglycemic unawareness (not able to tell if you have low blood sugar)
- Within 2 hours of a meal, exercise, or medication
- You will be operating machinery or driving a car.
- During times of stress
- You are sick.
- You think your blood glucose is low.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

**Consult Your Healthcare Professional To Decide If Alternate Site Testing Is Right For You.**

**LA PRUEBA DE SITIO ALTERNATIVO NO DEBE SER USADA CUANDO:**

- Usted tiene desconocimiento de hipoglucemia (no es capaz de decir si tiene niveles bajos de azúcar)
- Dentro de 2 horas de una comida, ejercicio o medicamentos
- Usted va a operar maquinaria o conducir un coche.
- Durante los momentos de estrés.
- Usted cree que su glucosa en la sangre es baja.
- Sus resultados de AST no son iguales a como se siente.
- Usted está haciendo la prueba para hiperglucemia.
- Sus resultados de glucosa de rutina a menudo son fluctuantes.

Consulte a su médico para decidir si las pruebas de sitio alternativo son adecuadas para usted.

**EXPECTED VALUES** - Blood glucose value will vary depending on food intake, medication, health, stress, and exercise. The ideal range for adults with and without diabetes should be:

- 70 to 100 mg/dL before meals, and
- 70 to 140 mg/dL after meals

Consult with your healthcare professional to decide upon a suitable target range for you.

**VALORES ESPERADOS** - El valor de glucemia puede variar dependiendo de la ingesta de alimentos, medicamentos, salud, estrés y ejercicio. El rango ideal para adultos con y sin diabetes debe ser:

- 70 a 100 mg/dL antes de las comidas, y
- 70 a 140 mg/dL después de las comidas

Consulte con su médico para decidir sobre un intervalo de referencia adecuado para usted.

**QUALITY CONTROL** - Run Low and High control solution tests. Follow the User's Guide instructions. Do control tests:

- If your test results do not agree with how you feel.
- At least once per week to make sure the meter and test strips are working properly.
- If your test strips were stored at temperatures and humidity outside proper storage conditions.
- When you use your meter for the first time.
- Every time you open a new bottle of test strips.
- To practice your testing technique.
- If you drop your meter.

**CONTROL DE CALIDAD** - Ejecute pruebas de solución de control alta y baja. Siga las instrucciones del Manual del usuario. Ejecute pruebas de control:

- Si los resultados de su prueba no están de acuerdo con cómo se siente.
- Al menos una vez por semana para asegurarse de que el medidor y las tiras reactivas funcionan correctamente.
- Si las tiras reactivas se almacenaron a temperaturas y humedad fuera de las condiciones de almacenamiento adecuadas.
- Cuando se utiliza el medidor por primera vez.
- Cada vez que abra un nuevo frasco de tiras reactivas.
- Para practicar su técnica de prueba.
- Si se le cae el medidor.

Use only EvenCare G2 Control Solutions. Your test results should fall within the control range 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.
- Expired or contaminated control solution.
- Test strip damaged.
- Meter malfunction.

If the results still fall outside of control range, please call 1-866-274-2131 for help.

Utilice solo Soluciones de Control EvenCare G2. Sus resultados de prueba deben estar dentro del rango de control impreso en el envase de tiras reactivas. Repita la prueba de solución de control si los resultados caen fuera de rango. Los resultados pueden caer fuera del rango debido a:

- Errores en la prueba de la solución de control.
- Solución de control caducada o contaminada.
- Tira reactiva dañada.
- Mal funcionamiento del medidor

Si los resultados aún están fuera del rango de control, por favor llame al 1-866-274-2131 para obtener ayuda.

### PROBLEM SOLVING

- Confirm the test strips are not expired.
- Make sure the blood fills the Sampling End. "Err 4" will be verbally announced if voice feature is on and displayed if there is too little blood. DO NOT add a second drop of blood. Discard the test strip from the meter and reset with a new test strip.
- Check the system with a Control Solutions test.
- Refer to "Solving Problems" in the User's Guide for additional information.

If the problem continues, please call 1-866-274-2131, or contact your healthcare professional.

### SOLUCIÓN DE PROBLEMAS

- Confirmar que las tiras de prueba no estén vencidas.
- Asegúrese de que la sangre llena el Extremo de Muestra. "Err 4" se anunciará verbalmente si está en función de voz y se mostrará si hay poca sangre. NO agregue una segunda gota de sangre. Descarte la tira reactiva del medidor y vuelva a probar con una nueva tira reactiva.
- Verifique el sistema con una Prueba de Soluciones de Control.
- Consulte "Solución de problemas" en la Guía del usuario para obtener información adicional.

Si el problema persiste, por favor llame al 1-866-274-2131, o comuníquese con su profesional de la salud.

### LIMITATIONS

- DO NOT use plasma or serum samples.
- DO NOT test on neonatal (newborn) samples.
- DO NOT test on venous or arterial samples.
- Altitudes up to 10,000 feet will not affect test results.
- Hematocrit range: 30 - 55%.
- Triglycerides: 260 to 360 mg/dL has no significant effect on test results (normal range 36 - 165 mg/dL).
- Iodocine and its metabolites (maltoase, maltotriose and maltotetraose) do not significantly affect test results.
- The following will not affect test results in expected blood concentrations: ascorbic acid (Vitamin C), uric acid, or methyl-dopa.
- Specific concentration of dopamine or L-dopa may affect results. People taking these drugs should not use this system to test blood sugar.
- Higher than therapeutic concentrations of acetaminophen, or glibenzamide, may affect test results. People taking higher than therapeutic concentrations should not use this system to test blood sugar.

### LIMITACIONES

- NO use muestras de plasma o suero.
- NO pruebe en muestras neonatales (recién nacidos).
- NO pruebe en muestras de sangre venosa o arterial.
- Altitudes de hasta 10,000 pies no afectarán los resultados de la prueba.
- Rango de hematocrito: 30 - 55%.
- Triglicéridos: 260 a 360 mg/dL no tienen efecto significativo sobre los resultados de la prueba (rango normal de 36 a 165 mg/dL).
- Iodocina y sus metabolitos (maltoasa, maltotriosa y maltotetraosa) no afectan significativamente los resultados de la prueba.
- Lo siguiente no afectará los resultados de prueba en las concentraciones esperadas en la sangre: ácido ascórbico (vitamina C), ácido úrico, o metil dopa.
- Concentración terapéutica de dopamina o L-dopa pueden afectar los resultados. Las personas que toman estos medicamentos no deben usar este sistema para probar el azúcar en la sangre.
- Concentraciones de acetaminofén o glibenzamida mayores que las terapéuticas pueden afectar los resultados de la prueba. Las personas que toman concentraciones mayores que las terapéuticas no deben utilizar este sistema para probar el azúcar en la sangre.

### PERFORMANCE EVALUATION DATA

**Accuracy:** A total of 158 fingertip blood samples were collected. Seventeen (17) samples were below 75 mg/dL. One hundred and forty-one (141) samples were above 75 mg/dL. A total of 152 fresh blood samples were collected from palm and forearm. Eleven (11) samples were below 75 mg/dL, 141 samples were above 75 mg/dL. Fingertip and alternate site samples were tested by healthcare professionals. Blood was tested on the YSI 2300 Analyzer as a reference test.

### DATOS DE EVALUACIÓN DE RENDIMIENTO

**Exactitud:** Un total de 158 muestras de sangre de la yema del dedo se recogieron. Diecisiete (17) muestras estaban por debajo de 75 mg/dL. Ciento cuarenta y uno (141) muestras estaban por encima de 75 mg/dL. Un total de 152 muestras de sangre fresca se obtuvieron de la palma y el antebrazo. Once (11) muestras estaban por debajo de 75 mg/dL, 141 muestras estaban por encima de 75 mg/dL. Muestras de yemas de punta de los dedos y antebrazos fueron probados por personal de salud. La sangre se puso a prueba en el Analizador YSI 2300 como prueba de referencia.

### TABLE 1: ACCURACY FOR BLOOD GLUCOSE LEVEL <75MG/DL/TABLA 1: PRECISIÓN PARA EL NIVEL DE GLUCEMIA <75 MG/DL

Sample Source/Fuente de Muestra	Within/Dentro de $\pm$ 5mg/dL	Within/Dentro de $\pm$ 10mg/dL	Within/Dentro de $\pm$ 15mg/dL
Fingertip vs. YSI/Punta de los dedos vs. YSI	71/71 (100%)	15/17 (88%)	17/17 (100%)
Palm vs. YSI/Palma vs. YSI	3/11 (27%)	7/11 (64%)	11/11 (100%)
Forearm vs. YSI/Antebrazo vs. YSI	5/11 (45%)	9/11 (82%)	11/11 (100%)

### TABLE 2: ACCURACY FOR BLOOD GLUCOSE LEVEL >75MG/DL/TABLA 2: PRECISIÓN DE NIVEL DE GLUCEMIA > 75 MG/DL

Sample Source/Muestra fuente	Within/Dentro de $\pm$ 5%	Within/Dentro de $\pm$ 10%	Within/Dentro de $\pm$ 15%	Within $\pm$ 20%/Dentro de $\pm$ 20%
Fingertip vs. YSI/Punta de los dedos vs. YSI	78/141 (55%)	127/141(89%)	138/141(98%)	141/141(100%)
Palm vs. YSI/Palma vs. YSI	82/141 (58%)	119/141(84%)	134/141(95%)	141/141(100%)
Forearm vs. YSI/Antebrazo vs. YSI	77/141 (55%)	112/141(79%)	136/141(96%)	141/141(100%)

**PRECISION:** A within-run precision study used 3 lots of EvenCare G2 test strips. Venous blood was spiked to 3 levels. Blood glucose readings were taken for 10 days with 100 data points at each level.

**PRECISIÓN:** Un estudio de precisión dentro de una serie usó 3 lotes de tiras de prueba EvenCare G2. La sangre venosa se añadió a 3 niveles. Lecturas de glucemia se tomaron durante 10 días con 100 puntos de datos en cada nivel.

### REAGENT LOT FS 001A/LOTE DE REACTIVOS FS 001A

Number of Readings/Número de lecturas:	100	100	100	100
Average (mg/dL)/Promedio (mg/dL):	46	113	192	303
Mean S.D. (mg/dL)/S.D. Promedio (mg/dL):	2.1	3.9	6.9	9.7
Mean C.V.%/C.V% Promedio:	—	3.4	3.6	3.2

### Reagent Lot FS 001J/Lote de reactivos FS 001J

Number of Readings/Número de lecturas:	100	100	100	100
Average (mg/dL)/Promedio (mg/dL):	46	111	189	301
Mean S.D. (mg/dL)/S.D. Promedio (mg/dL):	2.7	4.3	6.3	10.8
Mean C.V.%/C.V% Promedio:	—	3.9	3.3	3.6

### Reagent Lot FS 001K/Lote de reactivos FS 001K

Number of Readings/Número de lecturas:	100	100	100	100
Average (mg/dL)/Promedio (mg/dL):	46	109	185	296
Mean S.D. (mg/dL)/S.D. Promedio (mg/dL):	3.0	4.6	7.4	11.9
Mean C.V.%/C.V% Promedio:	—	4.2	4.0	4.0

### REFERENCES/REFERENCIAS:

- Junghenn K., Koschinsky T. "Risky delay of hypoglycemia detection by glucose monitoring at the arm."
- Diabetes Care 2007 : 24(7):1362-64.
- American Diabetes Association, Standards of Medical Care in Diabetes—2008, Diabetes Care, 2008;31:S12-S54.

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EvenCare<sup>G2</sup>

## Glucose Control Solutions/Soluciones de Control de Glucosa

**INTENDED USE** – The purpose of the control solution test is to validate the performance of the EvenCare G2 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 test strip and meter are functioning properly.

**USO PREVISTO** – El propósito de la prueba de solución de control es validar el rendimiento del Sistema de Monitoreo de Glucosa en Sangre EvenCare G2 mediante una solución de prueba con un área de distribución conocida de glucosa. Una prueba de control que cae dentro del rango aceptable técnica indica que el usuario es correcto y la tira de prueba y el medidor están funcionando correctamente.

### CONTROL SOLUTIONS SHOULD BE USED IN THE FOLLOWING INSTANCES:

- Before testing with the Blood Glucose System for the first time.
- Every time you open a new bottle of test strips.
- Whenever you suspect that the meter or test strips are not working properly.
- When your blood glucose results do not reflect how you feel.
- If you drop the meter.
- If your readings appear to be abnormally high or low.

### SOLUCIONES DE CONTROL DEBEN SER UTILIZADAS EN LOS SIGUIENTES CASOS:

- Antes de hacer pruebas con el Sistema de Glucemia por primera vez.
- Cada vez que abra un nuevo frasco de tiras reactivas.
- Siempre que sospeche que el medidor o las tiras reactivas no están funcionando correctamente.
- Cuando los resultados de su glucemia no reflejan cómo se siente.
- Si se le cae el medidor.
- Si las lecturas se consideran anormalmente altas o bajas.

**SUMMARY** – The EvenCare G2 Control are solutions containing a measured amount of glucose. These solutions are used with your EvenCare G2 Blood Glucose Test Strips to confirm the acceptance performance of the test strips and the meter.

**RESUMEN** – Control EvenCare G2 son soluciones que contienen una cantidad medida de glucosa. Estas soluciones se utilizan con sus tiras de prueba de glucemia EvenCare G2 para confirmar la aceptación de los resultados las tiras de prueba y el medidor.

### CHEMICAL COMPOSITION

The EvenCare G2 Control Solution is an aqueous solution containing D-glucose as the reactive ingredient in approximate concentrations of:

Low Control	0.03%
High Control	0.15%

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

### COMPOSICIÓN QUÍMICA

La Solución de Control EvenCare G2 es una solución acuosa que contiene D-glucosa como ingrediente reactivo en concentraciones aproximadas de:

Bajo Control	0.03%
Control Alto Dos	0.15%

Los ingredientes no reactivos incluidos en la solución son tampones, estabilizantes y conservantes.

### WARNINGS AND PRECAUTIONS

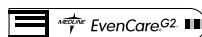
Control solutions are for In Vitro diagnostic use only and are not intended for human consumption or injection.

- Shake the EvenCare G2 Control Solutions well before using.
- DO NOT apply a second drop of control solution to the Sampling End of the test strip.
- DO NOT touch the Sampling End of the test strip with the bottle of control solution.  
See Illustration of Sampling End below.
- Replace the cap of the control solution immediately after use.
- Use only EvenCare G2 Glucose Control Solutions.
- Always check the expiration date. DO NOT use control solutions if they have expired.

### ALERTAS Y PRECAUCIONES

Las soluciones de control son para uso diagnóstico in vitro y no se destinan al consumo humano o inyección.

- Agitar las bien Soluciones de Control EvenCare G2 antes de usar.
- NO se debe aplicar una segunda gota de solución de control al Extremo de Muestreo de la tira reactiva.
- NO toque el Extremo de Muestreo de la tira reactiva con la botella de solución de control. Vea la ilustración del Extremo de Muestreo abajo.
- Coloque la tapa de la solución de control inmediatamente después de su uso.
- Utilice sólo Soluciones de Control de Glucosa EvenCare G2.
- Siempre revise la fecha de vencimiento. NO use soluciones de control si han caducado.



Sampling End/Extremo de Muestreo

### STORAGE AND HANDLING

- Control solutions should be stored at 59°F - 86°F. DO NOT FREEZE OR REFRIGERATE.
- Do not use if the expiration date has passed.
- Discard any unused control solution 90 days after first opening or after expiration date.

### ALMACENAMIENTO Y MANEJO

- Las soluciones de control deben ser almacenadas a 59° C - 86° F. NO CONGELAR O REFRIGERAR.
- No use si la fecha de caducidad ha pasado.
- Deseche cualquier solución de control sin utilizar 90 días después de abierta o después de la fecha de caducidad.

### CONTROL SOLUTION TEST PROCEDURE - Materials needed to perform a control solution test include:

- EvenCare G2 Control Solutions (Low and High)
- EvenCare G2 Meters and User's Guide.
- EvenCare G2 Test Strips.

### PROCEDIMIENTO DE PRUEBA DE SOLUCIÓN DE CONTROL - Materiales necesarios para realizar una prueba de solución de control incluyen:

- Soluciones de Control EvenCare G2 (baja y alta)
- Medidores y guía del usuario de EvenCare G2.
- Tiras reactivas EvenCare G2.

### TO PERFORM A TEST WITH CONTROL SOLUTIONS FOLLOW THESE STEPS:

1. Newly opened bottles of control solutions must be marked on the space provided on the control solutions label with the date that it was opened.  
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. Refer to User's Guide for instructions in using EvenCare G2 control solutions with meter.

### PARA LLEVAR A CABO UNA PRUEBA CON SOLUCIONES DE CONTROL SIGA ESTOS PASOS:

1. Botellas de soluciones de control de reciente apertura deben estar marcadas en el espacio provisto en la etiqueta de soluciones de control con la fecha en que se abrió. Compruebe la fecha de vencimiento de las soluciones de control para asegurarse de que no han caducado. Deseche cualquier solución de control sin usar 90 días después de la apertura o después de la fecha de caducidad. Consulte la Guía del usuario para instrucciones en el uso de soluciones de control EvenCare G2 con medidor.

**EXPECTED VALUES** – The EvenCare G2 Control Solutions testing should provide results within the expected range indicated on the test strip bottle. If results are not within the acceptable ranges, the user should carefully review each step of their technique before performing another test. Any error in technique or meter use could cause results to be outside the acceptable range. If the control test values continue to be outside the acceptable range and technique is proper, use a strip from a previously unopened bottle and repeat the test. If readings are still not within the acceptable range, please call us at 1-866-274-2131.

**VALORES ESPERADOS** – La prueba de soluciones de control EvenCare G2 debe dar resultados dentro del rango esperado indicado en el frasco de tiras reactivas. Si los resultados no están dentro de los rangos aceptables, el usuario debe revisar cuidadosamente cada paso de su técnica antes de realizar otra prueba. Cualquier error en la técnica o uso del medidor podría causar que los resultados estén fuera del rango aceptable. Si los valores de la prueba de control siguen estando fuera del rango aceptable y la técnica es correcta, use una tira de una botella previamente sin abrir y repita la prueba. Si las lecturas siguen estando fuera del rango aceptable, por favor llámenos al 1-866-274-2131.

**CAUTION:** If results continue to be out of range after all instructions have been followed, the system is not functioning properly. DO NOT use the system to test your blood glucose until you get a reading that is within the acceptable range.

If you need assistance, please call Medline's Technical Service Center at 866-274-2131 Monday through Friday between 8:00 a.m. and 5:00 p.m.(Central Time). Contact your Healthcare Provider at all other times.

**PRECAUCIÓN:** Si los resultados siguen estando fuera de rango después de seguir todas las instrucciones, el sistema no está funcionando correctamente. NO utilice el sistema para medir su glucemia hasta obtener una lectura que esté dentro del rango aceptable.

Si necesita ayuda, llame al Centro de Servicio Técnico de Medline al 866-274-2131 Lunes a Viernes entre las 8:00 am y 5:00 pm (Hora del Centro). Comuníquese con su proveedor de atención médica en todas las otras veces.

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







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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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